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

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

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

2 CFR Part 1800

[Document Number NASA–20–090; Docket Number NASA–2020–0006]

RIN 2700–AE61

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Direct final rule.

SUMMARY: This direct final rule amends NASA's regulations on Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, to align with the Office of Management and Budget's (OMB) recent amendments to its regulations on Grants and Agreements.

DATES: This direct final rule is effective on January 11, 2021 without further action, unless adverse comment is received by December 14, 2020. If adverse comment is received, NASA will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: Comments must be identified with RINs 2700–AE61 and may be sent to NASA via the *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Please note that NASA will post all comments on the internet without changes, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Corey Walz, 202–940–6581, *corey.a.walz@nasa.gov.*

SUPPLEMENTARY INFORMATION:

Direct Final Rule and Significant Adverse Comments

NASA has determined this rulemaking meets the criteria for a direct final rule because it makes nonsubstantive changes to NASA's regulations on Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards to align with OMB's recent amendments to its regulations on Grants and Agreements. No opposition to the changes and no significant adverse comments are expected. However, if NASA receives significant adverse comments, it will withdraw this direct final rule by publishing a document in the **Federal Register**. A significant adverse comment is one that explains: (1) Why the direct final rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this direct final rule, NASA will consider whether it warrants a substantive response in a notice and comment process.

Background

Title 2 CFR part 1800, last amended on May 9, 2019 [84 FR 20240], adopts OMB's guidance in subparts A through F of 2 CFR part 200 as NASA's policies and procedures for uniform administrative requirements, cost principles, and audit requirement for Federal awards. NASA is amending 2 CFR part 1800 to align with the OMB's recent amendments to its regulations on Grants and Agreements published on August 13, 2020, at 85 FR 49506, which will become effective on November 12, 2020.

Statutory Authority

The National Aeronautics and Space Act (the Space Act), 51 U.S.C. 20113(a), authorizes the Administrator of NASA to make, promulgate, issue, rescind, and amend rules and regulations governing the manner of its operations and the exercise of the powers vested in it by law.

Regulatory Analysis

Executive Order 12866, Regulatory Planning and Review and Executive Order 13563, Improving Regulation and Regulatory Review

Executive Orders (E.O.) 13563 and 12866 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 rule has been designated as ''not significant'' under section 3(f) of E.O. 12866.

Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to prepare an initial regulatory flexibility analysis to be published at the time the proposed rule is published. This requirement does not apply if the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities'' (5 U.S.C. 603). This rule aligns NASA's regulations on uniform administrative requirements, cost principles, and audit requirement for Federal awards with OMB's recent amendments to its regulations on Grants and Agreements published on August 13, 2020, at 85 FR 49506, which will become effective on November 12, 2020, and does not have a significant economic impact on a substantial number of small entities.

Review Under the Paperwork Reduction Act

This direct final rule does not contain any information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Review Under E.O. 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999) requires that regulations be reviewed for federalism effects on the institutional interest of states and local governments, and if the effects are sufficiently substantial, preparation of the Federal assessment is required to assist senior policy makers. These amendments will not have any substantial direct effects on state and local governments within the meaning of the E.O.. Therefore, no federalism assessment is required.

Executive Order 13771—Reducing Regulation and Controlling Regulatory Costs

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

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments.

List of subjects in 2 CFR Part 1800

Grant programs, Grants administration.

For reasons set forth in the preamble, NASA is amending 2 CFR part 1800 as follows:

PART 1800—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS

■ 1. The authority citation for part 1800 continues to read as follows:

Authority: 51 U.S.C. 20113 (e), Pub. L. 97–258, 96 Stat. 1003 (31 U.S.C. 6301 *et seq.*), and 2 CFR part 200.

■ 2. Revise § 1800.3 to read as follows:

§ 1800.3 Applicability.

(a) This part establishes policies and procedures for grants and cooperative agreements awarded by NASA to non-Federal entities, for-profit organization, foreign organizations, and foreign public entities as allowed by 2 CFR 200.101. For supplemental guidance, NASA has adopted section numbers that correspond to those in the OMB guidance in 2 CFR part 200.

(1) Non-Federal entities must follow the policies and procedures appearing in subparts A through F of 2 CFR part 200 and as supplemented by this part.

(2) Foreign organizations and foreign public entities must follow the policies and procedures appearing in subparts A through E of 2 CFR part 200 and as supplemented by this part.

(3) U.S. and foreign for-profit organizations must follow the policies and procedures appearing in subparts A through D of 2 CFR part 200 and as supplemented by this part. The Federal Acquisition Regulation (FAR) at 48 CFR parts 30 and 31 take precedence over the cost principles in subpart E of 2 CFR part 200 for Federal awards to U.S. and foreign for-profit organizations.

(b) Throughout this part, the term ''award'' refers to both ''grant'' and ''cooperative agreement'' unless otherwise indicated.

(c)(1) In general, research with foreign organizations will not be conducted through grants or cooperative agreements, but instead will be accomplished on a no-exchange-of-funds basis. In these cases, NASA enters into agreements undertaking projects of international scientific collaboration. NASA's policy on performing research with foreign organizations on a no-exchange-of-funds basis is set forth at NASA FAR Supplement (NFS) at 48 CFR 1835.016–70 and 1835.016–72. In rare instances, NASA may enter into an international agreement under which funds will be transferred to a foreign recipient.

(2) Grants or cooperative agreements awarded to foreign organizations are made on an exceptional basis only. Awards require the prior approval of the Headquarters Office of International and Interagency Relations and the Headquarters Office of the General Counsel. Requests to issue awards to foreign organizations are to be coordinated through the Office of the Chief Financial Officer, Policy Division.

■ 3. Revise § 1800.5 to read as follows:

§ 1800.5 Publication.

The official site for accessing the NASA grant and cooperative agreement policies, including notices, internal guidance, certifications, the NASA Grant and Cooperative Agreement Manual (GCAM), and other source information is on the internet at: *https://prod.nais.nasa.gov/pub/pub_library/srba/index.html.*

Subpart A—Acronyms and Definitions

■ 4. Revise § 1800.10 to read as follows:

§ 1800.10 Acronyms.

The following acronyms supplement the acronyms set forth at 2 CFR 200.0:

ACH Automated Clearing House
AO Announcement of Opportunity
CAN Cooperative Agreement Notice
CFR Code of Federal Regulations
CNSI Classified National Security Information
EPA Environmental Protection Agency
GCAM Grant and Cooperative Agreement Manual
HBCU Historically Black Colleges and Universities
LEP Limited English Proficiency
MSI Minority-serving Institutions
MYA Multiple Year Award
NASA National Aeronautics and Space Administration
NFS NASA FAR Supplement
NPR NASA Procedural Requirements
NRA NASA Research Announcement
NSPIRES NASA Solicitation and Proposal Integrated Review and Evaluation System
NSSC NASA Shared Services Center
OMB Office of Management and Budget
ONR Office of Naval Research
RPPR Research Performance Progress Report
STIP NASA Scientific and Technical Information Program

■ 5. Revise § 1800.11 to read as follows:

§ 1800.11 Definitions.

The following definitions are a supplement to the definitions set forth at 2 CFR 200.1.

Administrative Grant Officer means a Federal employee delegated responsibility for award administration; *e.g.,* a NASA Grant Officer who has retained award administration responsibilities, or an Office of Naval Research (ONR) Grant Officer delegated award administration by a NASA Grant Officer.

Effective date means the date work can begin under an awarded instrument. This date is the beginning of the period of performance and can be earlier or later than the date of signature on a basic award. Expenditures made prior to the effective date are incurred at the recipient's risk unless prior written permission has been given by the Grant Officer.

For-profit organization means any corporation, trust, or other organization that is organized primarily for profit.

Grant Officer means a Federal employee responsible for the signing of the Federal award documents.

Historically Black Colleges and Universities (HBCUs) means institutions determined by the Secretary of Education to meet the requirements of 34 CFR 608.2 and listed therein.

Minority-serving Institutions (MSIs) means an institution of higher education whose enrollment of a single minority or a combination of minorities (minority meaning American Indian, Alaskan Native, Black (not of Hispanic origin), Hispanic (including persons of Mexican, Puerto Rican, Cuban, and Central or South American origin), Pacific Islander or other ethnic group underrepresented in science and engineering) exceeds 50 percent of the total enrollment, as defined by the Higher Education Act (HEA) (20 U.S.C. 1067k(3)).

NASA Technical Officer means the NASA official responsible for the programmatic, scientific, and/or technical aspects of assigned applications and awards.

Original signature means an authorized signature as described in this definition. If the system (such as NSPIRES) used to submit required documents allows for electronic signatures, then the submission of the documents, by the authorized representative of the organization serves as the required original signature. If, however, a paper copy submission is

required, all documents submitted shall be appropriately signed in ink with an actual signature by the authorized representative of the organization.

Prescription is defined as the written instructions, to the Grants Officer, for the application of terms and conditions.

Research misconduct is defined in 14 CFR 1275.101. NASA policies and procedures regarding research misconduct are set forth in 14 CFR part 1275.

Summary of research means a document summarizing the results of the entire project, which includes bibliographies, abstracts, and lists of other media in which the research was discussed.

Subpart B—Pre-Federal Award Requirements and Contents of Federal Awards

§§ 1800.208, 1800.209, and 1800.210 [Redesignated as §§ 1800.209, 1800.210, and 1800.211]

■ 6. Redesignate §§ 1800.208, 1800.209, and 1800.210 as §§ 1800.209, 1800.210, 1800.211.

■ 7. Revise newly redesignated § 1800.209 to read as follows:

§ 1800.209 Certifications and representations.

The certifications and representations for NASA may be found in Appendix C of the GCAM, at: *https://prod.nais.nasa.gov/pub/pub_library/srba/index.html.*

■ 8. Revise newly reedesignated § 1800.211 to read as follows:

§ 1800.211 Information contained in a Federal award.

NASA waives the requirement for the inclusion of indirect cost rates on any notice of Federal award for for-profit organizations. The terms and conditions for NASA may be found in Appendix D of the GCAM at: *https://prod.nais.nasa.gov/pub/pub_library/srba/index.html.*

Subpart C—Post Federal Award Requirements

■ 9. Revise § 1800.305 to read as follows:

§ 1800.305 Federal payment.

Payments under awards with for-profit organizations will be made based on incurred costs. Standard Form 425 is not required. For-profit organizations shall not submit invoices more frequently than quarterly. Payments to be made on a more frequent basis require the written approval of the Grant Officer.

■ 10. Revise § 1800.306 to read as follows:

§ 1800.306 Cost sharing or matching.

In some cases, NASA research projects require cost sharing or matching. Where cost sharing or matching is required, recipients must secure and document matching funds to receive the Federal award.

■ 11. Revise § 1800.312 to read as follows:

§ 1800.312 Federally-owned and exempt property.

Under the authority of the Chiles Act, 31 U.S.C. 6301 to 6308, NASA has decided to vest title to tangible personal property acquired with Federal funds in nonprofit institutions of higher education and nonprofit organizations whose primary purpose is conducting scientific research without further obligation to NASA, including reporting requirements. Award recipients that are not nonprofit institutions of higher education or nonprofit organizations whose primary purpose is conducting scientific research shall adhere to regulations at 2 CFR 200.312 through 200.316.

■ 12. Revise § 1800.339 to read as follows:

§ 1800.339 Remedies for noncompliance.

NASA reserves the ability to impose additional conditions in response to award recipient noncompliance and terminate a Federal award in accordance with 2 CFR 200.339 through 200.343 and as set forth in the GCAM.

■ 13. Revise § 1800.400 to read as follows:

§ 1800.400 Policy guide.

Payment of fee or profit is consistent with an activity whose principal purpose is the acquisition of goods and services for the direct benefit or use of the United States Government, rather than an activity whose principal purpose is Federal financial assistance to a recipient to carry out a public purpose. Therefore, the Grants Officer shall use a procurement contract, rather than a grant or cooperative agreement, in all cases where fee or profit is to be paid to the recipient of the instrument or the instrument is to be used to carry out a program where fee or profit is necessary to achieving program objectives. Grants and cooperative agreements shall not provide for the payment of any fee or profit to the recipient.

Nanette Smith,

Team Lead, NASA Directives and Regulations.

[FR Doc. 2020–24638 Filed 11–10–20; 8:45 am]

BILLING CODE P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 704

RIN 3133–AF13

Corporate Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: The NCUA Board (Board) is issuing a final rule that amends the NCUA's corporate credit union regulation. The final rule updates, clarifies, and simplifies several provisions of the NCUA's corporate credit union regulation, including: Permitting a corporate credit union to make a minimal investment in a credit union service organization (CUSO) without the CUSO being classified as a corporate CUSO under the NCUA's rules; expanding the categories of senior staff positions at member credit unions eligible to serve on a corporate credit union's board; and amending the minimum experience and independence requirement for a corporate credit union's enterprise risk management expert.

DATES: The final rule is effective December 14, 2020.

FOR FURTHER INFORMATION CONTACT: *Policy and Analysis:* Robert Dean, National Supervision Analyst, Office of National Examinations and Supervision, (703) 518–6652; *Legal:* Rachel Ackmann, Senior Staff Attorney, Office of General Counsel, (703) 548–2601; or by mail at National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Introduction

a. Legal Authority and Background

The Board is issuing this rule pursuant to its authority under the Federal Credit Union Act (FCU Act).[1] Under the FCU Act, the NCUA is the chartering and supervisory authority for Federal credit unions (FCUs) and the federal supervisory authority for federally insured credit unions (FICUs).

[1] 12 U.S.C. 1751 *et seq.*

The FCU Act grants the NCUA a broad mandate to issue regulations governing both FCUs and FICUs. Section 120 of the FCU Act is a general grant of regulatory authority and authorizes the Board to prescribe regulations for the administration of the FCU Act.[2] Section 209 of the FCU Act is a plenary grant of regulatory authority to the NCUA to issue regulations necessary or appropriate to carry out its role as share insurer for all FICUs.[3] The FCU Act also includes an express grant of authority for the Board to subject federally chartered central, or corporate, credit unions to such rules, regulations, and orders as the Board deems appropriate.[4]

Part 704 of the NCUA's regulations implements the requirements of the FCU Act regarding corporate credit unions.[5] In 2010, the Board comprehensively revised the regulations governing corporate credit unions to provide longer-term structural enhancements to the corporate system in response to the financial crisis of 2007–2009.[6] The provisions of the 2010 rule successfully stabilized the corporate system and improved corporate credit unions' ability to function and provide services to natural person credit unions. Since 2010, and as part of the Board's continuous reevaluation of its regulation of corporate credit unions, the Board has amended part 704 on several occasions.[7] Part 704 was last amended in 2017, when the Board amended corporate credit union capital standards to change the calculation of capital after a consolidation and to set a retained earnings ratio target in meeting prompt corrective action (commonly referred to as PCA) standards.[8]

b. Regulatory Review

Generally, the NCUA reviews all of its existing regulations every three years. The NCUA's Office of General Counsel maintains a rolling review schedule that identifies one-third of its existing regulations for review each year and provides notice to the public of those regulations under review so the public may have an opportunity to comment. Part 704 was part of the Office of General Counsel's 2019 annual regulatory review.[9] The Board received several comments on updating part 704 as part of the 2019 annual regulatory review.

II. Proposed Rule

On February 20, 2020, the Board approved a notice of proposed rulemaking to update, clarify, and simplify several provisions of part 704 (proposed rule).[10] The proposal provided for a 60-day comment period, which was later extended by 60 days due to COVID–19.[11] The comment period ended on July 27, 2020.

III. Final Rule and Discussion of Comments

The NCUA received 35 comment letters on the proposed rule. Comments were received from credit unions, both corporate and natural persons, credit union leagues and trade associations, individuals, corporate CUSOs, and an association of state credit union supervisors. Many of the commenters supported the stated goal, to update, clarify, and simplify several provisions of the NCUA's corporate credit union regulation, however, almost all of the commenters expressed concerns about specific aspects of the proposal. Most commenters believed that the proposed rule did not provide sufficient relief and requested additional areas of burden reduction that were beyond the scope of the proposed rule. In response to the comments received, the Board has made several changes to the final rule. The final rule: (1) Permits a corporate credit union to make a minimal investment in a CUSO without the CUSO being classified as a corporate CUSO and subject to heightened NCUA oversight; (2) expands the categories of senior staff positions at member credit unions eligible to serve on a corporate credit union's board; (3) removes the experience and independence requirement for a corporate credit union's enterprise risk management expert; (4) clarifies the definition of a collateralized debt obligation; and (5) simplifies the requirement for net interest income modeling. The specific details of the final rule, including changes as a result of the comments received, are discussed below.

A. Minimal Investment in Natural Person CUSOs

Part 704 includes specific regulations for a corporate credit union's investment and lending activity and permits a corporate credit union to invest in and lend to a corporate CUSO. A corporate CUSO is defined as an entity that is at least partly owned by a corporate credit union; primarily serves credit unions; restricts its services to those related to the normal course of business of credit unions;[12] and is structured as a corporation, limited liability company, or limited partnership under state law.[13]

Similar to natural person credit union service organizations (NP CUSOs), the Board cannot regulate corporate CUSOs directly, but it can, for safety and soundness reasons, regulate the types of investments that corporate credit unions make and whether a corporate credit union may invest in a CUSO. Part 704 includes several prudential requirements to ensure corporate credit union investment in and lending to corporate CUSOs is safe and sound. For example, part 704 regulates aggregate corporate credit union investment in and lending to corporate CUSOs. Part 704 also includes customer base requirements, permissible activities, accounting and audit standards, and requires NCUA access to corporate CUSO facilities, books, and records. In general, many of the prudential standards for corporate CUSOs are more restrictive than the standards for NP CUSOs.[14] The Board has historically imposed more restrictive standards for corporate CUSOs as they may serve hundreds or even thousands of natural person credit unions and pose unique systemic risk.[15] Additionally, core functions of corporate credit unions that pose systemic risk could be moved to corporate CUSOs. The Board has expressed concern that the movement of these core functions to entities that are not directly regulated by the NCUA could increase the systemic risk associated with corporate CUSOs, and the Board wants to ensure it has a degree of oversight and control of these activities.[16]

[2] 12 U.S.C. 1766(a).

[3] 12 U.S.C. 1789.

[4] 12 U.S.C. 1766(a).

[5] 12 CFR part 704.

[6] 75 FR 64786 (Oct. 20, 2010).

[7] *See e.g.,* 80 FR 25932 (May 6, 2015), 80 FR 57283 (Sept. 23, 2015), and 82 FR 55497 (Nov. 22, 2017).

[8] 82 FR 55497 (Nov. 22, 2017).

[9] *See, https://www.ncua.gov/regulation-supervision/rules-regulations/regulatory-review.*

[10] 85 FR 17288 (Mar. 27, 2020).

[11] 85 FR 20431 (Apr. 13, 2020).

[12] *See,* 12 CFR 704.11(e).

[13] 12 CFR 704.11(a).

[14] For example, the permissible activities for a corporate CUSO are more limited than the permissible activities for a NP CUSO. A corporate CUSO may seek Board permission to engage in additional activities, but the process can be burdensome. In addition, corporate CUSOs are also subject to more rigorous NCUA oversight. A corporate CUSO must agree to give the NCUA complete access to its personnel, facilities, equipment, books, records, and other documentation that the NCUA deems pertinent. In contrast, NP CUSOs must provide the NCUA with complete access to its books and records and the ability to review its internal controls, as deemed necessary by the NCUA. Finally, corporate CUSOs must provide quarterly financial statements to the corporate credit union. In contrast, NP CUSOs must prepare quarterly financial statements, but do not have to provide the statements to FCUs.

[15] 74 FR 65210 (Dec. 9, 2009).

[16] *Id.*

As stated above, a corporate CUSO is defined as an entity that is at least partly owned by a corporate credit union; primarily serves credit unions; restricts its services to those related to the normal course of business of credit unions; and is structured as a corporation, limited liability company, or limited partnership under state law.[17] The definition is broad and includes no exception for de minimis, non-controlling equity investments. Accordingly, any corporate credit union equity interest in a CUSO, regardless of how small a share of the CUSO the corporate credit union owns, is sufficient to designate the CUSO as a corporate CUSO and subject it to additional requirements under part 704.

The proposed rule amended the definition of corporate CUSO so that a corporate credit union could make a de minimis, non-controlling investment in a NP CUSO without the CUSO being deemed a corporate CUSO. Almost all commenters explicitly approved of this proposed change, and no commenters objected to it. The Board is finalizing it as proposed.

As stated in the proposed rule, the Board has reconsidered its position that any corporate credit union investment in a CUSO must be subject to enhanced standards under part 704 because the Board believes that a corporate credit union's non-controlling investment does not pose the same systemic risks to the credit union system as a controlling investment. In particular, it is unlikely that a corporate credit union would move its essential functions into a non-controlled CUSO.

The Board has also considered the benefits of permitting corporate credit unions to make de minimis, non-controlling investments in NP CUSOs. Compared to corporate CUSOs, NP CUSOs are permitted to engage in a broader range of permissible activities and services. Consequently, NP CUSOs are often a source of collaboration and innovation among FICUs that may result in the origination of new products and services. To compete effectively in today's technology-based financial service market, FICUs may need to rely increasingly on pooling their resources to fund CUSOs and to build the necessary infrastructure. The costs for research and development, acquisition, implementation, and specialized staff capable of managing these new technologies may be prohibitive for all but a very few of the largest FICUs. CUSOs may provide the means for FICUs to collectively address these challenges and may enable FICUs to collaboratively develop technologies that better serve their members.

Without the opportunity to invest in NP CUSOs, a corporate credit union may be restricted in its ability to participate in this process. The Board believes that by expanding corporate credit union investment authorities, while still maintaining necessary safeguards, it can place corporate credit unions in a better position to participate in the development of new products and services. NP CUSOs will also benefit from a larger pool of potential investors, which may enable further research and development during this period of rapid technological growth.

In addition to amending the definition of corporate CUSO to permit de minimis, non-controlling investments in NP CUSOs, the final rule also makes several conforming amendments to part 704. The specific details of the amendments are discussed below.

§ 704.2 Definitions

Consolidated credit union service organization. Generally, consolidated CUSOs are those majority-owned by a corporate credit union. The proposed rule amended the definition of consolidated CUSO to use the newly defined term ''CUSO'' for clarity. Under the proposed rule, a consolidated CUSO was defined as any CUSO the assets of which are consolidated with those of the corporate credit union for purposes of reporting under Generally Accepted Accounting Principles (GAAP). The Board received no comment on the definition of consolidated CUSO and is finalizing the definition as proposed.

Corporate CUSO. As discussed above, the proposed rule amended the definition of a corporate CUSO. Under the proposed rule, a CUSO is designated as a corporate CUSO only if one or more corporate credit unions have a controlling interest. A corporate credit union is considered to have a controlling interest if: (1) The CUSO is consolidated on a corporate credit union's balance sheet; (2) a corporate credit union has the power, directly or indirectly, to direct the CUSO's management or policies; or (3) a corporate credit union owns 25 percent or more of the CUSO's contributed equity, stock, or membership interests.[18] A CUSO also is designated as a corporate CUSO if the aggregate corporate credit union ownership of all corporates investing in the CUSO meets or exceeds 50 percent of the CUSO's contributed equity, stock, or membership interests. The Board is concerned that if several corporate credit unions have a majority ownership interest in a CUSO, the CUSO could present the same risk to the credit union system as a CUSO that is controlled by one corporate credit union. If any of these four conditions are met, then the CUSO meets the definition of a corporate CUSO and is subject to additional requirements under part 704.[19] No commenters suggested any changes to the definition of a corporate CUSO and the Board is finalizing the definition as proposed.

Credit Union Service Organization (CUSO). The proposed rule defined the term CUSO for purposes of part 704. Under the proposed rule, a CUSO is both a NP CUSO under part 712 and a corporate CUSO under § 704.11. The definition makes it clear that the term CUSO applies to both NP CUSOs and corporate CUSOs unless otherwise stated. For example, when calculating tier 1 capital under part 704, a corporate credit union must deduct, in part, investments in any ''unconsolidated CUSO.'' By using the term ''CUSO,'' instead of the defined terms ''corporate CUSO'' and ''consolidated CUSO,'' the proposed rule made clear that a corporate credit union must deduct unconsolidated investments in both a NP CUSO and a corporate CUSO. The Board received no comments on this definition and is finalizing it as proposed.[20]

§§ 704.5 Investments, 704.6 Credit Risk Management, and 704.7 Lending

The proposed rule removed references to corporate CUSOs and instead referred to the general term CUSO because those provisions continue to apply to a corporate credit union investing in and lending to both NP CUSOs and corporate CUSOs, as explained in detail below in the discussion of the proposed changes to § 704.11. The Board received no comments on these changes and is finalizing it as proposed.[21]

§ 704.11 Credit Union Service Organizations (CUSOs)

Under the proposed rule, § 704.11 was reorganized for clarity, however, the substantive requirements for corporate

[17] 12 CFR 704.11(a).

[18] The definition is related to the definition of control in the Federal Deposit Insurance Act for notices filed under the Change in Bank Control Act. 12 U.S.C. 1817(j).

[19] The definition of corporate CUSO also is moved to § 704.2 for consistency with the location of other definitions in part 704.

[20] The Board received a substantial number of comments on the aggregation of loans to NP CUSOs and corporate CUSOs. Those comments will be discussed below.

[21] As noted above, the Board received a substantial number of comments on the aggregation of loans to NP CUSOs and corporate CUSOs and addresses these below.

CUSOs were not amended. The intent of the reorganization is to be clear that certain requirements apply to a corporate credit union's investment in or lending to both NP CUSOs and corporate CUSOs, certain requirements apply only to NP CUSOs, and other requirements apply only to corporate CUSOs.

The proposed rule set forth the requirements for all corporate credit union investments in or lending to CUSOs. The proposed rule, in § 704.11(a), stated that the aggregate investment and lending limits apply regardless of whether a corporate credit union's investment or loan is to a NP CUSO or a corporate CUSO. The proposed rule did not intend to amend the current aggregate limitations on investments and lending.[22] Under the current rule, however, the aggregate investment and lending limits applied only to corporate CUSOs. A majority of commenters were concerned that including loans made to NP CUSOs in the aggregate limits would unintentionally limit corporate credit union lending to NP CUSOs. Commenters generally requested that the final rule exclude loans to NP CUSOs from the aggregate lending limits. A few commenters stated that they are supportive of aggregate limitations for investments in NP and corporate CUSOs, as well as combined limits for loans to and investments to an individual CUSO set as a percentage of total capital, but not aggregating lending to NP and corporate CUSOs. The Board disagrees that the proposed rule would substantially limit lending to NP CUSOs. First, the Board does not believe that corporate credit unions are currently engaging in substantial lending activities to NP CUSOs. In addition, under the current rule, corporate credit unions are not generally permitted to make loans to NP CUSOs.[23] Additionally, for safety and soundness reasons, the Board believes it is prudent for lending and investments to both natural person and corporate CUSOs to be subject to the aggregate limitations. The Board would have safety and soundness concerns if corporate credit unions lending to NP CUSOs were not subject to the limitations otherwise applicable to corporate CUSOs. The Board, however, notes that if a particular corporate credit union has a material volume of loans to a natural person CUSO, it may request that the Board issue a waiver from the aggregate lending and investment limits in the final rule under 12 CFR 704.1(b). The Board would consider such a waiver on a case-by-case basis. Therefore, the Board has not made any changes to the aggregate investment and lending limits and is adopting the limitations without change in the final rule. Therefore, a corporate credit union that has already invested in or loaned the maximum permitted under the current rule is not authorized to invest or lend any additional money. Instead, such a corporate credit union must reallocate its investments or loans if it seeks to make any new investments that are prohibited.

In § 704.11(b), the proposed rule stated that all corporate credit union loans to CUSOs are subject to due diligence requirements.[24] The proposed rule, as does the current rule, required corporate credit unions to comply with certain due diligence requirements from the NCUA's member business loans rule before making a loan to a CUSO. Under the proposed rule, corporate credit unions are subject to the commercial loan policy and due diligence requirements in the NCUA's member business loans rule[25] for lending to both NP CUSOs and corporate CUSOs. Several commenters objected to subjecting corporate credit union loans to the commercial loan policy and due diligence requirements in the revised MBL rule. Commenters generally stated that the requirements in the MBL rule are written for the lending activities and capital structure of natural person credit unions. Commenters also stated that corporate credit union lending activities are adequately regulated by the requirements of § 704.7 and, if there is a need for additional rulemaking regarding lending to CUSOs, that it is better to make changes to § 704.7 directly. One commenter also noted that an issue with referencing the MBL rule is that its lending limits are based upon net worth, which is a term that is undefined for corporate credit unions. The Board notes that part 723 adopted principles-based standards for commercial loan policies and due diligence standards. In general, part 723 does not require prescriptive standards. Accordingly, the Board believes that the principles outlined in part 723 are appropriate for most loans to corporate and NP CUSOs, which the Board considers general commercial loans. The Board notes that to the extent part 723 refers to credit unions establishing limitations based on net worth, such limitations established by a corporate credit union would be based on tier 1 capital. As discussed by the commenters, corporate credit unions do not use the terminology net worth.

Therefore, under the final rule, a corporate credit union making loans to NP or corporate CUSOs must have a board-approved policy that ensures corporate credit union lending activities are performed in a safe and sound manner by providing for ongoing control, measurement, and management of CUSO lending. The policy should also include qualifications and experience requirements for personnel involved in underwriting, processing, approving, administering, and collecting loans to CUSOs. The corporate credit union must also have a loan approval process, underwriting standards, and risk management processes commensurate with the size, scope and complexity of its CUSO lending. The Board believes these due diligence requirements are the minimum requirements necessary to ensure that corporate credit unions are engaging in safe and sound lending practices.

The Board has made one change to this section in light of commenters concerns about burden. The Board has added an exception for loans and lines of credit to NP and corporate CUSOs that are fully secured by U.S. Treasury or agency securities. Loans that are fully secured by U.S. Treasury or agency securities present less risk and do not require the same due diligence requirements as standard commercial loans. With this limited modification, the Board does not believe these requirements should place a new burden on corporate credit unions because any corporate credit union that is currently making a loan to a corporate CUSO should be following these basic safety and soundness principles.

In § 704.11(c), the proposed rule set forth the regulations governing corporate credit union investment in and lending to NP CUSOs. The proposed rule stated that corporate credit union investment in and lending to NP CUSOs are subject to part 712 of

[22] 12 CFR 704.11(b). In general, the aggregate of all investments in corporate CUSOs that a corporate credit union may make must not exceed 15 percent of a corporate credit union's total capital. The aggregate of all investments in and loans to corporate CUSOs that a corporate credit union may make must not exceed 30 percent of a corporate credit union's total capital. A corporate credit union may lend to corporate CUSOs an additional 15 percent of total capital if the loan is collateralized by assets in which the corporate has a perfected security interest under state law.

[23] 12 CFR 704.11(h) ("A corporate credit union is not authorized to . . . loan to a CUSO under part 712 of this chapter.").

[24] 12 CFR 704.11(c). The current rule includes a cross-reference to due diligence requirements in the member business loan rule. The member business loan rule, however, was updated in 2015 and the cross-referenced requirements have been removed. Accordingly, the proposed rule updated the cross references to reflect the revised member business loan rule.

[25] 12 CFR 723.4.

this chapter. The intent of this section is to be clear that a CUSO is either governed under part 704 as a corporate CUSO, as discussed below, or subject to part 712 as a NP CUSO. A corporate credit union investment in a CUSO of a state-chartered natural person credit union is also subject to the requirements in part 712. The Board has made one clarifying change to this section. Under the final rule, the Board is clarifying that the CUSO of a state-chartered natural person credit union is subject to the requirements in part 712 as if the CUSO is a CUSO of an FCU. The Board wants to clarify that all of the requirements in part 712, such as the activity limitations in § 712.5, are necessary for any corporate credit union to invest in or loan to a NP CUSO, regardless of the charter type of the natural person credit union. If a CUSO does not meet the standards in part 712, then a corporate credit union cannot make the investment or loan.

In § 704.11(d), the proposed rule, like the current rule, included safety and soundness requirements for corporate credit union investments in and loans to corporate CUSOs. In general, the proposed rule did not make any substantive changes to the existing prudential requirements. The requirements were reorganized for clarity and as part of the general restructuring of § 704.11, but were not otherwise substantively amended.[26] No commenters objected to these proposed provisions, and the Board is finalizing them as proposed.

Finally, in § 704.11(e), the proposed rule included one new prudential requirement for corporate credit union investments in and loans to corporate CUSOs. The proposed rule stated that any subsidiary of a corporate CUSO is automatically designated a corporate CUSO. The proposed rule also provided that all tiers or levels of a corporate CUSO's structure are subject to the requirements for corporate CUSOs. No commenters objected to this proposed provision, and the Board is finalizing it as proposed. The Board believes this level of oversight is necessary for all tiers of a corporate CUSO because corporate CUSOs affect not only the health of the investing corporate credit union, but also the health of the credit union system as a whole. Many corporate CUSOs serve natural person credit unions directly. As stated previously, the Board has historically been concerned that some activities might migrate from corporate credit unions to CUSOs and their subsidiaries, and the Board needs to ensure each layer in the corporate structure is subject to certain minimal prudential requirements.

§ 704.19 Disclosure of Executive Compensation

Section 704.19 currently requires that each corporate credit union annually prepare and maintain a document that discloses the compensation of certain employees, including compensation received from a corporate CUSO.[27] The proposal amended § 704.19 to require that employee compensation from either a NP CUSO or a corporate CUSO must be reported. The Board notes that under the current rule to facilitate this disclosure, § 704.11(g) requires a corporate CUSO to disclose compensation paid to any employees that are also employees of a corporate credit union lending to, or investing in, the CUSO. This provision places the burden of disclosure on the corporate CUSO. The proposed rule, however, did not include a similar requirement for NP CUSOs.[28] No commenters objected to this proposed provision, and the Board is finalizing it as proposed. Accordingly, under the final rule, the dual employee is required to disclose his or her compensation from the NP CUSO for the corporate credit union to make the required disclosure.

B. Corporate Credit Union Board Representation

Section 704.14 currently requires that at least a majority of a corporate credit union's board members must serve on the corporate credit union's board as a representative of a member credit union.[29] In addition, any candidate for a position on the board of a corporate credit union must hold a senior management position at a member credit union and hold that position at the time he or she is seated on the board of a corporate credit union. Currently, only an individual who holds the position of chief executive officer, chief financial officer, chief operating officer, or treasurer/manager at a member credit union, and will hold that position at the time he or she is seated on the corporate credit union board if elected, may seek election or re-election to the corporate credit union board.

The proposed rule expanded the credit union officials eligible to serve on a corporate credit union board. The proposed rule no longer expressly limited the corporate credit union board to the above stated positions and instead included any person in a senior staff position at a member credit union. The proposed rule then listed the current positions as examples of senior staff positions that are eligible to serve on a corporate credit union board. The proposed rule also included two new positions, chief information officer and chief risk officer, in the list of examples of senior staff positions eligible to serve on a corporate credit union board. No commenters objected to this proposed provision and the Board is finalizing it as proposed. One commenter, however, urged the Board to defer to state rules with respect to governance matters such as board qualifications. The commenter further stated that it believes that the homogenization of the corporate credit union governance system presents risks by stifling innovation. The commenter, however, offered no specific suggestions. The Board believes that certain minimum standards are necessary to ensure adequate corporate governance.

The Board believes that officials who hold a senior management position at a member credit union are qualified individuals who could offer expertise as a corporate credit union board member. Not only do corporate credit union members have more flexibility in choosing board members, but expanding eligible senior staff positions, such as chief information officer and chief risk officer, widens the range of expertise on corporate credit union boards.

C. Enterprise Risk Management

Section 704.21 requires corporate credit unions to develop and follow an enterprise risk management policy.[30] A corporate credit union must also establish an enterprise risk management committee (ERMC) and include an independent risk management expert on the committee. The Board adopted these requirements in 2011 due to concerns that corporate credit unions were not adequately focused on the aggregation of exposures across entire institutions, even though the Board believed that corporate credit unions were adequately focused on individual risk exposures.[31]

The current rule includes several specific requirements regarding the

[26] The proposed rule included a few non-substantive language changes that are only intended to streamline the provision and enhance clarity.

[27] 12 CFR 704.19(a).

[28] The Board notes, however, that part 712 prohibits officials and senior management employees, and their immediate family members of an FCU with an outstanding loan or investment from receiving any salary, commission, investment income, or other income or compensation from the CUSO, either directly or directly. 12 CFR 712.8.

[29] 12 CFR 704.14.

[30] 12 CFR 704.21.

[31] 76 FR 23861 (Apr. 29, 2011) and 80 FR 25932 (May 6, 2015).

independent risk management expert on the committee. The risk management expert must have at least five years of experience in identifying, assessing, and managing risk exposures.[32] This experience must be commensurate with the size of the corporate credit union and the complexity of its operations. In addition, the current rule provides what constitutes independence. A risk management expert qualifies as independent if: (1) The expert reports to the ERMC and to the corporate credit union's board of directors; (2) neither the expert, nor any immediate family member of the expert, is supervised by or has any material business or professional relationship with the chief executive officer (CEO) of the corporate credit union, or anyone directly or indirectly supervised by the CEO; and (3) neither the expert, nor any immediate family member of the expert, has had any of the previously described relationships for at least the past three years.[33] The Board specifically included experience and independence requirements to ensure the enterprise risk management expert is adequately qualified and not influenced by the operational side of the corporate credit union.[34] The proposed rule removed the prescriptive independence and experience requirements. No commenters objected to this proposed provision, and the Board is finalizing with one technical amendment. The final rule clarifies that the risk management expert may report either to the corporate credit union's board of directors or to the ERMC. Several commenters also requested that the prescriptive independence requirements be removed from the final rule. The Board clarifies that the prescriptive independence provisions are also removed under the final rule.

The Board no longer believes that it is necessary for prescriptive experience and independence requirements. The Board believes the corporate credit union should have more discretion in choosing a qualified risk management expert. The Board does not believe that a prescriptive five-year experience requirement is necessary. The Board believes that corporate credit unions are in the best position to determine the appropriate level of experience necessary for the position. The final rule also permits the risk management expert to report directly to the ERMC or the corporate credit union's board.

Additionally, the Board believes that the effectiveness of risk management practices is driven by a multitude of factors, to include policies, processes, and qualified knowledge. Many corporate credit unions have integrated their enterprise risk management function into their business decision making, and at many corporate credit unions, internal corporate staff possess the skills and experience to capably manage the enterprise risk management program. By and large, corporate credit unions have improved their ability to assess risk and effectively challenge evaluations of risk since the current rule was first adopted. The final rule provides the corporate credit unions flexibility to choose an internal risk management expert instead of engaging an outside consultant.

The Board, however, notes that even though independence is no longer an explicit requirement, for best enterprise risk management practices, the expert should have appropriate stature and authority to effectively manage and lead an enterprise risk management program. The expert must be competent to analyze risks across the institution and have the capability to communicate those risks to the board or ERMC despite potential influence from the operational side of the corporate credit union. The NCUA will evaluate the adequacy of a corporate credit union's enterprise risk management practices through the supervisory process. Sound risk management is a cornerstone responsibility of a credit union's leadership; therefore, Capital Adequacy, Asset Quality, Management, Earnings, and Liquidity/Asset-Liability Management (CAMEL) and risk ratings will incorporate the supervisory team's assessment of this area. Weaknesses in risk management may result in supervisory actions.

D. Natural Person Credit Union Subordinated Debt Instruments

The Board recently issued a proposed rule to permit low-income designated credit unions, complex credit unions, and new credit unions to issue subordinated debt instruments for purposes of regulatory capital treatment (subordinated debt NPRM).[35] If the Board adopts the proposed rule as final, it expects additional credit unions to begin issuing subordinated debt instruments. Therefore, the Board believes it is necessary to clarify whether corporate credit unions may purchase such instruments and, if so, the treatment of the investments under part 704.

The proposed rule created a new definition for the term natural person credit union subordinated debt instrument. The proposed rule defined a natural person credit union subordinated debt instrument as any debt instrument issued by a natural person credit union that is subordinate to all other claims against the credit union, including the claims of creditors, shareholders, and either the National Credit Union Share Insurance Fund (NCUSIF) or the insurer of a privately insured credit union. The Board intends for this definition to include all instruments issued under the subordinated debt NPRM. No commenters objected to this proposed definition. The Board, however, is not finalizing the definition as part of this final rule. The Board believes it is prudent to include any changes related to the subordinated debt NPRM with the associated subordinated debt final rule. At this time, the Board does not envision any changes to the proposed definition.

The proposed rule also clarified that corporate credit unions may purchase the natural person subordinated debt instruments. This authority is derived from their lending authority because subordinated debt instruments are issued under a natural person credit union's borrowing authority. Additionally, natural person credit unions are also permitted, subject to various restrictions and limits, to purchase such subordinated debt instruments from other natural person credit unions under their lending authority. Treating the purchase of such subordinated debt instruments as lending ensures consistent treatment between natural person credit unions and corporate credit unions. The final rule does not explicitly state that a corporate credit union may purchase a natural person credit union subordinate debt instrument because the Board believes corporate credit unions' current lending authority is sufficiently broad to include purchasing subordinated debt instruments.

The proposed rule, however, required that a corporate credit union fully deduct the amount of the subordinated debt instrument from its tier 1 capital to ensure consistent treatment between investments in the capital of other corporate credit unions and natural person credit unions. Corporate credit unions are currently required to deduct from tier 1 capital any investments in perpetual contributed capital and nonperpetual capital accounts that are maintained at other corporate credit unions.[36] The proposed rule also asked

[32] 12 CFR 704.21(c).

[33] 12 CFR 704.21(d).

[34] 76 FR 23861 (Apr. 29, 2011).

[35] 85 FR 13982 (Mar. 10, 2020).

[36] See the definition of tier 1 capital in 12 CFR 704.2.

a question on whether it would be more appropriate to prohibit corporate credit unions from purchasing subordinated debt instruments. No commenter recommended restricting corporate credit union authority to purchase subordinated debt instruments.

The Board believes that investments in natural person credit union subordinated debt instruments should be treated similar to investments in perpetual contributed capital and nonperpetual capital accounts that are maintained at other corporate credit unions as such instruments may qualify as regulatory capital for the natural person credit union. The Board is also concerned about systemic risk if corporate credit unions own a significant amount of natural person credit union issued subordinated debt. Finally, a natural person credit union subordinated debt instrument would be in a first loss position, even before the NCUSIF and any private insurance fund or entity. Therefore, an involuntary liquidation of the issuing credit union would potentially mean large, and likely total, losses for the holders of those subordinated obligations. The Board believes that fully deducting such instruments from tier 1 capital ensures any potential losses do not affect the capital position of the investing corporate credit union. This measured approach strikes the right balance between providing corporate credit unions the flexibility to purchase natural person credit union subordinated debt instruments and avoiding undue systemic risk to the credit union system. For the same reasons as the definition of natural person subordinated debt instrument, the final rule is not including this amendment. The amendment will be included with any final rule on subordinated debt.

E. Approved Corporate CUSO Activities

Part 704 does not list the permissible activities for corporate CUSOs in the regulatory text of part 704 of the Code of Federal Regulations, unlike part 712, which does so for NP CUSOs.[37] Instead, § 704.11 requires that, generally, a corporate CUSO must agree that it will limit its services to brokerage services, investment advisory services, and other categories of services as preapproved by NCUA and published on NCUA's website.[38] A CUSO that desires to engage in an activity not preapproved by NCUA can apply to NCUA for that approval. To increase transparency and make it easier for corporate credit unions to determine if an activity has previously been determined by the Board to be permissible, the proposed rule contained a provision to replace the permissible activities list from the NCUA website with a new appendix to part 704. No commenter supported this change, and almost all commenters specifically objected to it. Commenters generally stated that the change would increase regulatory burden and make it more difficult for corporate CUSOs to obtain timely approval to add permissible activities to the list. Commenters were primarily concerned about the added burden of formally adding activities through notice-and-comment rulemaking. Other commenters also discussed the need to make rapid changes to the list of preapproved activities in response to the pace of development from financial technology (fintech) companies. Commenters also suggested moving the list of preapproved activities for NP CUSOs to the NCUA's website. The Board notes that moving the list of preapproved activities for NP CUSOs would be outside the scope of the proposed rule. Finally, one commenter recommended codifying the practice of consulting with state regulators before making a determination on ''other activities'' for state chartered corporate credit union CUSOs.

In light of commenters' feedback, the Board will not adopt this proposed change regarding approval of corporate CUSO activities. The proposed change was intended to increase transparency. The Board is mindful of any unintended procedural burden the change might entail and therefore declines to adopt it. Instead, the agency's website will continue to list approved corporate CUSO activities. The current process to request approval of new corporate CUSO activities remains unchanged and is described on the web page that includes the list of approved activities.[39]

F. Definition of Collateralized Debt Obligation

Corporate credit unions are prohibited from purchasing certain overly complex or leveraged investments, including collateralized debt obligations (commonly referred to as CDOs).[40] Under the current rule, the term CDO means a debt security collateralized by mortgage-backed securities, other asset-backed securities, or corporate obligations in the form of nonmortgage loans or debt. The term does not include: (1) Senior tranches of Re-REMICs consisting of senior mortgage- and asset-backed securities; (2) Any security that is fully guaranteed as to principal and interest by the U.S. Government or its agencies or its sponsored enterprises; or (3) Any security collateralized by other securities where all the underlying securities are fully guaranteed as to principal and interest by the U.S. Government or its agencies or its sponsored enterprises.[41] The proposed rule amended the definition of CDO to clarify that the definition includes both loans and debt securities. The proposed rule changed the defined term to ''collateralized loan or debt obligation,'' but did not otherwise amend the definition. No commenter objected to the substance of the change, however, several commenters requested a revision to the proposed language. Commenters generally wanted to use language that is consistent with industry terminology and recommended having separate definitions for CDOs and Collateralized Loan Obligations (referred to as ''CLOs''). In response to commenter concerns about clarity, the final rule uses the term ''collateralized debt obligation or collateralized loan obligation.'' The Board intends no substantive changes as a result of the amended terminology and has made no change to the definition. This amendment is only intended to resolve any confusion among industry participants concerning whether collateralized loans meet the definition and are therefore prohibited. The Board believes amending the name of the defined term clarifies the Board's intent that collateralized loans meeting the definition are also prohibited.

G. Net Interest Income Modeling

Under the current rule, a corporate credit union must perform net interest income (NII) modeling to project earnings in multiple interest rate environments for a period of no less than two years.[42] NII modeling must, at minimum, be performed quarterly, including once on the last day of the calendar quarter. The proposed rule made a change to the timeframe for NII. Under the proposed rule, a corporate credit union is not required to perform NII modeling for two years and instead only is required to perform modeling for

[37] 12 CFR 712.5(b).

[38] *https://www.ncua.gov/regulation-supervision/corporate-credit-unions/corporate-cuso-activities/approved-corporate-cuso-activities.*

[39] Corporate CUSO Activities, *https://www.ncua.gov/regulation-supervision/corporate-credit-unions/corporate-cuso-activities.*

[40] The prohibition on purchasing CDOs was intended to protect corporate credit unions from the potential for excessive investment losses. 75 FR 64786, 64793 (Oct. 20, 2010).

[41] 12 CFR 704.2.

[42] 12 CFR 704.8(e).

a period of no less than one year. In general, commenters were either indifferent to or not supportive of the proposed change. Some commenters noted that ALM models already are built for the two-year NII projections, so this change will not provide any real regulatory relief. Some commenters stated that reducing the required NII modeling from two years to one year will not increase the accuracy of the NII forecast (however another commenter stated that the one-year forecasts are more accurate as there are more unknowns impacting a balance sheet using the two-year timeframe). Several commenters stated that the same inputs and assumptions will still have to be incorporated into the NII model and that the two-year timeframe was appropriate. Other commenters recommended that the NCUA instead increase the ''weighted-average life'' (WAL) limit beyond the current two-year limit. These commenters stated that a longer-term WAL would allow corporate credit unions to more effectively manage NII through varying economic and interest rate scenarios. The Board has not adopted any amendments to the WAL at this time. The Board continues to believe that the two-year WAL limit reflects the fact that corporate credit unions are, first and foremost, providers of payment systems, which, in turn, requires some matching of the investment portfolio to the short term payment liabilities to ensure liquidity for the payments system. The Board believes that a longer-term WAL is unnecessary given the primary purpose of corporate credit unions as providers of payment systems.

Therefore, the Board is only amending the requirements for NII given that corporate credit unions are also subject to a two-year WAL limit.[43] Under the current rule, a corporate credit union must test its financial assets at least quarterly, including once on the last day of the calendar quarter, for compliance with this limitation. If the WAL of a corporate credit union's assets exceeds two years on the testing date, this test must be calculated at least monthly, including once on the last day of the month, until the WAL is below two years.

The Board believes that NII modeling performed over a longer period than the WAL limits for asset maturities is less useful because the corporate credit union also has to estimate what reinvestments occur over the two-year period beyond simply estimating interest cash flows on assets. In addition, corporate credit unions already conduct net economic value analyses which capture a long-term view of interest rate risk. Allowing corporate credit unions to model NII over a one year period provides increased flexibility for corporate credit unions to measure NII over a shorter, and more appropriate, time period, such as when financial assets and liabilities are predominately short term (such as less than one year). The Board believes that NII modeling over a one-year period sufficiently captures a corporate credit union's short-term interest rate risk. To the extent commenters stated their models are already based on two-year projections, the final rule does not require corporate credit unions to change their models. The final rule only requires that a corporate credit union must perform NII modeling for a period of *no less than* 1 year. Therefore, a model projecting a period of two years still complies with the final rule.

H. Technical Amendment

A few commenters requested that the Board clarify which type of loans would need to comply with the MBL rule. The current rule states that loans, lines of credit, and letters of credit to other members not excluded under § 723.1(b) must comply with part 723 unless the loan or line of credit is fully guaranteed by a credit union or fully secured by U.S. Treasury or agency securities. The current regulation also states that those guaranteed and secured loans must comply with the aggregate limits of § 723.16 but are exempt from the other requirements of part 723. Commenters suggested a technical correction to update the cross-reference, which cites to an outdated provision of the MBL rule. The Board has made the requested technical amendment. Under the final rule, the section of the MBL rule cross-referenced is § 723.8.

I. Comments Outside the Scope of the Proposed Rule

Many commenters recommended that the Board consider additional burden reduction for corporate credit unions. In general, these recommendations are not a logical outgrowth of the proposed rule and, thus, are outside the scope of this rulemaking. A general discussion of the recommendations is included below.

1. A few commenters requested that the Board clarify that the existing 15 percent limit on commercial mortgage-backed securities applies to ''private'' commercial mortgage-backed securities and not agency commercial mortgage-backed securities (ACMBS). These commenters stated that ACMBS carry the same credit risk as agency residential MBS.

2. Several commenters requested additional flexibility to allow corporate credit unions with higher capital ratios to extend their WAL limitations. These commenters also recommended that a liquidity management policy and procedures be established that incorporate the following: Liquidity strategy for various economic conditions; defined liquidity risk profiles under various economic conditions; and liquidity buffer consisting of highly liquid assets. Some commenters also suggested including permission for longer WAL limitations in Appendix B, Expanded Authorities.

3. Several commenters also recommended that the Board extend the maturity limit on secured borrowing from 180 days to 1 year to cover a full cycle of seasonal cash outflows (one commenter recommended two years). Commenters also requested a change in the limit for secured non-liquidity borrowings from the tier 1 capital in excess of five percent of moving daily average net assets to 100 percent of total capital (one commenter recommended using tier 1 capital).

4. Several commenters requested that the Board permit non-CUSO investments for the purpose of allowing corporate credit unions reasonable ability to invest a small percentage of their capital in entities outside the credit union system (such as fintechs).

5. Two commenters requested that the Board permit a modest increase in the individual borrower limit.

6. A few commenters recommended that Appendix B, Expanded Authorities, clarify that any investment that deteriorates below investment grade, as defined in § 704.2, would require an investment action plan in compliance with § 704.10.

7. One commenter recommended establishing a task force with state regulators to review future adjustments to the corporate credit union rules. The commenter also recommended reintroducing meaningful dual chartering by eliminating unnecessary preemption of state rules, particularly with respect to corporate credit union governance; and enhancing the joint supervision of corporates. The commenter also recommended increased information sharing between the NCUA and the state regulators supervising the corporate credit union's natural person credit union members.

8. One trade organization commenter recommended that the agency should consider ways in which it can wind down the NCUA guaranteed notes program (known as the NGN Program) so that credit unions that paid into the Temporary Corporate Credit Union

[43] 12 CFR 704.8(f).

Stabilization Fund and invested in certain corporates are made whole. The commenter stated that the NCUA's determination that the asset management estates of the various failed corporates must remain distinct means that recoveries from one estate cannot be comingled to pay obligations of other estates; however, the commenter stated that the agency still has time to reconsider this position and invite comments from credit unions who might bear a greater loss if the NCUA proceeds along its present course.

9. One trade organization commenter also recommended that the Board explore a framework to engage with fintech companies so credit unions can more easily sustain continued innovation in the credit union industry.

VII. Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a final rule, an agency prepare and make available for public comment a final regulatory flexibility analysis that describes the impact of a final rule on small entities (defined for purposes of the RFA to include credit unions with assets less than $100 million).[44] A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities and publishes its certification and a short, explanatory statement in the **Federal Register** together with the rule.

This final rule does not have a significant economic impact on a substantial number of small entities. There are no corporate credit unions under $100 million in assets. Therefore, the Board certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to information collection requirements in which an agency creates a new paperwork burden on regulated entities or modifies an existing burden. For purposes of the PRA, a paperwork burden may take the form of a reporting, recordkeeping, or third-party disclosure requirement, each referred to as an information collection. The NCUA may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The final rule amends 12 CFR part 704, in part, to address minimal investments by a corporate credit union in a CUSO without the CUSO being classified as a corporate CUSO. The information collection requirements associated with this provision are cleared under OMB control number 3133–0129 and there are no other new information collection requirements associated with this final rule.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, the NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the principles of the Executive Order. This rulemaking will not have a substantial direct effect on the states, on the connection between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The NCUA has determined that this final rule does not constitute a policy that has federalism implications for purposes of the Executive Order.

Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this final rule does not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105–277, 112 Stat. 2681 (1998).

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) (SBREFA) generally provides for congressional review of agency rules.[45] A reporting requirement is triggered in instances where the NCUA issues a final rule as defined by Section 551 of the APA.[46] An agency rule, in addition to being subject to congressional oversight, may also be subject to a delayed effective date if the rule is a ''major rule.''[47] The NCUA does not believe this rule is a ''major rule'' within the meaning of the relevant sections of SBREFA. As required by SBREFA, the NCUA will submit this final rule to OMB for it to determine if the final rule is a ''major rule'' for purposes of SBREFA. The NCUA also will file appropriate reports with Congress and the Government Accountability Office so this rule may be reviewed.

List of Subjects in 12 CFR Part 704

Credit unions, Corporate credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board on October 15, 2020.

Melane Conyers-Ausbrooks,

Secretary of the Board.

For the reasons discussed in the preamble, the Board amends 12 CFR part 704, as follows:

PART 704—CORPORATE CREDIT UNIONS

■ 1. The authority citation for part 704 continues to read as follows:

Authority: 12 U.S.C. 1766(a), 1781, and 1789.

■ 2. In § 704.2:

■ a. Revise the definitions for ''*Collateralized Debt Obligation*'', and ''*Consolidated Credit Union Service Organization*''; and

■ b. Add definitions for ''*Corporate CUSO*'', and ''*Credit Union Service Organization (CUSO)*'', in alphabetical order, to read as follows:

§ 704.2 Definitions.

* * * * *

Collateralized Debt Obligation or Collateralized Loan Obligation means a debt security collateralized by mortgage-backed securities, other asset-backed securities, or corporate obligations in the form of nonmortgage loans or debt. For purposes of this part, the term collateralized debt obligation or collateralized loan obligation does not include:

(1) Senior tranches of Re-REMIC's consisting of senior mortgage-and asset-backed securities;

(2) Any security that is fully guaranteed as to principal and interest by the U.S. Government or its agencies or its sponsored enterprises; or

(3) Any security collateralized by other securities where all the underlying securities are fully guaranteed as to principal and interest by the U.S. Government or its agencies or its sponsored enterprises.

* * * * *

Consolidated Credit Union Service Organization (Consolidated CUSO) means any CUSO the assets of which are consolidated with those of the corporate credit union for purposes of reporting under Generally Accepted Accounting Principles (GAAP). Generally,

[44] *See* 80 FR 57512 (Sept. 24, 2015).

[45] 5 U.S.C. 801–804.

[46] 5 U.S.C. 551.

[47] 5 U.S.C. 804(2).

consolidated CUSOs are majority-owned CUSOs.

* * * * *

Corporate CUSO means a CUSO, as defined in part 712 of this chapter, that:

(1) Is a consolidated CUSO;

(2) A corporate credit union has the power, directly or indirectly, to direct the CUSO's management or policies;

(3) A corporate credit union owns 25 percent or more of the CUSO's contributed equity, stock, or membership interests; or

(4) The aggregate corporate credit union ownership meets or exceeds 50 percent of the CUSO's contributed equity, stock, or membership interests.

Credit union service organization (CUSO) means both a CUSO under part 712 of this chapter and a corporate CUSO under this part.

* * * * *

■ 3. Revise § 704.5(c)(3) and (h)(6) to read as follows:

§ 704.5 Investments.

* * * * *

(c) * * *

(3) CUSOs, subject to the limitations of § 704.11;

* * * * *

(h) * * *

(6) Purchasing collateralized debt obligations or collateralized loan obligations;

* * * * *

§ 704.6 [Amended]

■ 4. In § 704.6(c)(2)(vi), remove the word ''corporate'' before the word ''CUSO.''

§ 704.7 [Amended]

■ 5. In § 704.7 remove the word ''corporate'' before the word ''CUSO'' each place the word appears and replace ''§ 723.16'' with ''§ 723.8.''

§ 704.8 [Amended]

■ 6. In § 704.8(e) replace the phrase ''no less than 2 years'' with ''no less than 1 year.''

■ 7. Revise § 704.11 to read as follows:

§ 704.11 Credit Union Service Organizations (CUSOs).

(a) *Investment and loan limitations.* (1) The aggregate of all investments in member and non-member CUSOs that a corporate credit union may make must not exceed 15 percent of a corporate credit union's total capital.

(2) The aggregate of all investments in and loans to member and nonmember CUSOs a corporate credit union may make must not exceed 30 percent of a corporate credit union's total capital. A corporate credit union may lend to member and nonmember CUSOs an additional 15 percent of total capital if the loan is collateralized by assets in which the corporate has a perfected security interest under state law.

(3) If the limitations in paragraphs (a)(1) and (2) of this section are reached or exceeded because of the profitability of the CUSO and the related GAAP valuation of the investment under the equity method without an additional cash outlay by the corporate, divestiture is not required. A corporate credit union may continue to invest up to the regulatory limit without regard to the increase in the GAAP valuation resulting from the CUSO's profitability.

(b) *Due diligence.* A corporate credit union must comply with the commercial loan policy and due diligence requirements of § 723.4 of this chapter for all loans to CUSOs unless the loan or line of credit is fully secured by U.S. Treasury or agency securities.

(c) *Requirements for CUSOs that are not corporate CUSOs.* Corporate credit union investments in and lending to CUSOs that are not corporate CUSOs are subject to part 712 of this chapter, except that investment and loan limitations and due diligence requirements are governed by this section. CUSOs of state-chartered natural person credit unions are subject to part 712 of this chapter to the same extent as a CUSO of a federal credit union.

(d) *Requirements for corporate CUSOs.* Corporate credit union authority to invest in or loan to a corporate CUSO is limited to that provided in this section.

(1) *Structure.* A corporate CUSO must be structured as a corporation, limited liability company, or limited partnership under state law.

(2) *Separate entity.* (i) A corporate CUSO must be operated as an entity separate from a corporate credit union.

(ii) A corporate credit union investing in or lending to a corporate CUSO must obtain a written legal opinion that concludes the corporate CUSO is organized and operated in a manner that the corporate credit union will not reasonably be held liable for the obligations of the corporate CUSO. This opinion must address factors that have led courts to ''pierce the corporate veil,'' such as inadequate capitalization, lack of corporate identity, common boards of directors and employees, control of one entity over another, and lack of separate books and records.

(3) *Permissible activities.* (i) A corporate CUSO must agree to limit its activities to:

(A) Brokerage services,

(B) Investment advisory services, and

(C) Other categories of activities as approved in writing by the NCUA and published on the NCUA's website.

(ii) Once the NCUA has approved an activity and published that activity on its website, the NCUA will not remove that particular activity from the approved list, or make substantial changes to the content or description of that approved activity, except through the formal rulemaking process.

(4) *Compensation restrictions.* An official of a corporate credit union which has invested in or loaned to a corporate CUSO may not receive, either directly or indirectly, any salary, commission, investment income, or other income, compensation, or consideration from the corporate CUSO. This prohibition also extends to immediate family members of officials.

(5) *Written agreement between the corporate credit union and corporate CUSO.* Prior to making an investment in or loan to a corporate CUSO, a corporate credit union must obtain a written agreement that the corporate CUSO:

(i) Will follow GAAP;

(ii) Will provide financial statements to the corporate credit union at least quarterly;

(iii) Will obtain an annual CPA opinion audit and provide a copy to the corporate credit union. A consolidated CUSO is not required to obtain a separate annual audit if it is included in the corporate credit union's annual audit;

(iv) Will provide the reports as required by § 712.3(d)(4) and (5) of this chapter;

(v) Will not acquire control, directly or indirectly, of another depository financial institution or to invest in shares, stocks, or obligations of an insurance company, trade association, liquidity facility, or similar organization;

(vi) Will allow the auditor, board of directors, and NCUA complete access to the CUSO's personnel, facilities, equipment, books, records, and any other documentation that the auditor, directors, or NCUA deem pertinent;

(vii) Will inform the corporate, at least quarterly, of all the compensation paid by the CUSO to its employees who are also employees of the corporate credit union; and

(viii) Will comply with all the requirements of this section.

(e) *Subsidiary restrictions.* Any subsidiary of a corporate CUSO is automatically designated a corporate CUSO and subject to all the requirements of this section. The requirements of this section apply to all tiers or levels of a corporate CUSO's structure.

■ 8. Revise § 704.14(a)(2) to read as follows:

§ 704.14 Representation.

* * * * *

(a) * * *

(2) Only an individual who currently holds a senior staff position (*e.g.,* position of chief executive officer, chief financial officer, chief operating officer, chief information officer, chief risk officer, treasurer/manager, etc.) at a member credit union, and will hold that position at the time he or she is seated on the corporate credit union board if elected, may seek election or re-election to the corporate credit union board;

* * * * *

§ 704.19 [Amended]

■ 9. In § 704.19(a), remove the word ''corporate'' before the word ''CUSO''.

■ 10. In § 704.21, revise paragraph (c) and remove paragraphs (d) and (e) to read as follows:

§ 704.21 Enterprise risk management.

* * * * *

(c) The ERMC must include at least one risk management expert who may report either directly to the board of directors or to the ERMC. The risk management expert's experience must be commensurate with the size of the corporate credit union and the complexity of its operations.

[FR Doc. 2020–23185 Filed 11–10–20; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1221

[Document No: NASA–20–088; Docket No: NASA–2020–0005]

RIN 2700–AE57

NASA Seal, NASA Insignia, NASA Logotype, NASA Program Identifiers, NASA Flags, and the Agency's Unified Visual Communications System

AGENCY: National Aeronautics and Space Administration.

ACTION: Direct final rule.

SUMMARY: This direct final rule makes nonsubstantive changes to add the NASA Graphics Standards Manual and make other administrative updates.

DATES: This direct final rule is effective on January 11, 2021. Comments due on or before December 14, 2020.

ADDRESSES: Comments must be identified with RINs 2700–AE57 and may be sent to NASA via the Federal E-Rulemaking Portal: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Please note that NASA will post all comments on the internet with changes, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Bert Ulrich, 202–358–1713, *bert.ulrich@nasa.gov*.

SUPPLEMENTARY INFORMATION:

Direct Final Rule and Significant Adverse Comments

NASA has determined this rulemaking meets the criteria for a direct final rule because it makes nonsubstantive changes to add the NASA Graphics Standards Manual and makes other administrative updates. No opposition to the changes and no significant adverse comments are expected. However, if NASA receives significant adverse comments, it will withdraw this direct final rule by publishing a notice in the **Federal Register**. A significant adverse comment is one that explains: (1) Why the direct final rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this direct final rule, NASA will consider whether it warrants a substantive response in a notice and comment process.

Background

Subpart 1 of part 1221, last amended November 5, 1993 [58 FR 58944], sets forth the policy governing the use of the NASA Seal, the NASA Insignia, NASA Logotype, NASA Program Identifiers, and the NASA Flags. This subpart also establishes and sets forth the concept and scope of the NASA Unified Visual Communications System and prescribes the policy and guidelines for implementation of the system. It is amended to add the NASA Graphics Standards Manual and make other administrative updates.

Statutory Authority

The National Aeronautics and Space Act (the Space Act), 51 U.S.C. 20113 (a), authorizes the Administrator of NASA to make, promulgate, issue, rescind, and amend rules and regulations governing the manner of its operations and the exercise of the powers vested in it by law.

Regulatory Analysis

Executive Order 12866, Regulatory Planning and Review and Executive Order 13563, Improvement Regulation and Regulation Review

Executive Orders 13563 and 12866 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 rule has been designated as ''not significant'' under section 3(f) of E.O. 12866.

Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to prepare an initial regulatory flexibility analysis to be published at the time the proposed rule is published. This requirement does not apply if the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities'' (5 U.S.C. 603). This rule adds the NASA Graphics Standards Manual and make other administrative updates Subpart 1 of part 1221 and, therefore, does not have a significant economic impact on a substantial number of small entities.

Review Under the Paperwork Reduction Act

This direct final rule does not contain any information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Review Under E.O. 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999) requires regulations be reviewed for Federalism effects on the institutional interest of states and local governments, and if the effects are sufficiently substantial, preparation of the Federal assessment is required to assist senior policy makers. The amendments will not have any substantial direct effects on state and local governments within the meaning of the E.O. Therefore, no Federalism assessment is required.

Executive Order 13771—Reducing Regulations and Controlling Regulatory Costs

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

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments.

List of Subjects in 14 CFR Part 1221

Decorations, Medals, Awards, Flags, Seals, Insignia, Unified visual communication system.

For reasons set forth in the preamble, NASA is amending 14 CFR part 1221, subpart 1221.1 to read as follows:

PART 1221—THE NASA SEAL AND OTHER DEVICES, AND THE CONGRESSIONAL SPACE MEDAL OF HONOR

Subpart 1221.1—NASA Seal, NASA Insignia, NASA Logotype, NASA Program Identifiers, NASA Flags, and the Agency's Unified Visual Communications System

■ 1 The authority for subpart 1221.1 continues to read as follows:

Authority: 42 U.S.C. 2472(a) and 2473(c)(1).

■ 2. Revise § 1221.100 to read as follows:

§ 1221.100 Scope.

This subpart sets forth the policy governing the use of the NASA Seal, the NASA Insignia, NASA Logotype, NASA Program Identifiers, and the NASA Flags. This subpart also establishes and sets forth the concept and scope of the NASA Graphics Standards Manual and prescribes the policy and guidelines for implementation of the system. The NASA Graphics Standards Manual is accessible at *https://communications.nasa.gov/sites/default/files/files/NASA_Graphics_Standards_v3-TAGGED-v3.pdf*.

■ 3. Revise § 1221.103 to read as follows:

§ 1221.103 Establishment of the NASA Insignia.

The NASA Insignia was designed by the Army Institute of Heraldry and approved by the Commission of Fine Arts and the NASA Administrator. It symbolizes NASA's role in aeronautics and space and is established by the NASA Administrator as the signature and design element for visual communications formerly reserved for the NASA Logotype. The NASA Insignia shall be used as set forth in §§ 1221.108, the NASA Graphics Standards Manual, and any accompanying style guides or related NASA directive or specification approved by the NASA Administrator and published subsequent hereto.

FIGURE B

The NASA Insignia

TECHNICAL DESCRIPTION:

The official insignia of the National Aeronautics and Space Administration is a dark blue disc with white stars. The white hand-cut letters "NASA" are in the center of the disc and are encircled by a white diagonal orbit. A solid red vector symbol also appears behind and in front of the letters.

REPRODUCTION:

The NASA Insignia may be reproduced black-on-white (single color) as shown above or two-color (blue and red on white). The colors are PMS 286 blue and PMS 185 red.

The Insignia may be reproduced in various sizes but not less than five-eighths (5/8) of an inch. The sizes are determined on the basis of (a) desired effect for visual identification or publicity purposes, (b) relative size of the object on which the Insignia is to appear, and (c) consideration of any design, layout, reproduction, or other problems involved. For more information, refer to the NASA Insignia Standards Supplement.

■ 4. Revised § 1221.104 to read as follows:

§ 1221.104 Establishment of the NASA Logotype.

The NASA Logotype (also called ''the Worm'') was approved by the Commission of Fine Arts and the NASA Administrator. It symbolizes NASA's role in aeronautics and space from 1975 to 1992 and was retired between 1992–2020. The NASA Logotype shall be used as set forth in § 1221.111.

FIGURE C

The NASA Logotype

REPRODUCTION:

Black-on- white
or single color: As shown.

One color: The preferred color of the NASA Logotype is NASA red (PMS 179), used only when a second color is available and appropriate. Against a white background, the NASA Logotype may be shown in NASA red, black, or NASA warm gray (PMS 416). For background of other values, the Graphics Standards Manual is to be consulted and followed.

SIZE:

The NASA Logotype may be reproduced or used in various sizes. Size to be determined on the basis of (a) desired effect for visual identification or publicity purposes, (b) relative size of the object on which the NASA Logotype is to appear, and (c) consideration of any design, layout, reproduction or other problems involved. Refer to the Graphics Standards Manual for details.

RESTRICTION:

The NASA Logotype will not be used for any purpose without the written approval of the Administrator.

■ 5. Revise § 1221.107 to read as follows:

§ 1221.107 Establishment of the NASA Administrator's, Deputy Administrator's, and Associate Administrator's Flags.

(a) Concurrently with the establishment of the NASA Flag in January 1960, the NASA Administrator also established NASA Flags to represent the NASA Administrator, Deputy Administrator, and Associate Administrator. Each of these flags conforms to the basic design of the NASA Flag except for the following:

(1) The size of the flag is 3 feet x 4 feet;

(2) The Administrator's Flag has four stars;

(3) The Deputy Administrator's Flag has three stars; and

(4) The Associate Administrator's Flag has two stars.

(b) Flags representing these senior officials shall be used as set forth in § 1221.113.

■ 6. Revise § 1221.108 to read as follows:

§ 1221.108 Establishment of the NASA Unified Visual Communications System.

(a) The NASA Administrator directed the establishment of a NASA Unified Visual Communications System. The system, which is comprised of the NASA Graphics Standards Manual and any accompanying style guides or related NASA directive or specification, was developed under the Federal Design Improvement Program initiated by the President in May 1972. This system is the Agency-wide program by which NASA projects a contemporary, business-like, progressive, and forward-looking image through the use of effective design for improved communications. The system provides a professional and cohesive NASA identity by imparting continuity of graphics design in all layout, reproduction art, stationery, forms, publications, signs, films, video productions, vehicles, aircraft, and spacecraft markings and other items. It creates a unified image which is representative and symbolic of NASA's progressive attitudes and programs.

(b) The Associate Administrator for Communications is responsible for the development and implementation of the NASA Graphics Standards Manual and any accompanying style guides for the Agency or related NASA directive or specification.

(c) The Associate Administrator for Communications has designated staff to implement and monitor Agency-wide design improvements in consonance with the NASA Graphics Standards Manual. Designated staff will develop and issue changes and additions to the Manual as required and as new design standards and specifications are developed and approved. The NASA Graphics Standards Manual can be downloaded at *https://communications.nasa.gov/sites/default/files/files/NASA_Graphics_Standards_v3-TAGGED-v3.pdf.*

(d) NASA Centers and Headquarters have designated staff to implement NASA's graphics standards and ensure compliance of the NASA Graphics Standards Manual and any accompanying Style Guides or related NASA directive or specification.

■ 7. Revise § 1221.109 to read as follows:

§ 1221.109 Use of the NASA Seal.

(a) The Associate Administrator for Communications shall be responsible for custody of the NASA Impression Seal and custody of NASA replica (plaques) seals. The NASA Seal is restricted to the following:

(1) NASA award certificates and medals.

(2) NASA awards for career service.

(3) Security credentials and employee identification cards.

(4) NASA Administrator's documents; the Seal may be used on documents such as interagency or intergovernmental agreements and special reports to the President and Congress, and on other documents, at the discretion of the NASA Administrator.

(5) Plaques; the design of the NASA Seal may be incorporated in plaques for display in Agency auditoriums, presentation rooms, lobbies, offices of senior officials, and on the fronts of buildings occupied by NASA. A separate NASA seal in the form of a 15-inch, round, bronze-colored plaque on a walnut-colored wood base is also available, but prohibited for use in the above representational manner. It is restricted to use only as a presentation item by the Administrator and the Deputy Administrator.

(6) The NASA Flag and the NASA Administrator's, Deputy Administrator's, and Associate Administrator's Flags, which incorporate the design of the Seal.

(7) NASA prestige publications which represent the achievements or missions of NASA as a whole.

(8) Publications (or documents) involving participation by another Government agency for which the other Government agency has authorized the use of its seal.

(b) Use of the NASA Seal for any purpose other than as prescribed in this section is prohibited, except that the Associate Administrator for Communications may authorize, on a case-by-case basis, the use of the NASA Seal for purposes other than those prescribed when the Associate Administrator for Communications deems such use to be appropriate.

■ 8. In § 1221.110, revise paragraph (c)(4) to read as follows:

§ 1221.110 Use of the NASA Insignia.

* * * * *

(c) * * *

(4) Items bearing the NASA Insignia and NASA Logotype such as souvenirs, novelties, toys, models, clothing, and similar items (including items for sale through the NASA employees' nonappropriated fund activities) may be manufactured and sold only after the a request has been submitted to, and approved by, the NASA Office for Communications, NASA Headquarters, Washington, DC 20546.

■ 9. Revise § 1221.111 to read as follows:

§ 1221.111 Use of the NASA Logotype.

The NASA Logotype which was retired from 1992–2020 can be used only in an authentic historical context, on merchandise in accordance with § 1221.110, paragraph (c), in the NASA graphics standards/style guide or with prior written approval of the NASA Administrator.

■ 10. Revise § 1221.112(a) to read as follows:

§ 1221.112 Use of the NASA Program Identifiers.

(a) Official NASA Program Identifiers will be restricted to the uses set forth in this section and to such other uses as the Associate Administrator for Communications may specifically approve.

* * * * *

■ 11. Revise § 1221.113(b), to read as follows:

§ 1221.113 Use of the NASA Flags.

* * * * *

(b) The NASA Administrator's, Deputy Administrator's and Associate Administrator's Flags shall be displayed with the United States Flag in the respective offices of these officials but may be temporarily removed for use at the discretion of the officials concerned.

■ 12. Revise § 1221.114(a) to read as follows:

§ 1221.114 Approval of new or change proposals.

(a) Except for NASA Astronaut Mission Crew Badges/Patches, any proposal to change or modify the emblematic devices set forth in this subpart or to introduce a new emblematic device other than as prescribed in this subpart requires the written approval of the NASA Administrator with prior approval and recommendation of the NASA Associate Administrator for Communications.

* * * * *

Nanette Smith,

Team Lead, NASA Directives and Regulations.

[FR Doc. 2020–23481 Filed 11–10–20; 8:45 am]

BILLING CODE 7510–13–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 3282 and 3284

[Docket No. FR–5848–F–02]

RIN 2502–AJ37

Manufactured Housing Program: Minimum Payments to the States

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This rule revises the minimum payments that HUD distributes to states that participate in the Manufactured Housing Program as State Administrative Agencies (SAAs) in order to provide for a more equitable guarantee of minimum funding and to reduce administrative burden. This rule changes the minimum payments to SAAs so that payments are based on SAAs' participation in the production or siting of new manufactured homes, regardless of whether the state was fully or conditionally approved to participate in the program as of December 27, 2000. This rule also changes the formula for minimum payments to SAAs by increasing the amount paid to SAAs for each transportable section of new manufactured housing that is produced in that state, and by ensuring that each state participating in the program will receive an annual payment no less than the amount of cumulative payments resulting from production and shipments due to that State for the Fiscal Year 2014 period.

DATES: *Effective date:* December 14, 2020.

FOR FURTHER INFORMATION CONTACT: Teresa B. Payne, Administrator, Office of Manufactured Housing Programs, Department of Housing and Urban Development, 451 Seventh Street SW, Room 9164, Washington, DC 20410; telephone number 202–402–5365. (This is not a toll-free number.) Individuals with speech or hearing impairments may access this number through TTY by calling the toll free Federal Information Relay Service at 1–800–877–8389.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 620(e)(3) of the National Manufactured Housing Construction and Safety Standards Act of 1974, (42 U.S.C. 5401–5426) (the Act), as amended, HUD regulations provide for minimum payments to the states participating in the Manufactured Housing Program as an SAA. Since August 13, 2002, HUD regulations at 24 CFR 3284.10 provide that each SAA would receive an amount not less than the amount paid to that SAA for the 12 months ending on December 26, 2000, if that state had a fully approved state plan on December 27, 2000. As HUD explained in a proposed rule published on March 1, 2004 (69 FR 9740), the fact that § 3284.10 only applied to states that had a fully approved state plan as of December 27, 2000, resulted in inequitable payments between states and resulted in some states receiving more funding than other states for each

unit of manufactured housing produced or sited in the state.

In accordance with section 620 of the Act, HUD's regulations also provide for HUD to establish and collect from manufactured home manufacturers a reasonable fee to, among other things, provide funding to States for the administration and implementation of approved State plans. At § 3282.307(b), HUD regulations provide that HUD will distribute a portion of the monitoring inspection fees collected from all manufactured home manufacturers to SAAs based on a formula. Prior to issuance of this rule, that formula provided each state $9.00 for each new manufactured housing unit that, after leaving the manufacturing plants, is first located on the premises of a retailer, distributor, or purchaser in that state, plus $2.50 for each transportable section of each new manufactured housing unit produced in a manufacturing plant in that State.

Since HUD's March 1, 2004, proposed rule, which was not finalized, HUD has sought a solution to the issue of inequitable payments between states and worked with its partner SAAs and the Manufactured Housing Consensus Committee (MHCC) to develop proposed solutions. On May 2, 2014 (79 FR 25035), HUD published a proposed rule to revise the amount of the fee collected from manufacturers. In response to HUD's proposed rule, several commenters stated that the fees paid to SAAs are not reflective of current production and shipment levels. HUD responded to these comments by stating that it would review revisions to the current fee distribution formula to ensure that states are provided with adequate funding to perform the required SAA function. (See, 79 FR 47373, August 13, 2014).

HUD agreed that it should establish a more equitable distribution of funds among SAAs and, in 2015, solicited comments from both its partner SAAs and the MHCC on how to more equitably distribute fees among the states. The MHCC recommended a formula of $9.00 per transportable section located in a state, and $14.00 per transportable section manufactured in a state. Under this formula, whether a state was fully or conditionally approved would cease to affect funding. Additionally, the formula provided that the amounts states would receive would not decrease below that received during Fiscal Year (FY) 2014.

On December 16, 2016, HUD issued a proposed rule (81 FR 91083) to adopt the proposal as recommended by MHCC. HUD proposed to amend § 3282.307(b) to increase the amount paid to both fully approved and conditionally approved states for each transportable section of new manufactured housing produced in that state from $2.50 to $14.00, in order to more appropriately reflect the responsibility of these states and to encourage states to participate in the Federal-State program to the maximum extent possible. HUD also proposed revising § 3284.10 to ensure participating states (regardless of approval status before December 27, 2000) would receive a funding level no less than the cumulative amount that state received in FY 2014. These proposed funding levels would also meet or exceed the allocated amounts paid to fully approved states based on the fee distribution system in effect on December 27, 2000, in accordance with 620(e)(3) of the Act. HUD noted in the proposed rule that these proposed changes would be more equitable for the participating states. HUD also noted its belief that the changes would simplify administrative burdens of HUD and the states, as payments would continue to be made to all participating states, regardless of whether they are fully or conditionally approved, using the methodology of § 3282.307, under which HUD and the states have been operating for years. As a result, the proposed rule noted that the revised approach would not require any new payment or accounting structures and states should be able to seamlessly implement the statutory requirement. Additionally, HUD noted that this new method of determining state payments would also largely eliminate the need for a year-end supplemental payment to states, as most states would meet or exceed their FY 14 manufacturing and location levels.

The proposed rule specifically invited comment on the following three questions:

1. In determining a revised equitable fee distribution formula, what methods and data should HUD consider to increase the amounts paid to the states? For example, should HUD rely on the past three years or more of fee income data received by both fully approved and conditionally approved states in assessing the amount of the increase of the payment to each SAA?

2. Should fully approved states be entitled to higher levels of payments than conditionally approved SAAs? In addition to the number of home placements and production levels in each state, should the increase in payment consider the number of complaints handled by each SAA for the past three years in determining the amount of the increase (HUD would need each SAA to provide a list of all complaints handled over the past three years)?

3. Should HUD revise 24 CFR 3282.307(b) to allow the amount of the distribution of fees among the states to be established by Notice in order to more timely address changes or fluctuations in production levels, in order to assure that the states are adequately funded for the inspections and work they perform?

II. Public Comments and Response

The public comment period for the proposed rule closed on February 14, 2016. HUD received three public comments in response to this proposed rule. One comment did not address the proposed rule and stated that people should be able to live in what they want. The other two comments were responsive to the rule and were submitted by national trade associations that represent the manufactured housing industry. The responsive comments supported the proposed rule and stressed the importance of state participation in the Manufactured Housing Program. One commenter said that SAAs are state entities that are accountable to the public. This commenter said that SAAs should receive increased funding while program monitoring contractors who needlessly increase regulatory compliance costs should receive less. The responsive comments approved of the proposal to pay SAAs $9.00 for each transportable section of a new manufactured home located in the state, and $14.00 for each transportable section of a new manufactured home produced in the state. The responsive comments also approved of the proposal to pay states a minimum of the amount they received in FY 2014, regardless of whether the state had been fully or conditionally approved. Additionally, the responsive commenters provided answers to the three questions that HUD had posed in the proposed rule.

In response to the first question of what methods HUD should consider to increase the amounts paid to states, one commenter said that it does not object to distribution increases based on an aggregate of cumulative in-state production and shipment data reflecting a reasonable time-defined period, as long as the minimum annual distribution level to any state, regardless of approval status, does not fall below the minimum level mandated by the 2000 law. The other responsive commenter said that the primary data that should be used to determine a revised fee distribution formula is the actual shipment and production in each

of the SAA states, and that HUD should consider overall performance of the SAAs both individually and collectively.

In response to the second question of whether fully approved states should be entitled to higher levels of payments than conditionally approved SAAs, and whether increases in payments should consider the number of complaints handled by each SAA for the past three years, both of the substantive commenters said that conditionally and fully approved states should receive the same level of funding. One commenter responded to the question of whether increases in payments should consider the number of complaints handled by each SAA by saying it does not believe this would be necessary or feasible, as it would require SAAs to undertake additional recordkeeping, and would eliminate the level playing field needed to ensure that all states can meet their responsibilities under the Act.

In response to the third question of whether HUD should revise 24 CFR 3282.307(b) to allow the amount of the distribution fees to be established by Notice, both of the responsive commenters said that there is a statutory requirement for HUD to go through rulemaking before changing payments to SAAs. One of the commenters said that because section 620(d) of the Act says that any fee collected under the section may only be modified pursuant to rulemaking, and subsection (a)(1)(B) of section 620 addresses funding to states using the fees collected, any utilization of those fees for payments to states is also subject to the requirement that modifications can only be done through rulemaking. The other commenter said that HUD should obtain public input when making revisions to the funding formula.

In response to these comments, HUD notes that it appreciates these responses and will consider them for future changes to the fee distribution formula. HUD understands commenters' concerns that HUD should seek input from interested parties before making changes to the distribution formula. HUD posed the question about whether HUD should consider making future changes to § 3282.307(b) by notice with the thought that this might facilitate HUD's ability to respond more quickly in the future to requests from the states for more adequate funding.

As requested by the commenters, this final rule maintains HUD's proposed changes in its December 16, 2016, proposed rule, with some minor edits for clarity. In the proposed rule, § 3282.307(b)(1) said that states will receive $9.00 for each transportable section of each new manufactured housing unit that, after leaving the manufacturing plant in another state, is first located in that state. This final rule says that states will receive $9.00 for each transportable section of each new manufactured housing unit that, after leaving the manufacturing plant, is first located in that state. This clarifies that the states where manufactured housing units are first located will receive the $9.00 whether the transportable section was manufactured in another state, or in the same state where it is first located. Thus, if a transportable section of a manufactured housing unit is produced in a state and first located in that same state, that state would receive $23.00 for that transportable section, the combination of the amounts in § 3282.307(b)(1) and (b)(2).

This final rule also revises § 3284.10 to clarify that the minimum payment to each state will be no less than that due to that state for production and shipments for the period between October 1, 2013 to September 30, 2014, rather than the minimum payment simply being the amount the state received during this time period. The change was needed because states typically receive payments after September 30th, up to December, for shipments and production that occurred during the FY 14 period.

Additionally, this final rule revises the wording of § 3284.10(a) for readability. The proposed rule said that states would receive $9.00, if after leaving the manufacturing plant, for every transportable section that is first located on the premises of a retailer, distributor, or purchaser in that state after leaving the manufacturing plant (or $0, if it is not) during the year for which payment is received. This final rule says that states will receive $9.00 for every transportable section that is first located on the premises of a retailer, distributor, or purchaser in that state after leaving the manufacturing plant (or $0, if it is not) during the year for which payment is received.

Finally, HUD is adding at this final rule stage language to §§ 3282.307(b) and 3284.10 that states that HUD shall distribute the monitoring fee under § 3282.307 and pay the minimum payment to states under § 3284.10 ''subject to the availability of appropriations.'' HUD is adding this language to clarify that should its annual appropriation fail to provide sufficient funds to pay the states at the formula levels established by this rule, section 620(e)(2) of the Act limits HUD to distribute fees ''only to the extent approved in advance in an annual appropriations Act.'' Consequently, the language added to §§ 3282.307(b) and 3284.10 codifies existing statutory authority.

III. Findings and Certifications

Executive Order 12866 and Executive Order 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. This rule was determined to not be a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and therefore was not reviewed by OMB.

Executive Order 13771

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. OMB's interim guidance issued on February 2, 2017, explains that for Fiscal Year 2017 the above requirements only apply to each new ''significant regulatory action that imposes costs.'' It has been determined that this rule is not a ''significant regulatory action that imposes costs'' and thus does not trigger the above requirements of Executive Order 13771.

Impact on Small Entities

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires

an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This rule will affect only states that participate in the manufactured housing program, and will have a negligible economic impact.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538)(UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This rule does not impose any federal mandates on any state, local, or tribal governments or the private sector within the meaning of the UMRA.

Environmental Impact

This rule establishes rates and sets forth related fiscal requirements which do not constitute a development decision that affects the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this rule is categorically excluded from the requirements of the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Federalism Impact

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either (1) imposes substantial direct compliance costs on state and local governments and is not required by statute, or (2) the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

List of Subjects

24 CFR Part 3282

Manufactured home procedural and enforcement regulations, Administrative practice and procedure, Consumer protection, Intergovernmental relations, Investigations, Manufactured homes, Reporting and recordkeeping requirements.

24 CFR Part 3284

Consumer protection, Intergovernmental relations, Manufactured homes.

Accordingly, for the reasons discussed in this preamble, HUD amends 24 CFR parts 3282 and 3284 as follows:

PART 3282—MANUFACTURED HOME PROCEDURAL AND ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 3282 continues to read as follows:

Authority: 15 U.S.C. 2697, 42 U.S.C. 3535(d), 5403, and 5424.

■ 2. Revise § 3282.307(b) to read as follows:

§ 3282.307 Monitoring inspection fee establishment and distribution.

* * * * *

(b) The monitoring inspection fee shall be paid by the manufacturer to the Secretary or to the Secretary's Agent, who shall distribute a portion of the fees collected from all manufactured home manufacturers among the approved and conditionally-approved States in accordance with an agreement between the Secretary and the States and based upon the following formula subject to the availability of appropriations:

(1) $9.00 of the monitoring inspection fee collected for each transportable section of each new manufactured housing unit that is first located on the premises of a retailer, distributor, or purchaser in that State; plus

(2) $14.00 of the monitoring inspection fee collected for each transportable section of each new manufactured housing unit produced in a manufacturing plant in that State.

* * * * *

PART 3284—MANUFACTURED HOUSING PROGRAM FEE

■ 3. The authority citation for 24 CFR part 3284 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 5419, and 5424.

■ 4. Revise § 3284.10 to read as follows:

§ 3284.10 Minimum payments to states.

For every State that has a State plan fully or conditionally approved pursuant to § 3282.302 of this chapter, and subject to the availability of appropriations, HUD will pay such State annually a total amount that is the greater of either the amount of cumulative payments resulting from production and shipments due to that State for the period between October 1, 2013, and September 30, 2014; or the total amount determined by adding:

(a) $9.00 for every transportable section that is first located on the premises of a retailer, distributor, or purchaser in that State after leaving the manufacturing plant (or $0, if it is not) during the year for which payment is received; and

(b) 14.00 for every transportable section that is produced in a manufacturing plant in that State (or $0, if it is not) during the year for which payment is received.

Dana T. Wade,

Assistant Secretary for Housing, Federal Housing Commissioner.

[FR Doc. 2020–24380 Filed 11–10–20; 8:45 am]

BILLING CODE 4210–67–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 202

[Docket No. 2016–03]

Mandatory Deposit of Electronic-Only Books

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

ACTION: Final rule.

SUMMARY: The Copyright Office is amending its regulations to make electronic-only books published in the United States subject to the Copyright Act's mandatory deposit provisions if they are affirmatively demanded by the Office. The final rule largely adopts the language set forth in the Office's June 2020 notice of proposed rulemaking, with one additional clarification regarding the rule's applicability to print-on-demand books.

DATES: Effective December 14, 2020.

FOR FURTHER INFORMATION CONTACT: Kevin R. Amer, Deputy General Counsel, *kamer@copyright.gov* or Mark T. Gray, Attorney-Advisor, *mgray@copyright.gov*. They can be reached by telephone at 202–707–3000.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 407 of title 17, the owner of the copyright or the exclusive right of publication in a work published in the United States must, within three months of publication, deposit ''two complete copies of the best edition'' with the Copyright Office ''for the use or disposition of the Library of Congress.'' [1] The ''best edition'' is defined as ''the edition, published in the United States at any time before the date of deposit, that the Library of Congress determines to be most suitable for its purposes.'' [2] These requirements are

[1] 17 U.S.C. 407(a), (b); *see generally* 37 CFR 202.19.

[2] 17 U.S.C. 101; *see also* 17 U.S.C. 407(b).

governed by section 202.19 and Appendix B of part 202 of the Office's regulations, which set forth rules and criteria, respectively, for the different types of works subject to the mandatory deposit requirement.

Under the statute, the Register of Copyrights may issue a written demand for works at any time after they have been published in the United States, and failure to deposit after a demand may subject the recipient to monetary liability.[3] Compliance with this section is separate from the copyright registration process, but the Copyright Act provides that deposits made under section 407 may be used to satisfy the registration deposit provisions under section 408, if all other registration conditions are met.[4]

The Register of Copyrights may, by regulation, exempt categories of works from the mandatory deposit requirement.[5] Under this authority, the Office issued an interim rule in 2010 (the ''2010 Interim Rule'') codifying its established practice of excluding from mandatory deposit requirements all ''[e]lectronic works published in the United States and available only online.'' [6] The 2010 Interim Rule referred to such works as ''electronic-only.'' The Office also, however, adopted an exception to this exemption, requiring the deposit of electronic-only serials if affirmatively demanded by the Office.[7]

In 2016, the Office issued a notice of inquiry (''NOI'') that proposed adding a new category of online works—electronic-only books—to the mandatory deposit framework. As with electronic-only serials, the Office proposed that electronic-only books would be subject to mandatory deposit only upon demand by the Office.[8] In April 2018, following consideration of public comments received in response to the NOI, the Office issued a notice of proposed rulemaking (''2018 NPRM'') setting forth regulatory language to implement this change. The 2018 NPRM proposed to define ''electronic-only book'' as ''an electronic literary work published in one volume or a finite number of volumes published in the United States and available only online,'' with some exclusions for specific types of works such as serials, audiobooks, websites, blogs, and emails.[9]

The Office received nine comments in response to the 2018 NPRM. Commenters generally expressed agreement with the broad goal of supporting the Library's acquisition and preservation of digital materials for the benefit of the American public,[10] but they raised questions about what material would be collected [11] and how the Library's IT security infrastructure would keep deposited materials secure.[12]

In response to those comments, the Office issued a revised NPRM on June 29, 2020 (''2020 NPRM'').[13] To address questions about the scope of the rule, the 2020 NPRM clarified that short online works such as social media posts would not be subject to demand but that that online-only books preloaded onto electronic devices such as tablets would be covered if otherwise available only online.[14] The 2020 NPRM also explained that the rule did not apply to copies of e-books printed by an author, publisher, or distributor in response to purchases by individual consumers. Such books would ''instead remain subject to the general mandatory deposit obligation under section 407.'' [15]

In addition, the 2020 NPRM revised the requirement proposed in the 2018 NPRM that technological protection measures (''TPMs'') controlling access to or use of deposits be removed. Instead, the Office proposed to update the Best Edition regulations in Appendix B to Part 202 to reflect the Library's preference for a TPM-free edition, if such a version has been published.[16] If no TPM-free edition has been published, the proposed rule would next accept a copy for which the copyright owner has elected to remove such measures.[17] If the owner declines to do so, the deposit must otherwise comply with the general requirement that copies can be accessed and reviewed on an ongoing basis.[18]

Finally, the 2020 NPRM addressed questions raised by commenters regarding the Library's collections policies and security practices. With respect to digital collections, the Office explained that, since the close of the 2018 NPRM comment period, the Library had provided additional information about its digital strategy and collections plans in several publicly available documents.[19] As to concerns about the Library's IT security, the 2020 NPRM noted the many steps the Library has taken to improve its IT systems in recent years, as reflected in congressional testimony, Inspector General's reports, and other public materials. Those efforts include hiring a Chief Information Officer, centralizing all IT efforts in a single office, and implementing almost all of the thirty-one public recommendations from a 2015 report by the Government Accountability Office.[20] The 2020 NPRM concluded that ''these security upgrades, together with the additional IT-related information made public since the close of the prior comment

[3] 17 U.S.C. 407(d).

[4] *Id.* at 408(b). Although section 408 states that copies deposited pursuant to the mandatory deposit provision in section 407 may be used to satisfy the registration deposit requirement in section 408, in practice the Office treats copies of works submitted for registration as satisfying the mandatory deposit requirement (assuming the deposit requirements are the same), and not vice versa. 37 CFR 202.19(f)(1), 202.20(e); *see* 43 FR 763, 768 (Jan. 4, 1978).

[5] 17 U.S.C. 407(c).

[6] Mandatory Deposit of Published Electronic Works Available Only Online, 75 FR 3863, 3869 (Jan. 25, 2010) (''2010 Interim Rule''); 37 CFR 202.19(c)(5).

[7] 2010 Interim Rule at 3865–66. ''Electronic works'' are themselves defined as ''works fixed and published solely in an electronic format.'' 37 CFR 202.24(c)(3).

[8] *Mandatory Deposit of Electronic Books and Sound Recordings Available Only Online: Notice of Inquiry,* 81 FR 30505, 30506–08 (May 17, 2016). The NOI also included online sound recordings as a potential additional category of works to subject to mandatory deposit, but the Office has decided to postpone further consideration of this issue until after the conclusion of this rulemaking.

[9] *Id.* at 16272.

[10] *See, e.g.,* Library Copyright Alliance 2018 NPRM Comment at 2 (supported the proposed rule ''because of the critical role of deposit in building the Library's collection and ensuring long-term preservation'' of digital materials); Authors Guild 2019 NPRM Comment at 2 (noting Library ''cannot fulfill [its] mission today without collecting books that are published only in electronic form''); American Association of Publishers 2018 NPRM Comment at 3–4 (stating ''[p]ublishers have long supported the special privilege of the Library to collect works'').

[11] *See, e.g.,* Authors Guild 2018 NPRM Comment at 3–4 (raising questions about the Library's collections policies and recommending changes to definition of ''electronic-only book''); National Writers Union 2018 NPRM Comment at 3–4 (expressing uncertainty about what material would be demanded based on Library collections policies); Copyright Alliance 2018 NPRM Comment at 3 (raising questions about Library's collections strategy). All public comments in this rulemaking may be accessed at *https://www.copyright.gov/rulemaking/ebookdeposit/.*

[12] Copyright Alliance 2018 NPRM Comment at 4 (requesting the Library ''demonstrat[e] the adequacy of the Library's IT system'' before finalizing the rule); Authors Guild 2018 NPRM Comment at 3 (seeking additional specifics about the ''security measures for e-books'' and requesting more information about Library's creation of a secure e-book repository); American Association of Publishers 2018 NPRM Comment at 2–3 (seeking additional information about ''the state of the Library's technology capabilities, protocols, and security measures'').

[13] 85 FR 38806 (June 29, 2020) (''2020 NPRM'').

[14] 2020 NPRM at 38809.

[15] 2020 NPRM at 38809–10.

[16] 2020 NPRM at 38811.

[17] *Id.*

[18] *Id.*

[19] 2020 NPRM at 38810 (citing Library of Congress, *Enriching the Library Experience: The FY2019–2023 Strategic Plan of the Library of Congress, https://www.loc.gov/static/portals/strategic-plan/documents/LOC_Strat_Plan_2018.pdf* and Library of Congress, *Digital Strategy* (Apr. 26, 2019), *https://www.loc.gov/static/portals/digital-strategy/documents/Library-of-Congress-Digital-Strategy-v1.1.2.pdf*).

[20] 2020 NPRM at 38812.

period, may reasonably address the concerns raised by commenters regarding the security of digital deposits.'' [21] To ensure, however, that stakeholders had an adequate opportunity to consider and respond to this new information, the Office invited further public comment.

II. The Final Rule

The Office received four comments on the 2020 NPRM, none of which objected to finalizing the rule. The Authors Guild stated that the revised rule ''adequately addresses almost all of our prior concerns'' and that it is ''satisfied by the Library of Congress' progress'' in securing and managing its IT infrastructure.[22] The Library Copyright Alliance also supported making the rule final, noting ''the critical role of deposit in building the Library's collection and ensuring long-term preservation of these works.'' [23] An individual commenter, Owen Linback, likewise expressed support for the proposed revisions.[24]

The University of Michigan Library Copyright Office (''UM Library'') did not state an objection to finalizing the rule, but it ''strongly urge[d]'' that the final rule require deposited copies to ''be free from encryptions and digital rights management technologies.'' [25] In the UM Library's view, ''[w]hen copies are encumbered with technological protection measures such as encryption or DRMs . . . they obstruct preservation, authorized access to information, and accessibility.'' [26] The Office appreciates the need to ensure appropriate access to deposit materials, and the 2020 NPRM noted that ''the Library generally prefers TPM-free editions of works to simplify and further its preservation efforts.'' [27] As the Office discussed, however, that interest must be balanced against the language of section 407, which requires only that copyright owners deposit the best *published* edition of a work. Additionally, section 1201 separately protects the right of copyright owners to distribute works with TPMs.[28] The Office must implement its regulatory authority against the backdrop of that legal protection. The Office accordingly proposed a more flexible approach under which TPM-free copies of a work, or copies from which the owner has voluntarily removed TPMs, are preferred for best-edition purposes. And, in all events, the rightsholder must comply with the existing requirement that deposits can be ''accessed and reviewed by the Copyright Office, Library of Congress, and the Library's authorized users on an ongoing basis.'' [29] The Office continues to believe that this framework will adequately serve the Library's collection needs in a manner consistent with the statute. The final rule therefore retains the Office's proposed language.

The Authors Guild raised three additional issues. First, it suggested that further guidance from the Office on the definition of ''publication'' in the online context would be helpful ''before or in concert with'' the proposed rule.[30] As the Authors Guild's comment notes, the Office is currently conducting a separate proceeding to consider potential regulatory updates interpreting the meaning of publication for purposes of copyright registration, and to provide policy guidance regarding the concept of publication more generally.[31] A work's publication status, however, presents somewhat less of a concern for copyright owners under this rule than in the registration context, as electronic-only books must first be affirmatively identified and demanded by the Office before a copyright owner must deposit them. Thus, as the Authors Guild acknowledges, publication ''need not be specifically defined in this particular rule.'' [32] For that reason, the Office believes that its separate proceeding on online publication is the more appropriate forum through which to provide additional guidance on the meaning of that term.

Second, the Authors Guild suggested clarifying edits to the language regarding the rule's applicability to print-on-demand books. The 2020 NPRM provided that ''[a] work shall be deemed to be *available only online* even if copies have been made available to individual consumers to print on demand, so long as the work is otherwise available only online.'' [33] The Authors Guild suggested the phrase ''individual consumers to print on demand'' may be ambiguous and proposed revising the language to instead read: ''made available to individual consumers by print on demand services.'' [34] The Authors Guild did not identify the specific ambiguity that this suggested change is intended to clarify, but the Office does not agree that it reflects the rule's intended scope. The reference to copies made available to consumers ''by print on demand services'' could be read to encompass *physical* copies printed by a service and distributed to individual purchasers. As discussed in the 2020 NPRM, ''[t]hese books are outside the scope of this rule, and instead remain subject to the general mandatory deposit obligation under section 407.'' [35]

As an alternative, or in addition to the foregoing suggestion, the Authors Guild suggested that ''it might add clarity'' to refer to ''individual'' copies, such that the language would read: ''A work shall be deemed to be *available only online* even if individual copies have been made available to individual consumers to print on demand, so long as the work is otherwise available only online.'' [36] In its view, ''[i]t is possible that the emphasis on individual consumers could create confusion with respect to print-on-demand copies purchased by institutional consumers for their use (a school or a library for instance).'' [37] It is not clear, however, that a reference to ''individual copies'' would address that concern, which relates to the phrase ''individual consumers.'' As to the latter phrase, the Office agrees that there could be uncertainty over whether the provision covers copies made available to institutional purchasers such as libraries. In the Office's view, these entities are similarly situated to individual consumers in that they typically purchase a fixed number of copies of a given e-book, and the number of physical copies they may print and circulate to patrons is dictated by the terms of the purchasing agreement. That arrangement is distinguishable from a model in which a retailer continues to print copies as additional orders are received. To clarify that the definition is not intended to exclude e-books purchased by libraries and similar institutions, the final rule thus provides: ''A work shall be deemed to be *available only online* even if copies have been made available to individual consumers or other end users to print on demand, so long as the

[21] 2020 NPRM at 38814.

[22] Authors Guild Comments at 1.

[23] Library Copyright Alliance (LCA) Comments at 2. LCA also urged the Office to initiate a rulemaking on access restrictions on deposited electronic materials and expand the proposed rule to sound recordings. *Id.* at 4–5. As noted in the 2018 NPRM with respect to deposit of electronic-only sound recordings, the Office is ''postponing further consideration of this issue until after the conclusion of the present rulemaking.'' 2018 NPRM at 16270.

[24] Comments of Owen Linback.

[25] Univ. of Mich. Library Copyright Office Comments at 1.

[26] *Id.*

[27] 2020 NPRM at 38811.

[28] 17 U.S.C. 1201(a).

[29] 37 CFR 202.24(a)(4).

[30] Authors Guild Comments at 1–2.

[31] *See* Online Publication Notification of Inquiry, 84 FR 66328 (Dec. 4, 2019).

[32] Authors Guild Comments at 2.

[33] 2020 NPRM at 38814–15.

[34] Authors Guild Comments at 2 (bolding in original).

[35] 2020 NPRM at 38809–10.

[36] *See* Authors Guild Comments at 2.

[37] *Id.*

work is otherwise available only online.'' The Office intends the reference to ''end users'' to cover institutions such as libraries and universities who are the actual users of these works and not intermediate distributors such as online booksellers.

Finally, the Authors Guild suggested that the final rule provide for periodic consultations between the Library and publishers ''to ensure that the Library's recommended formats and preferences—and the Office's adherence thereto—are aligned with the most commonly used as-published formats.'' [38] The Office appreciates that conversations between the Library and publishers can help the Library's collections preferences align with industry practice. Although the Office would welcome such consultations to be ongoing (and itself maintains an open door to receive stakeholder feedback), it does not believe including a mandate in the regulatory text is appropriate. As explained in the 2020 NPRM, the Library consistently seeks stakeholder input when crafting its policies,[39] and the Office expects that the Library will be open to continued outreach from publishers to that effect.

List of Subjects in 37 CFR Part 202

Claims, Copyright.

For the reasons set forth in the preamble, the Copyright Office amends 37 CFR part 202 as follows:

PART 202—GENERAL PROVISIONS

■ 1. The authority citation for part 202 continues to read as follows:

Authority: 17 U.S.C. 408(f), 702.

■ 2. Amend § 202.18 by:
■ a. In paragraph (a) in the first sentence adding the words ''and § 202.19, and transferred into the Library of Congress's collections,'' after ''under § 202.4(e)'';
■ b. In paragraph (b) in the first sentence adding the words ''and § 202.19'' after ''under § 202.4(e)'';
■ c. In paragraph (c) in the first sentence adding the words ''and § 202.19'' after ''under § 202.4(e)''; and
■ d. Adding paragraph (f).

The addition reads as follows:

§ 202.18 Access to electronic works.

* * * * *

(f) Except as provided under special relief agreements entered into pursuant to § 202.19(e) or § 202.20(d), electronic works will be transferred to the Library of Congress for its collections and made available only under the conditions specified by this section.

■ 3. Amend § 202.19 by:
■ a. Revising paragraph (b)(4).
■ b. In paragraph (c)(5), adding the phrase ''electronic-only books and'' after the phrase ''This exemption includes''.

The revision reads as follows:

§ 202.19 Deposit of published copies or phonorecords for the Library of Congress.

* * * * *

(b) * * *

(4) For purposes of paragraph (c)(5) of this section:

(i) An *electronic-only serial* is a serial as defined in § 202.3(b)(1)(v) that is published in electronic form in the United States and available only online.

(ii) An *electronic-only book* is an electronic literary work published in one volume or a finite number of volumes published in the United States and available only online. This class excludes literary works distributed solely in phonorecords (*e.g.,* audiobooks), serials (as defined in § 202.3(b)(1)(v)), computer programs, websites, blogs, emails, and short online literary works such as social media posts.

(iii) A work shall be deemed to be *available only online* even if copies have been made available to individual consumers or other end users to print on demand, so long as the work is otherwise available only online. A work also shall be deemed to be available only online even if copies have been loaded onto electronic devices, such as tablets or e-readers, in advance of sale to individual consumers, so long as the work is otherwise available only online.

* * * * *

■ 4. Amend § 202.24 as follows:
■ a. In paragraph (a)(2), remove the word ''works'' and add in its place ''electronic-only serials'';
■ b. Redesignate paragraphs (a)(3) and (4) as paragraphs (a)(4) and (5), and add a new paragraph (a)(3);
■ c. In paragraph (b), remove ''online-only'' and add in its place ''electronic-only''; and
■ d. Revise paragraph (c)(3).

The addition and revision reads as follows:

§ 202.24 Deposit of published electronic works available only online.

(a) * * *

(3) Demands may be made only for electronic-only books published on or after December 14, 2020.

* * * * *

(c) * * *

(3) ''Electronic-only'' works are electronic works that are published and available only online.

■ 6. Amend Appendix B to Part 202 by revising section IX to read as follows:

Appendix B to Part 202 ''Best Edition'' of Published Copyrighted Works for the Collections of the Library of Congress

* * * * *

IX. Electronic-Only Works Published in the United States and Available Only Online

The following encodings are listed in descending order of preference for all deposits in all categories below:

1. UTF–8.
2. UTF–16 (with BOM).
3. US–ASCII.
4. ISO 8859.
5. All other character encodings.

A. Electronic-Only Serials:

1. Content Format:

a. Serials-specific structured/markup format:

i. Content compliant with the NLM Journal Archiving (XML) Document Type Definition (DTD), with presentation stylesheet(s), rather than without NISO JATS: Journal Article Tag Suite (NISO Z39.96–201x) with XSD/XSL presentation stylesheet(s) and explicitly stated character encoding.

ii. Other widely used serials or journal XML DTDs/schemas, with presentation stylesheet(s), rather than without.

iii. Proprietary XML format for serials or journals (with documentation), with DTD/schema and presentation stylesheet(s), rather than without.

b. Page-oriented rendition:

i. PDF/UA (Portable Document Format/Universal Accessibility; compliant with ISO 14289–1).

ii. PDF/A (Portable Document Format/Archival; compliant with ISO 19005).

iii. PDF (Portable Document Format, with searchable text, rather than without; highest quality available, with features such as searchable text, embedded fonts, lossless compression, high resolution images, device-independent specification of colorspace; content tagging; includes document formats such as PDF/X).

c. Other structured or markup formats:

i. Widely-used serials or journal non-proprietary XML-based DTDs/schemas with presentation stylesheet(s).

ii. Proprietary XML-based format for serials or journals (with documentation) with DTD/schema and presentation stylesheet(s).

iii. XHTML or HTML, with DOCTYPE declaration and presentation stylesheet(s).

iv. XML-based document formats (widely used and publicly documented). With presentation stylesheets, if applicable. Includes ODF (ISO/IEC 26300) and OOXML (ISO/IEC 29500).

d. PDF (web-optimized with searchable text).

e. Other formats:

i. Rich text format.

ii. Plain text.

iii. Widely-used proprietary word processing or page-layout formats.

iv. Other text formats not listed here.

2. Metadata Elements: If included with published version of work, descriptive data (metadata) as described below should accompany the deposited material:

[38] Authors Guild Comments at 2.

[39] 2020 NPRM at 38814.

a. Title level metadata: serial or journal title, ISSN, publisher, frequency, place of publication.

b. Article level metadata, as relevant/or applicable: volume(s), number(s), issue dates(s), article title(s), article author(s), article identifier (DOI, etc.).

c. With other descriptive metadata (*e.g.,* subject heading(s), descriptor(s), abstract(s)), rather than without.

3. Completeness:

a. All elements considered integral to the publication and offered for sale or distribution must be deposited—*e.g.,* articles, table(s) of contents, front matter, back matter, etc. Includes all associated external files and fonts considered integral to or necessary to view the work as published.

b. All updates, supplements, releases, and supersessions published as part of the work and offered for sale or distribution must be deposited and received in a regular and timely manner for proper maintenance of the deposit.

4. Technological measures that control access to or use of the work should be removed.

B. Electronic-Only Books:

1. Content Format:

a. Book-specific structured/markup format, *i.e.,* XML-based markup formats, with included or accessible DTD/schema, XSD/XSL presentation stylesheet(s), and explicitly stated character encoding:

i. BITS-compliant (NLM Book DTD).

ii. EPUB-compliant.

iii. Other widely-used book DTD/schemas (*e.g.,* TEI, DocBook, etc.).

b. Page-oriented rendition:

i. PDF/UA (Portable Document Format/Universal Accessibility; compliant with ISO 14289–1).

ii. PDF/A (Portable Document Format/Archival; compliant with ISO 19005).

ii. PDF (Portable Document Format; highest quality available, with features such as searchable text, embedded fonts, lossless compression, high resolution images, device-independent specification of colorspace; content tagging; includes document formats such as PDF/X).

c. Other structured markup formats:

i. XHTML or HTML, with DOCTYPE declaration and presentation stylesheet(s).

ii. XML-based document formats (widely-used and publicly-documented), with presentation style sheet(s) if applicable. Includes ODF (ISO/IEC 26300) and OOXML (ISO/IEC 29500).

iii. SGML, with included or accessible DTD.

iv. Other XML-based non-proprietary formats, with presentation stylesheet(s).

v. XML-based formats that use proprietary DTDs or schemas, with presentation stylesheet(s).

d. PDF (web-optimized with searchable text).

e. Other formats:

i. Rich text format.

ii. Plain text.

iii. Widely-used proprietary word processing formats.

iv. Other text formats not listed here.

2. Metadata Elements: If included with published version of work, descriptive data (metadata) as described below should accompany the deposited material:

a. As supported by format (*e.g.,* standards-based formats such as ONIX, XMP, MODS, or MARCXML either embedded in or accompanying the digital item): title, creator, creation date, place of publication, publisher/producer/distributor, ISBN, contact information.

b. Include if part of published version of work: language of work, other relevant identifiers (*e.g.,* DOI, LCCN, etc.), edition, subject descriptors, abstracts.

3. Rarity and Special Features:

a. Limited editions (including those with special features such as high resolution images.)

b. Editions with the greatest number of unique features (such as additional content, multimedia, interactive elements.)

4. Completeness:

a. For items published in a finite number of separate components, all elements published as part of the work and offered for sale or distribution must be deposited. Includes all associated external files and fonts considered integral to or necessary to view the work as published.

b. All updates, supplements, releases, and supersessions published as part of the work and offered for sale or distribution must be submitted and received in a regular and timely manner for proper maintenance of the deposit.

5. Technological Protection Measures:

a. Copies published in formats that do not contain technological measures controlling access to or use of the work.

b. Copies published with technological measures that control access to or use of the work, and for which the owner has elected to remove such technological measures.

c. Copies otherwise provided in a manner that meets the requirements of § 202.24(a)(5).

Dated: October 5, 2020.

Maria Strong,

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

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2020–23101 Filed 11–10–20; 8:45 am]

BILLING CODE 1410–30–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ94

Authority of VA Professionals To Practice Health Care

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) is issuing this interim final rule to confirm that its health care professionals may practice their health care profession consistent with the scope and requirements of their VA employment, notwithstanding any State license, registration, certification, or other requirements that unduly interfere with their practice. Specifically, this rulemaking confirms VA's current practice of allowing VA health care professionals to deliver health care services in a State other than the health care professional's State of licensure, registration, certification, or other State requirement, thereby enhancing beneficiaries' access to critical VA health care services. This rulemaking also confirms VA's authority to establish national standards of practice for health care professionals which will standardize a health care professional's practice in all VA medical facilities.

DATES: *Effective Date:* This rule is effective on November 12, 2020.

Comments: Comments must be received on or before January 11, 2021.

ADDRESSES: Comments may be submitted through *www.Regulations.gov* or mailed to, Beth Taylor, 10A1, 810 Vermont Avenue NW, Washington, DC 20420. Comments should indicate that they are submitted in response to [''RIN 2900–AQ94—Authority of VA Professionals to Practice Health Care.''] Comments received will be available at *regulations.gov* for public viewing, inspection, or copies.

FOR FURTHER INFORMATION CONTACT: Beth Taylor, Chief Nursing Officer, Veterans Health Administration. 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–7250. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On January 30, 2020, the World Health Organization (WHO) declared the COVID–19 outbreak to be a Public Health Emergency of International Concern. On January 31, 2020, the Secretary of the Department of Health and Human Services declared a Public Health Emergency pursuant to 42 United States Code (U.S.C.) 247d, for the entire United States to aid in the nation's health care community response to the COVID–19 outbreak. On March 11, 2020, in light of new data and the rapid spread in Europe, WHO declared COVID–19 to be a pandemic. On March 13, 2020, the President declared a National Emergency due to COVID–19 under sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 *et seq.*) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b–5). As a result of responding to the needs of our veteran population and other non-veteran beneficiaries during the COVID–19 National Emergency, where VA has had to shift health care

professionals to other locations or duties to assist in the care of those affected by this pandemic, VA has become acutely aware of the need to promulgate this rule to clarify the policies governing VA's provision of health care.

This rule is intended to confirm that VA health care professionals may practice their health care profession consistent with the scope and requirements of their VA employment, notwithstanding any State license, registration, certification, or other requirements that unduly interfere with their practice. In particular, it will confirm (1) VA's continuing practice of authorizing VA health care professionals to deliver health care services in a State other than the health care professional's State of licensure, registration, certification, or other requirement; and (2) VA's authority to establish national standards of practice for health care professions via policy, which will govern their employment, subject only to State laws where the health care professional is licensed, credentialed, registered, or subject to some other State requirements that do not unduly interfere with those duties.

We note that the term State as it applies to this rule means each of the several States, Territories, and possessions of the United States, the District of Columbia, and the Commonwealth of Puerto Rico, or a political subdivision of such State. This definition is consistent with the term State as it is defined in 38 U.S.C. 101(20).

A conflicting State law is one that would unduly interfere with the fulfillment of a VA health care professional's Federal duties. We note that the policies and practices confirmed in this rule only apply to VA health care professionals appointed under 38 U.S.C. 7306, 7401, 7405, 7406, or 7408 or title 5 of the U.S. Code, which does not include contractors working in VA medical facilities or those working in the community.

VA has long understood its governing statutory authorities to permit VA to engage in these practices. Section 7301(b) of title 38 the U.S. Code establishes that the primary function of the Veterans Health Administration (VHA) within VA is to provide a complete medical and hospital service for the medical care and treatment of veterans. To allow VHA to carry out its medical care mission, Congress established a comprehensive personnel system for certain VA health care professionals, independent of the civil service rules. See Chapters 73–74 of title 38 of the U.S. Code. Congress granted the Secretary express statutory authority to establish the qualifications for VA's health care professionals, determine the hours and conditions of employment, take disciplinary action against employees, and otherwise regulate the professional activities of those individuals. 38 U.S.C. 7401–7464.

Section 7402 of 38 U.S.C. establishes the qualifications of appointees. To be eligible for appointment as a VA employee in a health care profession covered by section 7402(b) (other than a medical facility Director appointed under section 7402(b)(4)), most individuals, after appointment, must, among other requirements, be licensed, registered, or certified to practice their profession in a State, or satisfy some other State requirement. However, the standards prescribed in section 7402(b) establish only the basic qualifications for VA health care professionals and do not limit the Secretary from establishing other qualifications or rules for health care professionals.

In addition, the Secretary is responsible for the control, direction, and management of the Department, including agency personnel and management matters. See 38 U.S.C. 303.

Such authorities permit the Secretary to further regulate the health care professions to make certain that VA's health care system provides safe and effective health care by qualified health care professionals to ensure the well-being of those veterans who have borne the battle. In this rulemaking, VA is detailing its authority to manage its health care professionals by stating that they may practice their health care profession consistent with the scope and requirements of their VA employment, notwithstanding any State license, registration, certification, or other State requirements that unduly interfere with their practice. VA believes that this is necessary in order to provide additional protection for VA health care professionals against adverse State actions proposed or taken against them when they are practicing within the scope of their VA employment, particularly when they are practicing across State lines or when they are performing duties consistent with a VA national standard of practice for their health care profession.

Practice Across State Lines

Historically, VA has operated as a national health care system that authorizes VA health care professionals to practice in any State as long as they have a valid license, registration, certification, or fulfill other State requirements in at least one State. In doing so, VA health care professionals have been practicing within the scope of their VA employment regardless of any unduly burdensome State requirements that would restrict practice across State lines. We note, however, that VA may only hire health care professionals who are licensed, registered, certified, or satisfy some other requirement in a State, unless the statute requires or provides otherwise (*e.g.,* 38 U.S.C. 7402(b)(14)).

The COVID–19 pandemic has highlighted VA's acute need to exercise its statutory authority of allowing VA health care professionals to practice across State lines. In response to the pandemic, VA needed to and continues to need to move health care professionals quickly across the country to care for veterans and other beneficiaries and not have State licensure, registration, certification, or other State requirements hinder such actions. Put simply, it is crucial for VA to be able to determine the location and practice of its VA health care professionals to carry out its mission without any unduly burdensome restrictions imposed by State licensure, registration, certification, or other requirements. This rulemaking will support VA's authority to do so and will provide an increased level of protection against any adverse State action being proposed or taken against VA health care professionals who practice within the scope of their VA employment.

Since the start of the pandemic, in furtherance of VA's Fourth Mission, VA has rapidly utilized its resources to assist parts of the country that are undergoing serious and critical shortages of health care resources. VA's Fourth Mission is to improve the Nation's preparedness for response to war, terrorism, national emergencies, and natural disasters by developing plans and taking actions to ensure continued service to veterans, as well as to support national, State, and local emergency management, public health, safety and homeland security efforts.

VA has deployed personnel to support other VA medical facilities that have been impacted by COVID–19 as well as provided support to State and community nursing homes. As of July 2020, VA has deployed personnel to more than 45 States. VA utilized the Disaster Emergency Medical Personnel System (DEMPS), VA's main deployment program, for VA health care professionals to travel to locations deemed as national emergency or disaster areas, to help provide health care services in places such as New Orleans, Louisiana, and New York City, New York. As of June 2020, a total of 1,893 staff have been mobilized to meet the needs of our facilities and Fourth

Mission requests during the pandemic. VA deployed 877 staff to meet Federal Emergency Management Agency (FEMA) Mission requests, 420 health care professionals were deployed as DEMPS response, 414 employees were mobilized to cross level staffing needs within their Veterans Integrated Service Networks (VISN), 69 employees were mobilized to support needs in another VISN, and 113 Travel Nurse Corps staff responded specifically for COVID–19 staffing support. In light of the rapidly changing landscape of the pandemic, it is crucial for VA to be able to move its health care professionals quickly across the country to assist when a new hot spot emerges without fear of any adverse action from a State be proposed or taken against a VA health care professional.

We note that, in addition to providing in person health care across State lines during the pandemic, VA also provides telehealth across State lines. VA's video to home services have been heavily leveraged during the pandemic to deliver safe, quality VA health care while adhering to Centers for Disease Control and Prevention (CDC) physical distancing guidelines. Video visits to veterans' homes or other offsite location have increased from 41,425 in February 2020 to 657,423 in July of 2020. This represents a 1,478 percent utilization increase. VA has specific statutory authority under 38 U.S.C. 1730C to allow health care professionals to practice telehealth in any State regardless of where they are licensed, registered, certified, or satisfy some other State requirement. This rulemaking is consistent with Congressional intent under Public Law 115–185, sec. 151, June 6, 2018, codified at 38 U.S.C. 1730C for all VA health care professionals to practice across State lines regardless of the location of where they provide health care. This rulemaking will ensure that VA professionals are protected regardless of how they provide health care, whether it be via telehealth or in-person.

Beyond the current need to mobilize health care resources quickly to different parts of the country, this practice of allowing VA health care professionals to practice across State lines optimizes the VA health care workforce to meet the needs of all VA beneficiaries year-round. It is common practice within the VA health care system to have primary and specialty health care professionals routinely travel to smaller VA medical facilities or rural locations in nearby States to provide care that may be difficult to obtain or unavailable in that community. As of January 14, 2020, out of 182,100 licensed health care professionals who are employed by VA, 25,313 or 14 percent do not hold a State license, registration, or certification in the same State as their main VA medical facility. This number does not include the VA health care professionals who practice at a main VA medical facility in one State where they are licensed, registered, certified, or hold some other State requirement, but also practice at a nearby Community Based Outpatient Clinic (CBOC) in a neighboring State where they do not hold such credentials. Indeed, 49 out of the 140 VA medical facilities nationwide have one or more sites of care in a different State than the main VA medical facility.

Also, VA has rural mobile health units that provide health care services to veterans who have difficulty accessing VA health care facilities. These mobile units are a vital source of health care to veterans who live in rural and medically underserved communities. Some of the services provided by the mobile units include, but are not limited to, health care screening, mental health outreach, influenza and pneumonia vaccinations, and routine primary care. The rural mobile health units are an integral part of VA's goal of encouraging healthier communities and support VA's preventative health programs. Health care professionals who provide health care in these mobile units may provide services in various States where they may not hold a license, registration, or certification, or satisfy some other State requirement. It is critical that these health care professionals are protected from any adverse State action proposed or taken when performing these crucial services.

In addition, the practice of health care professionals of providing health care across State lines also gives VA the flexibility to hire qualified health care professionals from any State to meet the staffing needs of a VA health care facility where recruitment or retention is difficult. As of December 31, 2019, VA had approximately 13,000 vacancies for health care professions across the country. As a national health care system, it is imperative for VA to be able to recruit and retain health care professionals, where recruitment and retention is difficult, to ensure there is access to health care regardless of where the VA beneficiary resides. Permitting VA health care professionals to practice across State lines is an important incentive when trying to recruit for these vacancies, particularly during a pandemic, where private health care facilities have greater flexibility to offer more competitive pay and benefits. This is also especially beneficial in recruiting spouses of active service members who frequently move across the country.

National Standard of Practice

This rulemaking also confirms VA's authority to establish national standards of practice for health care professions. We note that this rulemaking does not create any such national standards; all national standards of practice will be created via policy. For the purposes of this rulemaking, a national standard of practice describes the tasks and duties that a VA health care professional practicing in the health care profession may perform and may be permitted to undertake. Having a national standard of practice means that individuals from the same VA health care profession may provide the same type of tasks and duties regardless of the VA medical facility where they are located or the State license, registration, certification, or other State requirement they hold. We emphasize that VA will determine, on an individual basis, that a health care professional has the necessary education, training, and skills to perform the tasks and duties detailed in the national standard of practice.

The need for national standards of practice have been highlighted by VA's large-scale initiative regarding the new electronic health record (EHR). VA's health care system is currently undergoing a transformational initiative to modernize the system by replacing its current EHR with a joint EHR with Department of Defense (DoD) to promote interoperability of medical data between VA and DoD. VA's new EHR system will provide VA and DoD health care professionals with quick and efficient access to the complete picture of a veteran's health information, improving VA's delivery of health care to our nation's veterans.

For this endeavor, DoD and VA established a joint governance over the EHR system. In order to be successful, VA must standardize clinical processes with DoD. This means that all health care professionals in DoD and VA who practice in a certain health care profession must be able to carry out the same duties and tasks irrespective of State requirements. The reason why this is important is because each health care profession is designated a role in the EHR system that sets forth specific privileges within the EHR that dictate allowed tasks for such profession. These tasks include, but are not limited to, dispensing and administrating medications; prescriptive practices; ordering of procedures and diagnostic imaging; and required level of oversight. VA has the ability to modify these privileges within EHR, however, VA

cannot do so on an individual user level, but rather at the role level for each health care profession. In other words, VA cannot modify the privileges for all health care professionals in one State to be consistent with that State's requirements; instead, the privileges can only be modified for every health care professional in that role across all States. Therefore, the privileges established within EHR cannot be made facility or State specific.

In order to achieve standardized clinical processes, VA and DoD must create the uniform standards of practice for each health care specialty. Currently, DoD has specific authority from Congress to create national standards of practice for their health care professionals under 10 U.S.C. 1094. While VA lacks a similarly specific statute, VA has the general statutory authority, as explained above, to regulate its health care professionals and authorize health care practices that preempt conflicting State law. This regulation will confirm VA's authority to do so. Absent such standardized practices, it will be incredibly difficult for VA to achieve its goal of being an active participant in EHR modernization because either some VA health care professionals would fear potential adverse State actions or DoD and VA would need to agree upon roles that are consistent with the most restrictive States' requirements to ensure that all health care professionals are acting within the scope of their State requirements. VA believes that agreement upon roles that are consistent with the most restrictive State is not an acceptable option because it will lead to delayed care and consequently decreased access and level of health care for VA beneficiaries.

One example that impacts multiple health care professions throughout the VA system is the ability to administer medication without a provider (physician or advanced practice nurse practitioner) co-signature. As it pertains to nursing, almost all States permit nurses to follow a protocol; however, some States, such as New York, North Carolina, and South Carolina, do not permit nurses to follow a protocol without a provider co-signature. A protocol is a standing order that has been approved by medical and clinical leadership if a certain sequence of health care events occur. For instance, if a patient is exhibiting certain signs of a heart attack, there is a protocol in place to administer potentially life-saving medication. If the nurse is the first person to see the signs, the nurse will follow the approved protocol and immediately administer the medication. However, if the nurse cannot follow the protocol and requires a provider co-signature, administration of the medication will be delayed until a provider is able to co-sign the order, which may lead to the deterioration of the patient's condition. This also increases the provider's workload and decreases the amount of time the provider can spend with patients.

Historically, VA physical therapists (PTs), occupational therapists, and speech therapists were routinely able to determine the need to administer topical medications during therapy sessions and were able to administer the topical without a provider co-signature. However, in order to accommodate the new EHR system and variance in State requirements, these therapists would need to place an order for all medications, including topicals, which would leave these therapists waiting for a provider co-signature in the middle of a therapy session, thus delaying care. Furthermore, these therapists also routinely ordered imaging to better assess the clinical needs of the patient, but would also have to wait for a provider co-signature, which will further delay care and increase provider workload.

In addition to requiring provider co-signatures, there will also be a significant decrease in access to care due to other variances in State requirements. For instance, direct access to PTs will be limited in order to ensure that the role is consistent with all State requirements. Direct access means that a beneficiary may request PT services without a provider's referral. However, while almost half of the States allow unrestricted direct access to PTs, over half of the States have some limitations on requesting PT services. For instance, in Alabama, a licensed PT may perform an initial evaluation and may only provide other services as delineated in specific subdivisions of the Alabama Physical Therapy Practice Act. Furthermore, in New York, PT treatment may be rendered by a licensed PT for 10 visits or 30 days, whichever shall occur first, without a referral from a physician, dentist, podiatrist, nurse practitioner, or licensed midwife. This is problematic as VA will not be able to allow for direct access due to these variances and direct access has been shown to be beneficial for patient care. Currently, VISN 23 is completing a two-year strategic initiative to implement direct access and have PTs embedded into patient aligned care teams (PACT). Outcomes thus far include decreased wait times, improved veteran satisfaction, improved provider satisfaction, and improved functional outcomes.

Therefore, VA will confirm its authority to ensure that health care professionals are protected against State action when they adhere to VA's national standards of practice. We reiterate that this rulemaking does not establish national standards of practice for each health care profession, but merely confirms VA's authority to do so, thereby preempting any State restrictions that unduly interfere with those practices. The actual national standards of practice will be developed in subregulatory policy for each health care profession. As such, VA will make a concerted effort to engage appropriate stakeholders when developing the national standards of practice.

Preemption

As previously explained, in this rulemaking, VA is confirming its authority to manage its health care professionals. Specifically, this rulemaking will confirm VA's long-standing practice of allowing its health care professionals to practice in a State where they do not hold a license, registration, certification, or satisfy some other State requirement. The rule will also confirm that VA health care professionals must adhere to VA's national standards of practice, as determined by VA policy, irrespective of conflicting State licensing, registration, certification, or other State requirements that unduly burden that practice. We do note that VA health care professionals will only be required to perform tasks and duties to the extent of their education, skill, and training. For instance, VA would not require a registered nurse to perform a task that the individual nurse was not trained to perform.

Currently, practice in accordance with VA employment, including practice across State lines or adhering to a VA standard of practice, may jeopardize VA health care professionals' credentials or result in fines and imprisonment for unauthorized health care practice. This is because most States have restrictions that limit health care professionals' practice or have rules that prohibit health care professionals from furnishing health care services within that State without a license, registration, certification, or other requirement from that State. We note that, some States, for example Rhode Island, Utah, and Michigan, have enacted legislation or regulations that specifically allow certain VA health care professionals to practice in those States when they do not hold a State license.

Several VA health care professionals have already had actions proposed or taken against them by various States

while practicing health care within the scope of their VA employment, while they either practiced in a State where they do not hold a license, registration, certification, or other State requirement that unduly interfered with their VA employment. In one instance, a VA psychologist was licensed in California but was employed and providing supervision of a trainee at the VA Medical Center (VAMC) in Nashville, Tennessee. California psychology licensing laws require supervisors to hold a license from the State where they are practicing and do not allow for California licensed psychologists to provide supervision to trainees or unlicensed psychologists outside the State of California. The California State Psychology Licensing Board proposed sanctions and fines of $1,000 for violating section 1387.4(a) of the CA Code of Regulations (CCR). The VA system did not qualify for the exemption of out of State supervision requirements listed in CCR section 1387.4. In addition, a VA physician who was licensed in Oregon, but was practicing at a VAMC in Biloxi, Mississippi had the status of their license changed from active to inactive because the Oregon Medical Board determined the professional did not reside in Oregon, in violation of Oregon's requirement that a physician physically reside in the State in order to maintain an active license.

This rulemaking serves to preempt State requirements, such as the ones discussed above, that were or can be used to take an action against VA health care professionals for practicing within the scope of their VA employment. State licensure, registration, certification, and other State requirements are preempted to the extent such State laws unduly interfere with the ability of VA health care professionals to practice health care while acting within the scope of their VA employment. As explained above, Congress provided general statutory provisions that permit the VA Secretary to authorize health care practices by health care professionals at VA, which serve to preempt conflicting State laws that unduly interfere with the exercise of health care by VA health care professionals pursuant to that authorization. Although some VA health care professionals are required by Federal statute to have a State license, *see, e.g.,* 38 U.S.C. 7402(b)(1)(C) (providing that, to be eligible to be appointed to a physician position at the VA, a physician must be licensed to practice medicine, surgery, or osteopathy in a State), a State may not attach a condition to the license that is unduly burdensome to or unduly interferes with the practice of health care within the scope of VA employment.

Under well-established interpretations of the Supremacy Clause, Federal laws and policies authorizing VA health care professionals to practice according to VA standards preempt conflicting State law: that is, a State law that prevents or unreasonably interferes with the performance of VA duties. *See, e.g., Hancock* v. *Train,* 426 U.S. 167, 178–81 (1976); *Sperry* v. *Florida,* 373 U.S. 379, 385 (1963); *Miller* v. *Arkansas,* 352 U.S. 187 (1956); *Ohio* v. *Thomas,* 173 U.S. 276, 282–84 (1899); *State Bar Disciplinary Rules as Applied to Federal Government Attorneys,* 9 Op. O.L.C. 71, 72–73 (1985). When a State law does not conflict with the performance of Federal duties in these ways, VA health care professionals are required to abide by the State law. Therefore, VA's policies and regulations will preempt State licensure, registration, and certification laws, rules, or other requirements only to the extent they conflict with the ability of VA health care professionals to practice health care while acting within the scope of their VA employment.

We emphasize that, in instances where there is no conflict with State requirements, VA health care professionals should abide by the State requirement. For example, if a State license requires a health care professional to have a certain number of hours of continuing professional education per year to maintain their license, the health care professional must adhere to this State requirement if it does not prevent or unduly interfere with the exercise of VA employment. To determine whether a State requirement is conflicting, VA would assess whether the State law unduly interferes on a case-by-case basis. For instance, if Oregon requires all licensed physicians to reside in Oregon, VA would likely find that it unduly interferes with already licensed VA physicians who reside and work for VA in the State of Mississippi. We emphasize that the intent of the regulation is to only preempt State requirements that are unduly burdensome and interfere with a VA health care professionals' practice for the VA. For instance, it would not require a State to issue a license to an individual who does not meet the education requirements to receive a license in that State. We note that this rulemaking also does not affect VA's existing requirement that all VA health care professionals adhere to restrictions imposed by the Controlled Substances Act, 21 U.S.C. 801 *et seq.* and implementing regulations at 21 CFR 1300, *et seq.,* to prescribe or administer controlled substances.

Any preemption of conflicting State requirements will be the minimum necessary for VA to effectively furnish health care services. It would be costly and time-consuming for VA to lobby each State board for each health care profession specialty to remove restrictions that impair VA's ability to furnish health care services to beneficiaries and then wait for the State to implement appropriate changes. Doing so would not guarantee a successful result.

Regulation

For these reasons, VA is establishing a new regulation titled Health care professionals' practice in VA, which will be located at 38 CFR 17.419. This rule will confirm the ability of VA health care professionals to practice their health care profession consistent with the scope and requirements of their VA employment, notwithstanding any State license, registration, certification, or other requirements that unduly interfere with their practice.

Subsection (a) of § 17.419 contains the definitions that will apply to the new section. Subsection (a)(1) contains the definition for beneficiary. We are defining the term beneficiary to mean a veteran or any other individual receiving health care under title 38 of the U.S. Code. We are using this definition because VA provides health care to veterans, certain family members of veterans, servicemembers, and others. This is VA's standard use of this term.

Subsection (a)(2) contains the definition for health care professional. We are defining the term health care professional to be an individual who meets specific criteria that is listed below.

Subsection (a)(2)(i) will require that a health care professional be appointed to an occupation in VHA that is listed or authorized under 38 U.S.C. 7306, 7401, 7405, 7406, or 7408 or title 5 of the U.S. Code.

Subsection (a)(2)(ii) requires that the individual is not a VA-contracted health care professional. A health care professional does not include a contractor or a community health care professional because they are not considered VA employees nor appointed under 38 U.S.C. 7306, 7401, 7405, 7406, or 7408 or title 5 of the U.S. Code.

Subsection (a)(2)(iii) lists the required qualifications for a health care professional. We note that these qualifications do not include all general

qualifications for appointment, such as to hold a degree of doctor of medicine; these qualifications are related to licensure, registration, certification, or other State requirements.

Subsection (a)(2)(iii)(A) states that the health care professional must have an active, current, full, and unrestricted license, registration, certification, or satisfies another State requirement in a State to practice the health care specialty identified under 38 U.S.C. 7402(b). This standard ensures that VA health care professionals are qualified to practice their individual health care specialty if the specialty requires such credential.

Subsection (a)(2)(iii)(B) states that the individual has other qualifications as prescribed by the Secretary for one of the health care professions listed under 38 U.S.C. 7402(b). Some health care professionals appointed under 38 U.S.C. 7401(3) whose qualifications are listed in 38 U.S.C. 7402(b) are not required to meet State license, registration, certification, or other requirements and rely on the qualifications prescribed by the Secretary. Therefore, these individuals would be included in this subsection and required to have the qualifications prescribed by the Secretary for their health care profession.

Subsection (a)(2)(iii)(C) states that the individual is otherwise authorized by the Secretary to provide health care services. This would include those individuals who practice a health care profession that does not require a State license, registration, certification, or other requirement and is also not listed in 38 U.S.C. 7402(b), but is authorized by the Secretary to provide health care services.

Subsection (a)(2)(iii)(D) includes individuals who are trainees or may have a time limited appointment to finish clinicals or other requirements prior to being fully licensed. Therefore, the regulation will state that the individual is under the clinical supervision of a health care professional that meets the requirements listed in subsection (a)(2)(iii)(A)–(C) and the individual must meet the requirements in subsection (a)(2)(iii)(D)(*i*) or (a)(2)(iii)(D)(*ii*).

Subsection (a)(2)(iii)(D)(*i*) states that the individual is a health professions trainee appointed under 38 U.S.C. 7405 or 7406 participating in clinical or research training under supervision to satisfy program or degree requirements.

Subsection (a)(2)(iii)(D)(*ii*) states that the individual is a health care employee, appointed under title 5 of the U.S. Code, 38 U.S.C. 7401(1) or (3), or 38 U.S.C. 7405 for any category of personnel described in 38 U.S.C. 7401(1) or (3) who must obtain an active, current, full and unrestricted licensure, registration, or certification or meet the qualification standards as defined by the Secretary within the specified time frame. These individuals have a time-limited appointment to obtain credentials. For example, marriage and family therapists require a certain number of supervised clinical post-graduate hours prior to receiving their license.

Lastly, as we previously discussed in this rulemaking, we are defining the term State in subsection (a)(3) as the term is defined in 38 U.S.C. 101(20), and also including political subdivisions of such States. This is consistent with the definition of State in 38 U.S.C. 1730C(f) which is VA's statutory authority to preempt State law when the covered health care professional is using telehealth to provide treatment to an individual under this title. We believe that it is important to define the term in the same way as it is defined for health care professionals practicing via telehealth so that way it is consistent regardless of whether the health care professional is practicing in-person or via telehealth. Moreover, as subdivisions of a State are granted legal authority from the State itself, it makes sense to subject entities created by a State, or authorized by a State to create themselves, to be subject to the same limitations and restrictions as the State itself.

Section 17.419(b) details that VA health care professionals must practice within the scope of their Federal employment irrespective of conflicting State requirements that would prevent or unduly interfere with the exercise of Federal duties. This provision confirms that VA health care professionals may furnish health care consistent with their VA employment obligations without fear of adverse action proposed or taken by any State. In order to clarify and make transparent how VA utilizes or intends to utilize our current statutory authority, we are providing a non-exhaustive list of examples.

The first example is listed in subsection (b)(1)(i). It states that a health care professional may practice their VA health care profession in any State irrespective of the State where they hold a valid license, registration, certification, or other qualification.

The second example is listed in subsection (b)(1)(ii). It states that a health care professional may practice their VA health care profession consistent with the VA national standard of practice as determined by VA. As previously explained, VA intends to establish national standards of practice via VA policy.

A health care professional's practice within VA will continue to be subject to the limitations imposed by the Controlled Substances Act, 21 U.S.C. 801, *et seq.* and implementing regulations at 21 CFR 1300, *et seq.,* on the authority to prescribe or administer controlled substances, as well as any other limitations on the provision of VA care set forth in applicable Federal law and policy. This will ensure that professionals are still in compliance with critical laws concerning the prescribing and administering of controlled substances. This requirement is stated in subsection (b)(2).

Subsection (c) expressly states the intended preemptive effect of § 17.419, to ensure that conflicting State and local laws, rules, regulations, and requirements related to health care professionals' practice will have no force or effect when such professionals are practicing health care while working within the scope of their VA employment. In circumstances where there is a conflict between Federal and State law, Federal law would prevail in accordance with Article VI, clause 2, of the U.S. Constitution.

Executive Order 13132, Federalism

Executive Order 13132 establishes principles for preemption of State law when it is implicated in rulemaking or proposed legislation. Where a Federal statute does not expressly preempt State law, agencies shall construe any authorization in the statute for the issuance of regulations as authorizing preemption of State law by rulemaking only when the exercise of State authority directly conflicts with the exercise of Federal authority or there is clear evidence to conclude that the Congress intended the agency to have the authority to preempt State law.

In this situation, the Federal statutes do not expressly preempt State laws; however, VA construes the authorization established in 38 U.S.C. 303, 501, and 7401–7464 as authorizing preemption because the exercise of State authority directly conflicts with the exercise of Federal authority under these statutes. Congress granted the Secretary express statutory authority to establish the qualifications for VA's health care professionals, determine the hours and conditions of employment, take disciplinary action against employees, and otherwise regulate the professional activities of those individuals. 38 U.S.C. 7401–7464. Specifically, section 7402(b) states that most health care professionals, after appointment by VA, must, among other

requirements, be licensed, registered, or certified to practice their profession in a State. To that end, VA's regulations and policies will preempt any State law or action that conflicts with the exercise of Federal duties in providing health care at VA.

In addition, any regulatory preemption of State law must be restricted to the minimum level necessary to achieve the objectives of the statute pursuant to the regulations that are promulgated. In this rulemaking, State licensure, registration, and certification laws, rules, regulations, or other requirements are preempted only to the extent such State laws unduly interfere with the ability of VA health care professionals to practice health care while acting within the scope of their VA employment. Therefore, VA believes that the rulemaking is restricted to the minimum level necessary to achieve the objectives of the Federal statutes.

The Executive Order also requires an agency that is publishing a regulation that preempts State law to follow certain procedures. These procedures include: The agency consult with, to the extent practicable, the appropriate State and local officials in an effort to avoid conflicts between State law and Federally protected interests; and the agency provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings. For the reasons below, VA believes that it is not practicable to consult with the appropriate State and local officials prior to the publication of this rulemaking.

The National Emergency caused by COVID–19 has highlighted VA's acute need to quickly shift health care professionals across the country. As both private and VA medical facilities in different parts of the country reach or exceed capacity, VA must be able to mobilize its health care professionals across State lines to provide critical care for those in need. As explained in the Supplementary Information above, as of June 2020, a total of 1,893 staff have been mobilized to meet the needs of our facilities and Fourth Mission requests during the pandemic. VA deployed 877 staff to meet Federal Emergency Management Agency (FEMA) Mission requests, 420 health care professionals were deployed as DEMPS response, 414 employees were mobilized to cross level staffing needs within their Veterans Integrated Service Networks (VISN), 69 employees were mobilized to support needs in another VISN, and 113 Travel Nurse Corps staff responded specifically for COVID–19 staffing support. Given the speed in which it is required for our health care professionals to go to these facilities and provide health care, it is also essential that the health care professionals can follow the same standards of practice irrespective of the location of the facility or the requirements of their individual State license. This is important because if multiple health care professionals, such as multiple registered nurses, licensed in different States are all sent to one VA medical facility to assist when there is a shortage of professionals, it would be difficult and cumbersome if they could not all perform the same duties and each supervising provider had to be briefed on the tasks each registered nurse could perform. In addition, not having a uniform national scope of practice could limit the tasks that the registered nurses could provide. This rulemaking will provide health care professionals an increased level of protection against adverse State actions while VA strives to increase access to high quality health care across the VA health care system during this National Emergency. It would be time consuming and contrary to the public health and safety to delay implementing this rulemaking until we consulted with State and local officials. For these reasons, it would be impractical to consult with State and local officials prior to the publication of this rulemaking.

We note that this rulemaking does not establish any national standards of practice; instead, VA will establish the national standards of practice via subregulatory guidance. VA will, to the extent practicable, make all efforts to engage with State and local officials when establishing the national standards of practice via subregulatory guidance. Also, this interim final rule will have a 60-day comment period that will allow State and local officials the opportunity to provide their input on the rule.

Administrative Procedures Act

An Agency may forgo notice and comment required under the Administrative Procedures Act (APA), 5 U.S.C. 553, if the agency for good cause finds that compliance would be impracticable, unnecessary, or contrary to the public interest. An agency may also bypass the APA's 30-day publication requirement if good cause exists. The Secretary of Veterans Affairs finds that there is good cause under the provisions of 5 U.S.C. 553(b)(B) to publish this rule without prior opportunity for public comment because it would be impracticable and contrary to the public interest and finds that there is good cause under 5 U.S.C. 553(d)(3) to bypass its 30-day publication requirement for the same reasons as outlined above in the Federalism section, above.

In short, this rulemaking will provide health care professionals protection against adverse State actions while VA strives to increase access to high quality health care across the VA health care system during this National Emergency.

In addition to the needs discussed above regarding the National Emergency, it is also imperative that VA move its health care professionals across State lines in order to facilitate the implementation of the new EHR system immediately. VA implemented EHR at the first VA facility in October 2020 and additional sites are scheduled to have EHR implemented over the course of the next eight years. The next site is scheduled for implementation in Quarter 2 of Fiscal Year 2021 (*i.e.,* between January to March 2021). Due to the implementation of the new EHR system, VA expects decreased productivity and reduced clinical staffing during training and other events surrounding EHR enactment. VA expects a productivity decrease of up to 30 percent for the 60 days before implementation and the 120 days after at each site. Any decrease in productivity could result in decreased access to health care for our Nation's veterans.

In order to support this anticipated productivity decrease, VA is engaging in a ''national supplement,'' where health care professionals from other VA medical facilities will be deployed to those VA medical facilities and VISNs that are undergoing EHR implementation. The national supplement would mitigate reduced access during EHR deployment activities, such as staff training, cutover, and other EHR implementation activities. Over the eight-year deployment timeline, the national supplement is estimated to have full time employee equivalents of approximately 60 nurses, 3 pharmacy technicians, 5 mental health and primary care providers, and other VA health care professionals. We note that the actual number of VA health care professionals deployed to each site will vary based on need. The national supplement will require VA health care professionals on a national level to practice health care in States where they do not hold a State license, registration, certification, or other requirement. In addition, VISNs will be providing local cross-leveling and intra-VISN staff deployments to support EHRM implementation activities. Put simply, in order to mitigate the decreased

productivity as a result of EHR implementation, VA must transfer VA health care professionals across the country to States where they do not hold a license, registration, certification, or other requirement to assist in training on the new system as well as to support patient care.

Therefore, it would be impracticable and contrary to the public health and safety to delay implementing this rulemaking until a full public notice-and-comment process is completed. This rulemaking will be effective upon publication in the **Federal Register**. As noted above, this interim final rule will have a 60-day comment period that will allow State and local officials the opportunity to provide their input on the rule, and VA will take those comments into consideration when deciding whether any modifications to this rule are warranted.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, is not applicable to this rulemaking because a notice of proposed rulemaking is not required under 5 U.S.C. 553. 5 U.S.C. 601(2), 603(a), 604(a).

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is a significant regulatory action under Executive Order 12866.

VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published From FY 2004 Through Fiscal Year to Date.''

This interim final rule is not subject to the requirements of E.O. 13771 because this rule results in no more than *de minimis* costs.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This interim final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are: 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; 64.039 CHAMPVA; 64.040 VHA Inpatient Medicine; 64.041 VHA Outpatient Specialty Care; 64.042 VHA Inpatient Surgery; 64.043 VHA Mental Health Residential; 64.044 VHA Home Care; 64.045 VHA Outpatient Ancillary Services; 64.046 VHA Inpatient Psychiatry; 64.047 VHA Primary Care; 64.048 VHA Mental Health Clinics; 64.049 VHA Community Living Center; and 64.050 VHA Diagnostic Care.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Brooks D. Tucker, Assistant Secretary for Congressional and Legislative Affairs, Performing the Delegable Duties of the Chief of Staff, Department of Veterans Affairs, approved this document on October 19, 2020, for publication.

Consuela Benjamin,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs is amending 38 CFR part 17 as set forth below:

PART 17—MEDICAL

■ 1. The authority citation for part 17 is amended by adding an entry for § 17.419 in numerical order to read in part as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

* * * * *

Section 17.419 also issued under 38 U.S.C. 1701 (note), 7301, 7306, 7330A, 7401–7403, 7405, 7406, 7408).

* * * * *

■ 2. Add § 17.419 to read as follows:

§ 17.419 Health care professionals' practice in VA.

(a) *Definitions.* The following definitions apply to this section.

(1) *Beneficiary.* The term beneficiary means a veteran or any other individual receiving health care under title 38 of the United States Code.

(2) *Health care professional.* The term health care professional is an individual who:

(i) Is appointed to an occupation in the Veterans Health Administration that is listed in or authorized under 38 U.S.C. 7306, 7401, 7405, 7406, or 7408 or title 5 of the U.S. Code;

(ii) Is not a VA-contracted health care professional; and

(iii) Is qualified to provide health care as follows:

(A) Has an active, current, full, and unrestricted license, registration, certification, or satisfies another State requirement in a State;

(B) Has other qualifications as prescribed by the Secretary for one of

the health care professions listed under 38 U.S.C. 7402(b);

(C) Is an employee otherwise authorized by the Secretary to provide health care services; or

(D) Is under the clinical supervision of a health care professional that meets the requirements of subsection (a)(2)(iii)(A)–(C) of this section and is either:

(*i*) A health professions trainee appointed under 38 U.S.C. 7405 or 7406 participating in clinical or research training under supervision to satisfy program or degree requirements; or

(*ii*) A health care employee, appointed under title 5 of the U.S. Code, 38 U.S.C. 7401(1) or (3), or 38 U.S.C. 7405 for any category of personnel described in 38 U.S.C. 7401(1) or (3) who must obtain an active, current, full and unrestricted licensure, registration, certification, or meet the qualification standards as defined by the Secretary within the specified time frame.

(3) *State.* The term State means a State as defined in 38 U.S.C. 101(20), or a political subdivision of such a State.

(b) *Health care professional's practice.* (1) When a State law or license, registration, certification, or other requirement prevents or unduly interferes with a health care professional's practice within the scope of their VA employment, the health care professional is required to abide by their Federal duties, which includes, but is not limited to, the following situations:

(i) A health care professional may practice their VA health care profession in any State irrespective of the State where they hold a valid license, registration, certification, or other State qualification; or

(ii) A health care professional may practice their VA health care profession within the scope of the VA national standard of practice as determined by VA.

(2) VA health care professional's practice is subject to the limitations imposed by the Controlled Substances Act, 21 U.S.C. 801 *et seq.* and implementing regulations at 21 CFR 1300 *et seq.,* on the authority to prescribe or administer controlled substances, as well as any other limitations on the provision of VA care set forth in applicable Federal law and policy.

(c) *Preemption of State law.* Pursuant to the Supremacy Clause, U.S. Const. art. IV, cl. 2, and in order to achieve important Federal interests, including, but not limited to, the ability to provide the same complete health care and hospital service to beneficiaries in all States as required by 38 U.S.C. 7301, conflicting State laws, rules, regulations or requirements pursuant to such laws are without any force or effect, and State governments have no legal authority to enforce them in relation to actions by health care professionals within the scope of their VA employment.

[FR Doc. 2020–24817 Filed 11–10–20; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2020–0122; FRL–10014–19–Region 9]

Air Plan Approval; California; Butte County; El Dorado County; Mojave Desert Air Quality Management District; San Diego County; Ventura County

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Butte County Air Quality Management District (BCAQMD), El Dorado County Air Quality Management District (EDCAQMD), Mojave Desert Air Quality Management District (MDAQMD), San Diego County Air Pollution Control District (SDCAPCD) and Ventura County Air Pollution Control District (VCAPCD) portions of the California State Implementation Plan (SIP). These revisions concern rules that include definitions for certain terms that are necessary for the implementation of local rules that regulate sources of air pollution. We are approving the definitions rules under the Clean Air Act (CAA or the Act).

DATES: This rule will be effective on December 14, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2020–0122. 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, *e.g.,* Confidential Business Information 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 availability information. 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: Arnold Lazarus, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–2304 or by email at *Lazarus.arnold@epa.gov.*

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

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I. Proposed Action

On July 6, 2020 (85 FR 40156), the EPA proposed to approve the five amended rules listed in Table 1 as revisions to the California SIP. With respect to BCAQMD Rule 102, we determined that the State had not provided sufficient public process documentation to provide the basis for a rescission of the rule from the applicable SIP, but we recognized that, because the remaining definitions in BCAQMD Rule 102 had been moved to BCAQMD Rule 101 and because we are approving BCAQMD Rule 101, there is no reason to retain BCAQMD Rule 102 in the applicable SIP.

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Rescinded	Amended/revised	Submitted
BCAQMD	101	Definitions		12/14/2017	[1] 5/23/2018
BCAQMD	102	Definitions	[2] 12/14/2017		[3] 5/23/2018
EDCAQMD	101	General Provisions and Definitions		6/20/2017	8/9/2017
MDAQMD	102	Definition of Terms		1/28/2019	[4] 8/19/2019

TABLE 1—SUBMITTED RULES—Continued

Local agency	Rule No.	Rule title	Rescinded	Amended/ revised	Submitted
SDCAPCD	2	Definitions		7/11/2017	11/13/2017
VCAPCD	2	Definitions		4/9/2019	[5] 8/19/2019

We proposed to approve these rules because we determined that they comply with the relevant CAA requirements. Our proposed action and related technical support documents (TSDs) contain more information on the rules and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received a comment letter from a member of the public who expressed support for the proposed rulemaking.

III. EPA Action

No comments were submitted that change our assessment of the rules as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving these rules into the California SIP. Our final action includes regulatory text in 40 CFR 52.220 that incorporates by reference the amended rules listed in Table 1 above, and identifies the previously approved rules that are being superseded in the California SIP by the approval of the amended rules. We are also including regulatory text that specifically identifies the remaining definitions in BCAQMD Rule 102 (''Definitions'') that were superseded by our approval in 2015 of BCAQMD Rule 300 (''Open Burning Requirements, Prohibitions and Exemptions'')[6] and the remaining definitions that are being superseded by today's approval of amended BCAQMD Rule 101.

[1] CARB submitted the amendment to BCAQMD Rule 101 electronically on May 23, 2018. CARB's submittal letter is dated May 18, 2018.

[2] The BCAQMD amended Rule 101 on this date but took no action on Rule 102. The date is from Enclosure A to CARB Executive Order S–18–004, May 18, 2018, which is included in CARB's May 23, 2018 SIP submittal.

[3] CARB submitted the rescission of BCAQMD Rule 102 electronically on May 23, 2018. CARB's submittal letter is dated May 18, 2018.

[4] CARB submitted the amendment to MDAQMD Rule 102 electronically on August 19, 2019. CARB's submittal letter is dated August 16, 2019.

[5] CARB submitted the amendment to VCAPCD Rule 2 electronically on August 19, 2019. CARB's submittal letter is dated August 16, 2019.

[6] We approved BCAQMD Rule 300 at 80 FR 38966 (July 8, 2015).

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the BCAQMD's, the EDAQMD's, the MDAQMD's, the SDCAPCD's and the VCAPCD's rules described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX 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 Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. 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);
- Is not an Executive Order 13771 (82 FR 9339, February 3, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the 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).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, 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. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United

States Court of Appeals for the appropriate circuit by January 11, 2021. 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, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: October 16, 2020.

John Busterud,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the EPA amends, part 52, Chapter I, Title 40 of the Code of Federal Regulations as follows:

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 F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(168)(i)(A)(*11*) and (*12*), (c)(280)(i)(B)(*3*), (c)(404)(i)(C)(*3*), (c)(457)(i)(C)(*7*), (c)(488)(i)(A)(*5*), (c)(503)(i)(C), (c)(516)(i)(B), (c)(518)(i)(B), (c)(520)(i)(A)(*2*) and (c)(542) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(168) * * *

(i) * * *

(A) * * *

(*11*) Previously approved on February 3, 1987 in paragraph (c)(168)(i)(A)(*1*) of this section and now deleted with replacement in paragraph (c)(423)(i)(G)(*1*), Rule 102 ''Definitions'': the definitions for ''approved ignition devices,'' ''open out-door fire'', ''permissive burn day'' and ''range improvement burning.''

(*12*) Previously approved on February 3, 1987 in paragraph (c)(168)(i)(A)(*1*) of this section and now deleted with replacement in paragraph (c)(518)(i)(B)(*1*), Rule 102 ''Definitions'': the definitions for ''submerged fill pipe'' and ''vapor recovery system''.

* * * * *

(280) * * *

(i) * * *

(B) * * *

(*3*) Previously approved on October 10, 2001 in paragraph (c)(280)(i)(B)(*2*) of this section and now deleted with replacement in paragraph (c)(503)(i)(C)(*1*), Rule 101, adopted on February 15, 2000.

* * * * *

(404) * * *

(i) * * *

(C) * * *

(*3*) Previously approved on December 7, 2012 in paragraph (c)(404)(i)(C)(*1*) of this section and now deleted with replacement in paragraph (c)(542)(i)(B)(*1*), Rule 2, ''Definitions,'' revised on October 22, 1968, as revised through April 12, 2011.

* * * * *

(457) * * *

(i) * * *

(C) * * *

(*7*) Previously approved on June 11, 2015 in paragraph (c)(457)(i)(C)(*1*) of this section and now deleted with replacement in paragraph (c)(518)(i)(B)(*1*), Rule 101, ''Definitions,'' amended on April 24, 2014.

* * * * *

(488) * * *

(i) * * *

(A) * * *

(*5*) Previously approved on June 21, 2017 in paragraph (c)(488)(i)(A)(*1*) of this section and now deleted with replacement in (c)(516)(i)(B)(*1*), Regulation 1, Rule 2, ''Definitions,'' Rev. Adopted and Effective on June 30, 1999, Table 1—Exempt Compounds: Rev. and Effective on June 14, 2016.

* * * * *

(503) * * *

(i) * * *

(C) El Dorado County Air Quality Management District.

(*1*) Rule 101, ''General Provisions and Definitions,'' amended on June 20, 2017.

(*2*) [Reserved]

* * * * *

(516) * * *

(i) * * *

(B) San Diego County Air Pollution Control District.

(*1*) Rule 2, ''Definitions,'' amended on July 11, 2017.

(*2*) [Reserved]

* * * * *

(518) * * *

(i) * * *

(B) Butte County Air Quality Management District.

(*1*) Rule 101, ''Definitions,'' amended on December 14, 2017.

(*2*) [Reserved]

* * * * *

(520) * * *

(i) * * *

(A) * * *

(*2*) Previously approved on July 2, 2019 in paragraph (c)(520)(i)(A)(*1*) of this section and now deleted with replacement in paragraph (c)(542)(i)(A)(*1*), Rule 102, ''Definition of Terms,'' amended on April 23, 2018.

* * * * *

(542) New regulations for the following APCDs were submitted on August 19, 2019 by the Governor's designee as an attachment to a letter dated August 16, 2019.

(i) *Incorporation by reference.* (A) Mojave Desert Air Quality Management District.

(*1*) Rule 102, ''Definition of Terms,'' amended on January 28, 2019.

(*2*) [Reserved]

(B) Ventura County Air Pollution Control District.

(*1*) Rule 2, ''Definitions,'' as amended through April 9, 2019.

(*2*) [Reserved]

(ii) [Reserved]

[FR Doc. 2020–23551 Filed 11–10–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket Nos. 19–347, 17–105, 10–71; FCC 20–135; FRS 17141]

Cable Service Change Notifications; Modernization of Media Regulation Initiative; Retransmission Consent

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission revises the regulations governing the notices that cable operators must provide subscribers and local franchise authorities (LFAs) regarding rate and service changes. Specifically, document amends the rules to clarify that when service changes occur due to retransmission consent or program carriage negotiations that fail within the last 30 days of a contract, cable operators must provide notice to subscribers ''as soon as possible,'' rather than 30 days in advance. The document also eliminates the requirement that cable operators not subject to rate regulation provide 30 days' advance notice to LFAs of rate or

service changes. Finally, it eliminates the requirement that cable operators provide notice of any significant change to the information required in the certain annual notices, as well as adopts several non-substantive revisions that clarify the rules and eliminate redundant provisions. The Commission concludes that these changes will make consumer notices more meaningful and accurate, reduce consumer confusion, better ensure that subscribers receive the information they need to make informed choices about their service options, and reduce unnecessary regulatory burdens.

DATES: Effective November 12, 2020.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact John Cobb, *John.Cobb@fcc.gov,* of the Policy Division, Media Bureau, (202) 418–2120.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* MB Docket Nos. 19–347, 17–105, 10–71; FCC 20–135, adopted on September 30, 2020 and released on October 1, 2020. The full text of this document is available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word, and/or Adobe Acrobat). To request these documents in accessible formats (computer diskettes, large print, audio recording, and Braille), send an email to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

In this *Report and Order,* we revise our regulations governing the notices that cable operators must provide subscribers and local franchise authorities (LFAs) regarding rate and service changes. Specifically, we amend § 76.1603 of our rules to clarify that when service changes occur due to retransmission consent or program carriage negotiations that fail within the last 30 days of a contract, cable operators must provide notice to subscribers ''as soon as possible,'' rather than 30 days in advance. We also amend § 76.1603(c) to eliminate the requirement that cable operators not subject to rate regulation provide 30 days' advance notice to LFAs of rate or service changes. Finally, we amend § 76.1603(b) to eliminate the requirement that cable operators provide notice of any significant change to the information required in the § 76.1602 annual notices, as well as adopt several non-substantive revisions to §§ 76.1601 and 76.1603 that clarify the rules and eliminate redundant provisions. We adopt these changes to make consumer notices more meaningful and accurate, reduce consumer confusion, better ensure that subscribers receive the information they need to make informed choices about their service options, and reduce unnecessary regulatory burdens. With this proceeding, we continue our efforts to modernize our regulations to better reflect today's media marketplace.

Background. As explained fully in the *NPRM,* several provisions of the Communications Act of 1934, as amended (the Act)—sections 623(b), 624(h), and 632—address the notices that cable operators must provide to their subscribers and LFAs regarding service or rate changes. The Commission adopted regulations implementing these notice requirements through several decisions in 1993 and consolidated those regulations into a newly created subpart T in 1999. Two sections within that subpart are at issue in this *Report and Order.* First, § 76.1601 obligates cable operators to provide 30 days' advance notice to broadcast television stations and to subscribers of the deletion or repositioning of any such station. Second, § 76.1603 places several additional notice obligations on cable operators. Subsection (b) requires that cable operators notify subscribers of ''any changes in rates, programming services or channel positions'' and any significant changes in the information required by § 76.1602 as soon as possible in writing and 30 days in advance if the change is within the control of the cable operator. Subsection (c) requires that cable operators notify LFAs 30 days ''before implementing any rate or service change.'' Finally, subsection (d) requires cable operators to ''provide written notice to a subscriber of any increase in the price to be charged for the basic service tier or associated equipment at least 30 days before any proposed increase is effective.'' These rules, which notably apply only to cable operators and not to other multichannel video programming distributors (MVPDs), have overlapping obligations as a result of the consolidation in 1999.

In 2011, the Commission sought comment on whether to revise § 76.1601 ''to require that notice of potential deletion of a broadcaster's signal be given to consumers once a retransmission consent agreement is within 30 days of expiration, unless a renewal or extension has been executed, and regardless of whether the station's signal is ultimately deleted.'' The Commission noted that while adequate advance notice of retransmission consent disputes can allow consumers to prepare for service disruptions, ''such notice can be unnecessarily costly and disruptive when it creates a false alarm, *i.e.,* concern about disruption that does not come to pass, and induces subscribers to switch MVPD providers in anticipation [thereof].''

In December 2019, we adopted the *NPRM* in this proceeding as a part of our ongoing Media Modernization Initiative. In the *NPRM,* we proposed three primary changes to the notice obligations in §§ 76.1601 and 76.1603: (1) Clarifying in § 76.1603(b) that cable operators have no obligation to provide notice to subscribers 30 days in advance of channel lineup changes when the change is due to retransmission consent or program carriage negotiations that fail during the last 30 days of a contract but that rather, in such a situation, they must provide notice ''as soon as possible;'' (2) modifying § 76.1603(c) to require service and rate change notices to LFAs only if required by an LFA; and (3) adopting several technical edits to §§ 76.1601 and 76.1603 to make the rules more readable and remove duplicative requirements. We received seven comments and three replies in response to the *NPRM.* Cable operators, ACA Connects (ACA) and NCTA—The internet and Television Association (NCTA) generally supported all of our proposals, while The National Association of Telecommunications Officers and Advisors (NATOA) and various LFAs raised concerns in opposition to the proposals to clarify the service change notice obligations in instances involving failed program carriage or retransmission consent negotiations and to require notice to LFAs only if they specifically request it.

Discussion. In this *Report and Order,* we adopt several revisions to the rules in §§ 76.1601 and 76.1603 governing the notices that cable operators must provide to subscribers and LFAs regarding rate and service changes. First, we adopt our proposal to clarify that cable operators must provide notice as soon as possible in the event of service changes that occur due to retransmission consent or program carriage negotiations that fail in the final 30 days of a contract, rather than 30 days in advance; we also provide guidance on which means are reasonable to provide that notice. Second, we amend the LFA notice requirements to eliminate the requirement that all cable operators provide 30 days' advance notice to LFAs of any changes in rates or services rather than adopting our initial proposal

concerning LFA notice. Instead, we conclude that only cable operators subject to rate regulation will be required to provide 30 days' advance written notice to LFAs of any proposed increase in the price to be charged for the basic service tier. Finally, we eliminate the requirement that cable operators provide notice of any significant change to the information required in the § 76.1602 annual notices, as well as adopt several technical edits to make the rules more readable and remove duplicative requirements.

Service Change Notice Due to Failed Retransmission Consent and Program Carriage Negotiations. We adopt our proposal to amend § 76.1603(b) to clarify that cable operators must provide subscribers notice ''as soon as possible'' when service changes occur due to retransmission consent or program carriage negotiations that fail within the last 30 days of a contract, rather than 30 days in advance. In doing so, we reverse our previous view that such negotiations are within the control of cable operators. Instead, we adopt a new rule that failed program carriage or retransmission consent negotiations will be deemed outside of cable operators' control. In all other circumstances, however, the subscriber notice requirements will continue to operate as they have previously. That is, rate and service changes must be provided 30 days in advance of any change, unless the change is outside the cable operators' control, in which case it must be provided as soon as possible. We conclude that this action will make subscriber notices more meaningful and accurate, reduce consumer confusion, and ensure that subscribers receive the information they need to make informed choices about their service options.

We reverse the Commission's previous interpretation that program carriage and retransmission consent negotiations are within the control of a cable operator for the purpose of § 76.1603(b). No commenter argued that the Commission should retain its current interpretation that negotiations are within the control of cable operators in this context. We agree with the multiple commenters that contend that retransmission consent and program carriage negotiations are not within the control of the cable operator because cable operators cannot unilaterally control the outcome of such negotiations. Or, as the saying goes, it takes two to tango. Thus, we find that service changes that occur as a result of failed program carriage or retransmission consent negotiations are not within the control of a cable operator and amend § 76.1603(b) to provide so explicitly. We emphasize that this change applies only in the specific context of program carriage or retransmission consent renewal negotiations that fail within the final 30 days of an existing contract and result in a service change.

We find that this change is consistent with the Act. As noted in the *NPRM,* section 632(b) of the Act directs the Commission to adopt ''standards by which cable operators may fulfill their customer service requirements,'' and section 632(c) affords cable operators the flexibility to ''provide notice of service and rate changes to subscribers using any reasonable written means at its sole discretion.'' These statutory provisions do not explicitly state that all notices must be provided in advance. In fact, section 632(c) refers only to ''notice,'' whereas various other provisions of the Act specifically require ''advance notice.''

We are persuaded that requiring cable operators to provide notice to subscribers that a channel may be dropped whenever a program carriage or retransmission consent renewal negotiation extends into the final 30 days of an existing contract would cause substantial consumer confusion and thus would not further the goal of facilitating informed choices. We are not persuaded by LFAs' contention that subscribers need advance notice of potential deletions so that they can seek alternative sources of the programming that could ultimately be deleted. Although the legislative history of the Telecommunications Act of 1996 indicates that Congress wanted ''to ensure that consumers have sufficient warning about rate and service changes so they can choose to disconnect their service prior to the implementation of the change,'' we conclude that notices about deletions that may never occur are confusing to consumers and, therefore, do not fulfill this goal. The record provides ample evidence that program carriage and retransmission consent negotiations often come down to the final days—if not hours—of an existing contract and rarely result in a signal deletion. For example, Altice notes that in 2019 at least 90 percent of Altice USA's programming negotiations were resolved during the final 30 days of an existing contract and that agreements were reached with all its programming partners without any channels going dark. Similarly, ACA contends that ''[c]arriage agreements are almost always renewed within days (or even hours) of their expiration, and sometimes following multiple short-term extensions.'' Likewise, NCTA asserts that ''[t]he vast majority of these negotiations end successfully.''

The record does not support requiring cable operators to bombard subscribers with notices whenever retransmission consent or program carriage negotiations continue into the last 30 days of a contract. As cable commenters observe, the most contentious negotiations—*i.e.,* those most likely to result in a programming blackout—are often the subject of news reports, advertisements, and social media posts, which provide consumers with information about potential programming disputes and encourage them to ''make their voices heard'' with their cable operator. Further, we do not agree with LFAs that notices could be sufficiently tailored to avoid causing consumer confusion given the large number of renewal negotiations that extend into the final 30 days of an existing contract and the concomitant volume of potential deletion notices in situations where the channel is not ultimately deleted. Rather, we agree with commenters that caution that providing inherently uncertain notices about potential channel deletions that ultimately do not come to pass could cause some consumers to incur ''the burden and expense of switching video providers under the belief that they will soon lose their favorite programming, only later to find (in the vast majority of cases) that a deal was reached that avoided this outcome.'' We also find that sending repeated notices about changes that do not ultimately occur would make it more likely that many subscribers would ignore those notices, resulting in their missing information about changes that actually do occur.

We interpret ''as soon as possible'' to require cable operators to provide notice without delay after negotiations have failed such that the cable operator is reasonably certain it will no longer be carrying the programming at issue, and, if possible, before the programming goes dark. The Commission has not previously defined what it means to provide notice ''as soon as possible'' in § 76.1603(b) when changes occur due to circumstances outside of a cable operator's control. No commenter offered any arguments in support of adopting a specific timeframe to satisfy the ''as soon as possible'' standard. We conclude that determining whether a notice was delivered as soon as possible is a necessarily fact-specific determination, and thus we decline to adopt any firm timeframe during which a notice would presumptively satisfy the standard. We disagree with Verizon's suggestion that a channel's going dark should be necessary to

trigger the delivery of a notice about the service change as soon as possible, because delivery could be triggered earlier if negotiations have reached the point where a cable operator is reasonably certain it will no longer be carrying the programming at issue. We do, however, agree that if the channel has gone dark, negotiations have clearly failed so as to trigger the notice requirement.

Form of Notice. We revise our rules to clarify that cable operators have some flexibility as to the means by which they provide written notice to communicate service changes to subscribers when those changes result from failed program carriage or retransmission consent negotiations or other changes that are outside the cable operator's control. Section 632(c) of the Act states that a cable operator may use ''any reasonable written means at its sole discretion'' to deliver notice of service and rate changes to subscribers, and in 2018, the Commission adopted new rules that interpret this section of the Act to permit the electronic delivery of consumer notices by cable operators. In the *Order* adopting those rules, the Commission indicated that it would address the issue of rate and service change notices in a separate proceeding, given that these notices ''provide targeted and immediate information about a single event rather than a comprehensive catalog of information.'' We conclude that in these cases where service change are due to circumstances outside a cable operator's control, our interpretation of ''reasonable notice'' must reflect that cable operators need flexibility in giving notice to consumers. Therefore, in these specific cases, we will not require cable operators to follow the electronic notification procedures set forth in § 76.1600 of our rules, but instead we amend §§ 76.1600 and 76.1603 of rules to permit them to provide notice through other direct and reliable written means that can reach subscribers more quickly.

In this regard, we conclude that a channel slate on the vacant channel that appears after the programming has been dropped is a reasonable means to communicate the service change to viewers in the immediate aftermath of a channel going dark. We agree with those commenters who assert that channel slates are the most direct form of notice to immediately inform interested subscribers about a channel deletion. We reject the Joint LFAs' contention that channel slates are an inadequate form of notice on their own because they only become available after the programming has been dropped. Rather, because these negotiations, by their very nature, often continue until the final minutes of existing contracts, we find that a channel slate could be the most immediate direct form of notice to reach affected subscribers in the event of a last-minute channel deletion. Thus, we conclude that channel slates would satisfy the ''any reasonable written means'' standard in the specific context of a service change due to retransmission consent or program carriage renewal negotiations that fail near the end of an existing contract, as they would communicate time-sensitive notice about service changes to subscribers via the quickest means possible. Accordingly, we revise § 76.1603 to provide that cable operators shall provide notice of service changes outside of their control ''as soon as possible using any reasonable written means at the operator's sole discretion, including channel slates.'' We note that there may be situations in which a channel slate may not satisfy the ''as soon as possible'' standard despite the service change resulting from program carriage or retransmission consent negotiations that fail within the final 30 days of an existing contract. For example, if carriage negotiations between a cable operator and a programmer fail well in advance of the expiration of the contract, and the cable operator does not intend to continue negotiating, we would expect such operator to deliver notice through other means—such as email—before the channel goes dark. Similarly, to the extent possible, we expect and encourage cable operators to inform subscribers through multiple types of ''written means'' to ensure that subscribers are adequately informed about any changes to their cable service.

In addition, we agree with Verizon that newspaper notice is not a reasonable written means of notice in this context. Notably, no commenter suggested that newspaper notice in this context should be deemed reasonable. As Verizon asserts, newspaper notices ''may not reach all customers and may be delayed, inaccurate by the time they are published, or unread altogether, [and do] not provide timely notice to allow customers to make informed decisions about potential service changes.'' Given this, we conclude that such notice is insufficient to satisfy the reasonable written means standard in the context of failed program carriage or retransmission consent negotiations.

Notices of Service or Other Changes to Local Franchise Authorities. We conclude that in areas that are no longer subject to rate regulation the substantial costs to cable operators of complying with the LFA rate and service change notice requirements outweigh any potential benefits that could accrue to consumers as a result of these notices. Accordingly, rather than adopting our initial proposal, we eliminate the LFA notice requirement for cable systems subject to effective competition under the Commission's rules and adopt a requirement that rate regulated systems provide LFAs with 30 days' advance notice of any proposed increase in the price to be charged for the basic service tier.

We are not persuaded that we should preserve the current requirements that cable operators notify LFAs before implementing any rate or service change with respect to those cable operators that face effective competition. First, in the absence of rate regulation, LFAs have little practical use for this information because changes in rates or services are no longer subject to an LFA's authority. And the cable operator is in fact better positioned to address subscriber inquiries concerning rate or service changes than LFAs because LFAs receive only the same information that subscribers already receive under the notice requirements in § 76.1603(b). Second, those LFAs that do rely on these notices to address subscriber inquiries or complaints can implement their own notice requirements, consistent with the Act. Given that there is evidence that cable operators incur significant costs to comply with the current requirements and little evidence that there is widespread use of these LFA notices to benefit subscribers, we eliminate the LFA notice requirement for most cable operators.

We are persuaded to eliminate the LFA rate and service change notice requirements on cable operators subject to effective competition by the multiple commenters who contend that the costs to cable operators of complying with these LFA notice requirements outweigh any benefit to consumers from retaining the requirements. Contradicting NATOA's assertion that notifying LFAs is a de minimis additional expense, cable operators present evidence in the record that they expend significant resources to comply with the LFA notice requirements. Specifically, NCTA highlights several examples from its members' experiences, including one cable operator who budgets $85,000 annually to deliver LFA notices, in addition to the internal resources devoted to ensure compliance. Further, NCTA points out that in some instances changes that affect only a handful of subscribers nationwide require that notice be delivered to all of the hundreds, if not thousands, of LFAs within a cable operator's service area.

Altice suggests that it has added difficulties complying with the LFA notice requirements, particularly in more rural and sparsely populated jurisdictions where it has had difficulty ascertaining the relevant contact information. We conclude that any benefit that may accrue to consumers from the LFA notice requirements does not outweigh the costs identified in the record. We disagree with those commenters that maintain that we should preserve the LFA notice requirement in its current form to enable LFAs to address inquiries and complaints from subscribers. Although NATOA argues that their LFA members rely on these notices to address inquiries and complaints, Altice asserts that LFAs rarely follow up with inquiries regarding these notices and that subscribers can obtain such information directly from the cable operator. Moreover, cable operators contend that the LFA notice requirements are the relic of an era of widespread rate regulation of cable systems and are no longer necessary now that there is effective competition nearly nationwide such that LFAs do not need the rate information to field consumer calls.

Although we disagree that the current notice requirement is necessary in areas that are subject to effective competition, we are persuaded that notice of certain rate changes is critical to LFAs certified to regulate cable operator rates because they must be made aware of those rate changes before they take effect to fully exercise their rate regulation authority. Thus, we retain the requirement to provide notice of certain rate changes only with respect to those cable operators in areas where they are not subject to effective competition. Specifically, we adopt a rule, consistent with the language of section 623(b)(6), that such operators must provide LFAs with 30 days' advance notice of any increase proposed in the price to be charged for the basic service tier. This requirement will ensure that relevant LFAs receive notice of any proposed increase in the rates they have the authority to regulate. We specifically do not require cable operators in areas where they are subject to rate regulation to provide advance notice of service changes or of rate changes other than the type described above. This type of notice is not contemplated by section 623(b)(6), and we find that the information gathered from such notices is of little if any use to LFAs, even in areas subject to rate regulation.

Other Rule Changes

Notice of Significant Changes to Information in Annual Notices. We eliminate from § 76.1603(b) the requirement that cable operators provide notice of any significant change to the information required in the § 76.1602 annual notices, as proposed by NCTA. No commenter contends that we should retain this requirement. NCTA asserts that ''[t]his rule is yet another artifact of a time when cable operators faced little competition and consumers did not have ready access to such information over the internet.'' We find that much of the information encompassed by the annual notice, such as that concerning installation policies and instructions for use, may not be as relevant to current subscribers as changes in rates and services. Changes to rates and services are still required under the rules we adopt today to be provided either ''as soon as possible'' or within 30 days of the change. With respect to the other categories of information, we agree with NCTA that interested subscribers would likely first turn to the internet for such information. We therefore conclude that we should eliminate this requirement.

Readability and Redundancy. We adopt as proposed in the *NPRM* three technical changes to §§ 76.1601 and 76.1603 to clean up the rules. Commenters who addressed these proposals—representing both cable providers and LFAs—expressed unanimous support for amending these provisions to eliminate redundancies, which resulted from previous streamlining efforts that consolidated multiple, disparate notice provisions into one new subpart. First, we amend § 76.1601 to delete the requirement that cable operators provide notice of the deletion or repositioning of a broadcast channel ''to subscribers of the cable system,'' as it is redundant of the subscriber notice requirements in § 76.1603. This action will consolidate all of the subscriber notice requirements into one provision, § 76.1603(b). Second, we delete § 76.1603(d), which requires that cable operators notify subscribers about changes in rates for equipment that is provided without charge under § 76.630, because it is duplicative of language in § 76.630(a)(1)(vi). Finally, we delete § 76.1603(e), which provides that a cable operator ''may provide such notice using any reasonable written means at its sole discretion.'' This provision is duplicative of language in section 632(c) of the Act and language in § 76.1603(b).

Other Proposals. We also adopt our proposal to eliminate the language regarding the carriage of multiplexed broadcast signals in § 76.1603(c), which was supported by NCTA and unopposed by all other commenters. This requirement was added at the advent of digital broadcast television and does not reflect the standard practices of cable operators with regard to multiplexed broadcast signals.

We decline to adopt Joint LFAs' proposal that we eliminate the requirement in §§ 76.1602(a) and 76.1603(a) that an LFA provide cable operators with 90 days' written notice of its intent to enforce the customer service standards found in §§ 76.1602 and 76.1603. We agree with NCTA that these LFA notices of intent to enforce requirements ''are a necessary and appropriate mechanism for alerting cable operators of an LFA's enforcement plans.'' Further, given that Joint LFAs' appear to have misunderstood these rules, their arguments for their removal are not persuasive.

Final Regulatory Flexibility Analysis. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) relating to this Order. The FRFA is set forth below.

Paperwork Reduction Act Analysis. This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

Congressional Review Act. The Commission has determined, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, concurs that, this rule is ''non-major'' under the Congressional Review Act, 5 U.S.C. 804(2). The Commission will send a copy of this *Report & Order* to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A).

Final Regulatory Flexibility Act Analysis. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Notice of Proposed Rulemaking* in this proceeding. The Commission sought written public comment on the proposals in the *NPRM,* including comment on the IRFA. We received no comments specifically directed toward the IRFA. This present Final Regulatory

Flexibility Analysis (FRFA) conforms to the RFA.

Need for, and Objective of, the Report and Order. In today's video marketplace, retransmission consent and program carriage negotiations are often concluded within days—if not hours—of the expiration of existing agreements. And in those cases, it is frequently unclear, 30 days prior to a contract's expiration, whether a new agreement will be reached, there will be a short-term extension, or programming will be dropped. This uncertainty led to difficult questions regarding what notice cable operators should be required to provide to subscribers and when they should be required to provide it. On the one hand, subscribers must receive meaningful information regarding their programming options so they can make informed decisions about their service. On the other hand, inaccurate or premature notices about theoretical programming disruptions that never come to pass can cause consumer confusion and lead subscribers to change providers unnecessarily.

This *Report and Order* modifies our rules concerning notices that cable operators must provide to subscribers and local franchise authorities (LFAs) regarding service or rate changes. First, we clarify that cable operators must provide notice as soon as possible in the event of service changes that occur due to retransmission consent or program carriage that fail in the final 30 days of a contract, rather than 30 days in advance. We are persuaded that requiring cable operators to provide notice to subscribers that a channel may be dropped anytime a program carriage or retransmission consent renewal negotiation extends into the final 30 days of an existing contract would cause substantial consumer confusion and thus would not further the goal of facilitating informed choices. In all other circumstances, however, the subscriber notice requirements will continue to operate as they have previously. That is, rate and service changes must otherwise be provided 30 days in advance of any change, unless the change is outside the cable operators' control, in which case it must be provided as soon as possible.

Second, we amend our rule to eliminate the requirement that cable operators not subject to rate regulation provide 30 days' advance notice to LFAs for rate or service changes, and instead retain a narrower requirement that rate-regulated cable systems continue to provide 30 days' advance notice to the relevant LFA of any increase proposed in the price to be charged for the basic service tier. Finally, we eliminate the requirement that cable operators provide notice of any significant change to the information required in the annual notices that must be sent to subscribers, as well as adopt several technical edits to make the rules more readable and remove duplicative requirements.

Summary of Significant Issues Raised by Public Comments in Response to the IRFA. There were no comments filed in response to the IRFA.

Response to comments by the Chief Counsel for Advocacy of the Small Business Administration. Pursuant to the Small Business Jobs Act of 2010, which amended the RFA, the Commission is required to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA), and to provide a detailed statement of any change made to the proposed rules as a result of those comments.

The Chief Counsel did not file any comments in response to the proposed rules in this proceeding.

Description and Estimate of the Number of Small Entities to Which Rules Will Apply. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA. Below, we provide a description of such small entities, as well as an estimate of the number of such small entities, where feasible.

Small Governmental Jurisdictions. A ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2017 Census of Governments indicates that there were 90,075 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number there were 36,431 General purpose governments (county, municipal and town or township) with populations of less than 50,000 and 12,040 Special purpose governments (independent school districts and special districts) with populations of less than 50,000. The 2017 U.S. Census Bureau data for most types of governments in the local government category shows that the majority of these governments have populations of less than 50,000. Based on this data we estimate that at least 48,471 local government jurisdictions fall in the category of ''small governmental jurisdictions.''

Cable Companies and Systems (Rate Regulation Standard). The Commission has developed its own small business size standards, for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers, nationwide. Industry data indicate that, of 4,200 cable operators nationwide, all but 9 are small under this size standard. In addition, under the Commission's rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Industry data indicate that, of 4,200 systems nationwide, 3,900 have fewer than 15,000 subscribers, based on the same records. Thus, under this second size standard, the Commission believes that most cable systems are small.

Cable System Operators. The Act also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' There are approximately 45,073,297 cable subscribers in the United States today. Accordingly, an operator serving fewer than 450,733 subscribers shall be deemed a small operator if its annual revenues, when combined with the total revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on the available data, we find that all but five independent cable operators serve fewer than 450,733 subscribers. Although it seems certain that some of these cable system operators are affiliated with entities whose gross annual revenues exceed $250 million, we note that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million, and therefore we are unable to estimate more accurately the number of cable system operators that would qualify as small under the definition in the Communications Act.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities. This *Report and Order* modifies three

requirements for cable operators pertaining to the notices they must deliver to subscribers and LFAs in advance of service changes. First, the rule that requires cable operators to notify subscribers about changes to rates, programming services, or channel positions with 30 days' advance notice will be clarified to instead require that cable operators notify subscribers ''as soon as possible'' in the case of retransmission consent or program carriage negotiations that fail during the last 30 days of a contract. This will reverse the Commission's past position that negotiations are ''within the control of the cable operator,'' eliminating the need to notify customers of an impending change in programming 30 days in advance when carriage negotiations have not yet concluded. Second, the requirement that cable operators to notify LFAs of any changes to rates, programming services, or channel positions will be eliminated entirely for cable operators that are subject to effective competition. Finally, it deletes the requirement that cable operators provide notice of any significant change to the information required in the annual notices that must be sent to subscribers.

Steps Taken to Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered. The RFA requires an agency to describe any significant alternatives that it has considered in developing its approach, which may include the following four alternatives (among others): ''(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance an reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

The *Report and Order,* as stated in Section A of this FRFA, modifies two rules to reduce the burden on all cable operators, including small operators, as they will not be required to provide as many notices. Likewise, this may reduce the burdens on small local governments, which would not have to review as many filings. As a part of the Commission's Media Modernization Initiative, the intent of changing these requirements is to reduce the costs of compliance with the Commission's rules, including any related managerial, administrative, legal, and operational costs. We anticipate that small entities, as well as larger entities, will benefit from this modification.

Report to Congress. The Commission will send a copy of the Report and Order, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Report and Order and FRFA (or summaries thereof) will also be published in the **Federal Register**.

Accordingly, *it is ordered* that, pursuant to the authority contained in sections 1, 4(i), 4(j), 623, 624, and 632 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 543, 544, and 552, the Report and Order *is adopted. It is further ordered* that the Commission's rules *are hereby amended* as set forth in Appendix A, effective as of the date of publication of a summary in the **Federal Register**. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this *Report and Order,* including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration. *It is further ordered* that the Commission will send a copy of the *Report and Order* in a report to Congress and the Government Accountability Office pursuant to the Congressional Review Act (CRA). *It is further ordered* that should no petitions for reconsideration or petitions for judicial review be timely filed, MB Docket No. 19–347 *shall be terminated* and its docket closed.

List of Subjects in 47 CFR Part 76

Administrative practice and procedure, Cable Television, Communications, Reporting and recordkeeping requirements, Telecommunications.

Federal Communications Commission.

Marlene Dortch,

Secretary.

For the reasons set forth in the preamble, the Federal Communications Commission amends part 76 of title 47 of the Code of Federal Regulations as follows:

PART 76—MULTICHANNEL VIDEO AND CABLE TELEVISION SERVICE

■ 1. The Authority citation for Part 76 continues to read as follows:

Authority: 47 U.S.C. 151, 152, 153, 154, 301, 302, 302a, 303, 303a, 307, 308, 309, 312, 315, 317, 325, 338, 339, 340, 341, 503, 521, 522, 531, 532, 534, 535, 536, 537, 543, 544, 544a, 545, 548, 549, 552, 554, 556, 558, 560, 561, 571, 572, 573.

■ 2. Amend § 76.5 by adding paragraph (rr) to read as follows:

§ 76.5 Definitions.

* * * * *

(rr) Channel Slates. A written notice that appears on screen in place of a dropped video feed.

■ 3. Amend § 76.1600 by revising paragraph (a) to read as follows:

§ 76.1600 Electronic delivery of notices.

(a) Except as provided in § 76.1603 for changes that occur due to circumstances outside a cable operator's control, which also may be provided as set forth in 76.1603(b), written information provided by cable operators to subscribers or customers pursuant to §§ 76.1601, 76.1602, 76.1603, 76.1604, 76.1618, and 76.1620 of this Subpart T, as well as subscriber privacy notifications required by cable operators, satellite providers, and open video systems pursuant to sections 631, 338(i), and 653 of the Communications Act, may be delivered electronically by email to any subscriber who has not opted out of electronic delivery under paragraph (a)(3) of this section if the entity:

* * * * *

■ 4. Revise § 76.1601 to read as follows:

§ 76.1601 Deletion or repositioning of broadcast signals.

A cable operator shall provide written notice to any broadcast television station at least 30 days prior to either deleting from carriage or repositioning that station.

■ 5. Amend § 76.1603 by:

■ a. Revising paragraphs (b) and (c);

■ b. Removing paragraphs (d) and (e); and

■ c. Redesignating paragraph (f) as paragraph (d).

The revisions read as follows:

§ 76.1603 Customer service—rate and service changes.

* * * * *

(b) Cable operators shall provide written notice to subscribers of any changes in rates or services. Notice shall be provided to subscribers at least 30 days in advance of the change, unless the change results from circumstances outside of the cable operator's control (including failed retransmission consent or program carriage negotiations during the last 30 days of a contract), in which case notice shall be provided as soon as possible using any reasonable written means at the operator's sole discretion, including Channel Slates. Notice of rate changes shall include the precise

amount of the rate change and explain the reason for the change in readily understandable terms. Notice of changes involving the addition or deletion of channels shall individually identify each channel affected.

(c) A cable operator not subject to effective competition shall provide 30 days' advance notice to its local franchising authority of any increase proposed in the price to be charged for the basic service tier.

* * * * *

[FR Doc. 2020–23305 Filed 11–10–20; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 85, No. 219
Thursday, November 12, 2020

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 888, 982, 983 and 985

[Docket No. FR–6092–N–02]

RIN 2577–AD06

Housing Opportunity Through Modernization Act of 2016—Housing Choice Voucher (HCV) and Project-Based Voucher Implementation; Additional Streamlining Changes; Extension of Comment Period

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On October 8, 2020, HUD published in the **Federal Register** a notice of proposed rulemaking entitled ''Housing Opportunity through Modernization Act of 2016: Housing Choice Voucher and Project-Based Voucher Implementation; Additional Streamlining Changes'', proposing comprehensive amendments to the regulations governing the Housing Choice Voucher (HCV) and Project-Based Voucher (PBV) programs, largely in response to the enactment of the Housing Opportunity Through Modernization Act (HOTMA). The proposed rule provided for a 60-day comment period, which would have ended December 7, 2020. HUD has determined that a 30-day extension of the comment period, until January 6, 2021, is appropriate. This additional time will allow interested persons additional time to analyze the proposal and prepare their comments.

DATES: The comment period for the proposed rule published on October 8, 2020, at 85 FR 63664, is extended. Comments should be received on or before January 6, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.* To receive consideration as public comments, comments must be submitted through one of two methods, specified below. All submissions must refer to the above docket number and title.

1. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

2. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410 0500.

FOR FURTHER INFORMATION CONTACT: Email *HOTMAquestions@hud.gov* with your questions about this proposed rule.

SUPPLEMENTARY INFORMATION: On October 8, 2020, at 85 FR 63664, HUD published a notice of proposed rulemaking entitled ''Housing Opportunity through Modernization Act of 2016: Housing Choice Voucher and Project-Based Voucher Implementation; Additional Streamlining Changes'', proposing comprehensive amendments to the regulations governing the Housing Choice Voucher (HCV) and Project-Based Voucher (PBV) programs, in response to the enactment of the Housing Opportunity Through Modernization Act (HOTMA). While the proposed rule had a 60-day comment period, HUD has received feedback from multiple stakeholders that additional time is needed to adequately review this lengthy and complex rule. Therefore, HUD is extending the deadline for comments for an additional 30 days.

R. Hunter Kurtz,
Assistant Secretary for Public and Indian Housing.

[FR Doc. 2020–25119 Filed 11–10–20; 8:45 am]
BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 3282 and 3284

[Docket No. FR–6234–A–01]

RIN 2502–AJ57

Manufactured Housing Program: Minimum Payments to the States; Advanced Notice of Proposed Rulemaking and Request for Public Comment

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Advanced notice of proposed rulemaking and request for public comment.

SUMMARY: This advanced notice of proposed rulemaking (ANPR) informs of and seeks public comment on changes that HUD is considering for the minimum payments that HUD distributes to states that participate in the Manufactured Housing Program as State Administrative Agencies (SAAs). HUD is considering two changes intended to achieve more equitable payments that more appropriately reflect state responsibilities and to incentivize continued and new state partnerships: First, HUD is considering payment to each SAA for its participation as partners in each of the various program elements, including SAA roles, participation in joint monitoring, and for administering installation and dispute resolution programs. Second, HUD is considering a change in annual funding from minimum end of Fiscal Year lump sum payments to payments for each operational element at the end of each Fiscal Year, and a sunset provision for states to strategize and plan for this change. HUD is seeking public comment on questions related to these changes and will consider the comments in developing a proposed rule to further streamline and enhance the minimum payment formula. This ANPR will also

be shared with the Manufactured Housing Consensus Committee (MHCC) and the relevant MHCC subcommittee and all state partners for feedback and comments prior to moving forward in the rulemaking process. A Proposed Rule developed in consideration of this ANPR will also be shared with the MHCC prior to moving forward in the rulemaking process in accordance with statutory requirements.

DATES: Comments due January 11, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this ANPR. Comments should refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of comments by mail: Comments may be submitted by mail to the HUD Regulations Division, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410–8000; telephone: (202) 708–2625 (this is not a toll-free number), (800) 481–9895 (this is a toll-free number). Hearing- or speech-impaired individuals may access these numbers through TTY by calling the Federal Relay Service at (800) 877–8339 (this is a toll-free number).

2. Electronic submission of comments: Comments may be submitted electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of this ANPR.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

3. Public inspection of public comments: All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an appointment to review the public comments must be scheduled in advance by calling the Regulations Division at (202) 402–5731 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at (800) 877–8339 (this is a toll-free number). Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Teresa B. Payne, Administrator, Office of Manufactured Housing Programs, Department of Housing and Urban Development, 451 Seventh Street SW, Room 9164, Washington, DC 20410; telephone number 202–402–5365. (This is not a toll-free number.) Individuals with speech or hearing impairments may access this number through TTY by calling the Federal Relay Service at 800–877–8389. (This is a toll-free number.)

SUPPLEMENTARY INFORMATION:

I. Background

HUD is considering streamlining and enhancing the minimum payment formula to provide more equitable payments to State Administrative Agencies (SAAs) that more appropriately reflect the responsibility of the corresponding state and better encourage states to participate to the maximum extent possible in the Federal-State manufactured housing partnership program. First, HUD is considering payment to each SAA for its participation as partners in various program elements, including SAA roles, participation in joint monitoring, and for administering installation and dispute resolution programs. Second, HUD is considering a change in annual funding from minimum end of Fiscal Year lump sum payments to payments for each operational element at the end of each Fiscal Year, and a sunset provision for states to strategize and plan for this change.

Elsewhere in today's issue of the **Federal Register**, HUD published a final rule that would revise HUD's regulations at 24 CFR 3282.307 and 3284.10 on minimum payments to states to provide more equitable and fair payments to states. HUD continues to seek solutions to the issue of inequitable payments between states and to encourage states to participate in the Federal-state manufactured housing partnership program to the maximum extent possible. Due to the preemptive nature of this building regulatory program and the geographical distribution of home production facilities combined with interstate commerce, Federal-state partnerships are integral to achieving the purposes of the National Manufactured Home Construction and Safety Standards Act of 1974 and to protecting the residents and general public. This ANPR will also be shared with the MHCC and the relevant MHCC subcommittee and all state partners for feedback and comments prior to moving forward in the rulemaking process. A Proposed Rule developed in consideration of this ANPR will also be shared with the MHCC prior to moving forward in the rulemaking process in accordance with statutory requirements (42 U.S.C. 5403(b)(3)).

Compensating state partners has been a cornerstone of HUD's commitment to its state partners. In accordance with section 620 of the National Manufactured Housing Construction and Safety Standards Act of 1974 (the Act), 42 U.S.C. 5401–5426, HUD regulations provide for HUD to establish and collect from manufactured home manufacturers a reasonable fee to, among other things, provide funding for states that offsets the costs of administering various responsibilities states choose to execute as identified in the respective state plan. 42 U.S.C. 5419(a)(1)(B). States that participate in the federal program as SAAs are currently compensated through a formula calculation. 42 U.S.C. 5419(e)(3). Currently, some SAAs with either fully or conditionally approved State plans receive an additional end-of-Fiscal-Year lump sum payment in the amounts which are not less than the total allocated amount, based on the fee distribution system in effect on December 27, 2000. 42 U.S.C. 5419(e)(3). Under the distributions included in this ANPR, eligible states would continue to receive fee distribution amounts which are not less than the allocated amounts in effect on December 27, 2000.

The Manufactured Housing Improvement Act of 2000 amended the National Manufactured Housing Construction and Safety Standards Act of 1974. Since then, HUD's payments to SAAs have consisted of evaluating each fully-approved SAA's total annual payment and ensuring that such total payment does not fall below the total HUD payments to the fully-approved SAA for Calendar Year 2000. 42 U.S.C. 5419(e)(3).

Elsewhere in today's issue of the **Federal Register** is a final rule by HUD, which would move the baseline payment to the amounts paid to the states in Fiscal Year 2014 (FY14) to ensure payments do not go below the

Calendar Year 2000 (CY00) payments, and now also includes states that have conditionally approved state plans to address previous inequities. This final rule followed from a proposed rule published December 16, 2016 (81 FR 91083) and the public comments received in response.

However, HUD believes that even with these changes there may be even more equitable approaches to ensure SAA compensation in compliance with statutory provisions. While the current formula establishes a payment that allows each SAA to obtain a minimum level of funding, that minimum funding level does not align workload with financial resource needs. For example, some states are still being provided funding under the statutory minimums, even though those states no longer have any operating manufacturing plants. Further, even with minimum payments now being based on production and shipment numbers that existed in FY14, minimum payments do not reflect workload due to changing dynamics of production and shipments. The updated regulation related to supplemental payment at the end of the fiscal year paid to eligible states is based on FY14 production outputs, and no other factors albeit update to the calculation based on CY00 production outputs. Therefore, HUD is considering an allocation of financial resources more closely based on the workload needs arising from the various levels of participation that any given state may experience or elect.

HUD is soliciting comment on potential action related to its partial funding of state programs in accordance with 42 U.S.C. 5419(e)(3), which directs that states do not receive less than the formula distribution amounts that were in place for production states ($2.50 per transportable section) and location states ($9.00 per transportable section) in CY00. Elsewhere in today's issue of the **Federal Register**, HUD published a final rule that would substantially increase the payment to production states from $2.50 per transportable section to $14.00 per transportable section. HUD is also now considering payment to each SAA for its participation as partners in various program elements, including SAA roles, participation in joint monitoring, and for administering installation and/or dispute resolution programs.

HUD is considering this change to better reinforce HUD's commitments to HUD-state partnerships while incentivizing states to maintain current partnerships and consider additional partnerships and participation in all aspects of the program. It is important to understand that these payments are distinct from any HUD funding to SAAs provided through formula distribution calculated from production and shipments. It is also important to understand that based on statute, only SAAs with state plans are eligible for funding, therefore, those states that may choose to operate individual optional programs such as Dispute Resolution and or Installation, would not get payments unless the state becomes an SAA.

This change from minimum end of Fiscal Year lump sum payments to payments for each operational element at the end of each Fiscal Year would occur over an established time period, such as 5 or 10 years. HUD is considering a sunset of the supplemental payment(s) over a to-be-determined time frame to better incentivize states to participate to the maximum extent possible in the manufactured housing program that was initially created as a Federal-state partnership.

HUD's current partnership elements include states that have chosen to partner as:

- State Administrative Agencies with manufacturers located in the state (SAAM)
- State Administrative Agencies without manufacturers located in the state (SAAL)
- State Administrative Agencies that partner with HUD to participate in Joint Monitoring (JM)
- States that partner with HUD to administer Dispute Resolution (DR)
- States that partner with HUD to administer Installation Oversight (IN)

HUD is considering the provision of lump sum annual payments for each partnership element to help offset the costs of standing up and operating each aspect in addition to the $9 and $14.00 that will be paid for location and production through a final rule being published elsewhere in today's issue of the **Federal Register**. HUD is contemplating setting the annual payments for each element within the following ranges:

- SAAM: $5,000–$8,000
- SAAL: $5,000–$8,000
- JM: $5,000–$8,000
- DR: $3,000–$5,000
- IN: $5,000–$7,000

In addition, because the work related to the oversight of installation of new manufactured homes is generally dependent on the number of home installations in each state, HUD is considering augmenting the per-unit formula up to $2.00 per transportable section to account for installation oversight work for each transportable section with a manufacturer-reported first destination in a state that administers a HUD-approved installation program.

Using FY21 as an example, production and shipments are estimated to be 5% to 8% above production and shipments for FY20. Therefore, in this following examples, FY21 total production and shipments are estimated to be around 150,000 to 158,000 transportable sections.

Hypothetical State A

State A is an SAA with production within the state and participates in the program as an SAAM and SAAL but does not participate as a state partner for JM, IN, or DR state. Production for the plants within this state are estimated to be about 4,500 transportable sections in FY21 and shipments within or to this state are estimated to be 2,500 transportable sections in FY21. Therefore, according to HUD's formula payments, payment to State A in FY21 would be comprised of:

- Production: 4,500 transportable sections × $14 per section = $63,000, and
- Shipments: 2,500 transportable sections × $9 per section = $22,500

In addition to the formula payments above, State A would receive an FY21 year end payment for participation as an SAAM and SAAL, comprised of the following:

- SAAM: $5,000–$8,000, and
- SAAL: $5,000–$8,000

Since FY21 is within the to be determined sunset period, State A would also receive a year end supplemental payment that would initially be calculated based on the FY14 total payment minus the sum of formula and participation payments: FY14 total payment—($63,000 + $22,500 + $10,000 to $16,000 [1]).

The end of year supplemental would continue to be paid through the sunset period, though in potentially reduced amounts (see Question 3).

After the sunset period, the year-end supplemental payment would be discontinued entirely and payments to the state would reflect potential increases in production and shipments as well as any additional program participation payment for program elements the state may choose and is approved to conduct within the HUD-state partnership (including Joint

[1] Depending on the established participation payment for each of the SAAM and SAAL elements, the participation payment for State A is expected to be $5,000 to $8,000 or SAAM plus $5,000 to $8,000 for SAAL, totaling a payment range of $10,000 to $16,000.

Monitoring at $5,000 to $8,000, Dispute Resolution at $3,000 to $5,000, and Installation at $5,000 to $7,000). In addition, if State A were to partner as an Installation state, aside from the Installation program element payment of $5,000 to $7,000, the state would receive up to $5,000 for per-section installation fees based on the number of transportable sections shipped within and to the state (2,500 transportable sections × up to $2 per section).

Hypothetical State B

State B is an SAA state that does not have any production within the state but otherwise fully participates in the program as an SAAL, JM, DR, and IN state. Shipments to this state are estimated to be 3,500 transportable sections in FY21. Therefore, according to HUD's formula payments, payment to State B would be comprised of:

- Production: 0 transportable sections × $14 = $0
- Shipments: 3,500 transportable sections × $9 = $31,500

In addition to the formula payments above, State B would receive an FY21 year end payment for participation, comprised of the following:

- SAAL: $5,000–$8,000
- JM: $5,000–$8,000
- DR: $3,000–$5,000
- IN: $5,000–$7,000
- Per-section Installation Fee: Up to $7,000 (3,500 transportable sections × up to $2 per section)

Since FY21 is within the to be determined sunset period, State B would continue to receive a year end supplemental payment that would initially be calculated based on the FY14 total payment minus the sum of formula and participation payments: FY14 total payment—($31,500 + $18,000 to $28,000 [2] + up to $7,000 [3]).

The end of year supplemental would continue to be paid through the sunset period, though in potentially reduced amounts (see Question 3).

After the sunset period, the year-end supplemental payment would be discontinued entirely and payments to the state would reflect potential increases in shipments and installations as well as production payments if a plant were to begin production within the state.

[2] Depending on the established participation payment for each of the SAAL, JM, DR, and IN elements, the participation payment for State B would be expected to be $5,000 to $8,000 for SAAL plus $5,000 to $8,000 for Joint Monitoring plus, $3,000 to $5,000 for Dispute Resolution plus $5,000 to $7,000 for Installation, totaling a payment range of $18,000 to $28,000.

[3] The per section Installation Fee would total up to $7,000 (3,500 transportable sections × up to $2 per section).

II. Request for Public Comment

HUD seeks public feedback on any elements of this ANPR. In particular, HUD seeks information and recommendations on the following issues:

1. Should HUD change from a minimum annual payment structure to a payment structure that is based on an eligible state's participation in the federal program? Are the activities proposed by HUD for incorporation into the payment structure appropriate? Are there activities that should be added to or removed from that list? Provide the reasoning for your response.

2. Should HUD provide a uniform annual funding amount associated with each partnership element? Is the range of funding proposed by HUD for each partnership element appropriate? What amounts within the ranges proposed by HUD are appropriate:

a. For incenting existing SAA states to continue participation in each partnership element?

b. For incenting existing SAA states to implement additional partnership elements?

3. Can a state determine its budgeting needs and establish and implement additional partnership elements to retain maximum compensation within a 5 or 10-year sunset period? Would another time frame be more appropriate? By what means, if any, should the remaining supplemental payment be phased out during the sunset period? For example, should the supplemental payment (calculated after subtracting payments for production and state participation) be reduced by a particular percentage each year (20% in year 2, 40% in year 3, and so on)? Provide the reasoning for your responses.

4. Will states that are not currently SAAs be incentivized to become SAAs? If so, will those states also be incentivized to become active participants to the maximum extent possible in each aspect of the manufactured housing program? Provide the reasoning for your response.

5. Should HUD consider payments to states that are not SAAs? If so, what instrument needs to be implemented to enable such payments? Provide the reasoning for your response.

6. Should HUD augment the per-unit formula to account for each transportable section with a manufacturer-reported first destination in a state that administers a HUD-approved installation program? What are states' costs of overseeing installation, and if HUD were to help offset those costs, what amount of payment per transportable unit would help to meaningfully offset those costs?

Dana T. Wade,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2020–24382 Filed 11–10–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2020–0094; FF09E21000 FXES11110900000 212]

RIN 1018–BE89

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for Sickle Darter

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding on a petition to list the sickle darter (*Percina williamsi*), a fish species from the upper Tennessee River drainage in North Carolina, Tennessee, and Virginia, as a threatened species under the Endangered Species Act of 1973, as amended (Act). After a review of the best available scientific and commercial information, we find that listing the species is warranted. Accordingly, we propose to list the sickle darter as a threatened species with a rule issued under section 4(d) of the Act (''4(d) rule''). If we finalize this rule as proposed, it would add this species to the List of Endangered and Threatened Wildlife and extend the Act's protections to the species.

DATES: We will accept comments received or postmarked on or before January 11, 2021. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by December 28, 2020.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov*. In the Search box, enter FWS–R4–ES–2020–0094, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the

Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R4–ES–2020–0094, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

FOR FURTHER INFORMATION CONTACT: Lee Andrews, Field Supervisor, U.S. Fish and Wildlife Service, Kentucky Ecological Services Field Office, 330 West Broadway, Suite 265, Frankfort, KY 40601; telephone 502–695–0468. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if we determine that a species may be an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within 1 year. To the maximum extent prudent and determinable, we must designate critical habitat for any species that we determine to be an endangered or threatened species under the Act. Listing a species as an endangered or threatened species and designation of critical habitat can only be completed by issuing a rule.

What this document does. This rule proposes the listing of the sickle darter as a threatened species with a rule under section 4(d) of the Act. This rule summarizes our analysis regarding the status of and threats to the sickle darter.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that threats to the sickle darter include habitat degradation or loss stemming from hydrologic alteration by impoundments, including dams and other barriers; resource extraction, including mining and timber operations; and diminished water quality from point and non-point source chemical contamination and siltation (Factor A). These threats contribute to the negative effects associated with the species' reduced range and potential effects of climate change (Factor E).

Peer review. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought the expert opinions of five appropriate specialists regarding the species status assessment report. We received responses from four specialists, which informed this proposed rule. The purpose of peer review is to ensure that our listing determinations and 4(d) rules are based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise in the biology, habitat, and threats to the species.

Because we will consider all comments and information we receive during the comment period, our final determination may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may conclude that the species is endangered instead of threatened, or we may conclude that the species does not warrant listing as either an endangered species or a threatened species. We invite comments on any of these possibilities, as well.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

(1) The species' biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this species, including the locations of any additional populations of this species.

(5) Information on regulations that are necessary and advisable to provide for the conservation of the sickle darter and that the Service can consider in developing a 4(d) rule for the species. In particular, we seek information concerning:

(a) The extent to which we should include any of the prohibitions in section 9 of the Act (16 U.S.C. 1531 *et seq.*) in the 4(d) rule or whether any other forms of take should be excepted from the prohibitions in the 4(d) rule;

(b) Whether we should add a specific provision to except from prohibition incidental take resulting from silviculture practices and forest management activities that implement highest-standard best management practices and comply with forest practice guidelines related to water quality standards; and

(c) Whether there are additional provisions the Service may wish to consider for the 4(d) rule that are necessary and advisable for the conservation of the sickle darter.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule

by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov*.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov*.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. For the immediate future, we will provide these public hearings using webinars that will be announced on the Service's website, in addition to the **Federal Register**. The use of these virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

On April 20, 2010, we received a petition from the Center for Biological Diversity (CBD), Alabama Rivers Alliance, Clinch Coalition, Dogwood Alliance, Gulf Restoration Network, Tennessee Forests Council, and West Virginia Highlands Conservancy (referred to below as the CBD petition) to list 404 aquatic, riparian, and wetland species, including the sickle darter, as endangered or threatened species under the Act. In response to the petition, we published a partial 90-day finding on September 27, 2011 (76 FR 59836), in which we announced our finding that the petition contained substantial information indicating that listing may be warranted for numerous species, including the sickle darter.

On February 18, 2015, the CBD filed a complaint alleging the Service failed to complete a 12-month finding for the sickle darter in accordance with statutory deadlines. On September 9, 2015, the Service and the CBD filed a stipulated settlement in the District of Columbia, agreeing that the Service will submit to the **Federal Register** a 12-month finding for the sickle darter no later than September 30, 2020 (*Center for Biological Diversity* v. *Jewell,* case 1:15–CV–00229–EGS (D.D.C.)). This document constitutes our concurrent 12-month warranted petition finding and proposed listing rule.

Supporting Documents

An SSA team prepared an SSA report for the sickle darter. The SSA team was composed of Service biologists, in consultation with other species experts from the Tennessee Valley Authority; State agencies in North Carolina, Tennessee, and Virginia; university researchers; and private fish conservation organizations. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species. As discussed above under *Peer review,* we solicited appropriate peer review for the SSA report. The Service sent the SSA report to five independent peer reviewers and received four responses. In addition, we sent the draft SSA report for review to Federal partners, State partners, and scientists with expertise in aquatic ecology and fish biology, taxonomy, and conservation.

I. Proposed Listing Determination

Background

The sickle darter is a small fish native to the upper Tennessee River drainage in North Carolina, Tennessee, and Virginia. The species currently has a disjunct distribution, with populations in the Emory River, Little River, Sequatchie River, and Emory River systems in Tennessee, and the upper Clinch River, North Fork Holston River, and Middle Fork Holston River systems in Virginia. Populations within the French Broad River system in North Carolina and Tennessee, and the South Fork Holston River, Powell River, and Watauga River systems in Tennessee are extirpated. A thorough review of the taxonomy, life history, and ecology of the sickle darter is presented in the SSA report (version 1.0; Service 2020a, pp. 9–13).

The sickle darter has a long, slender body reaching up to 120 millimeters (mm) (4.7 inches (in)) in length and an elongated, pointed snout. The body color is brown to olive above and white to pale yellow below with a thin black stripe along the top of the body. Spawning occurs in late winter (February–March), and the species has a maximum lifespan of 3 to 4 years.

Sickle darters typically occupy flowing pools over rocky, sandy, or silty substrates in clear creeks or small rivers. Occupied streams tend to have good water quality, with low turbidity and negligible siltation (Etnier and Starnes 1993, p. 576; Alford 2019, p. 9). In these habitats, the species is most often associated with clean sand-detritus or gravel-cobble-boulder substrates, stands of American water willow (*Justicia americana*), or woody debris piles at water depths ranging from 0.4–1.0 meter (m) (1.3–3.3 feet (ft)) (Etnier and Starnes 1993, p. 576; Page and Near 2007, p. 609; Alford 2019, p. 8). Streams supporting sickle darters range from 9–33 m (29–108 ft) wide and streamside tree canopy cover in these streams ranges from open to nearly closed (Alford 2019, p. 8). The species spends most of its time in the water column, often hovering a few inches above the stream or river bottom (Etnier and Starnes 1993, p. 576).

In winter, sickle darters have been observed in deep pools (depths of up to 3 m (10 ft)) or in slow-flowing, shallow pools in close proximity to cover (Etnier and Starnes 1993, p. 576; Service 2020b, p. 1). The species migrates from the deepest areas of pools to shallow, gravel shoals (riffles) in late winter or early spring (February–March) to spawn (Etnier and Starnes 1993, p. 576). Spawning begins when stream water temperatures reach 10 to 16 Celsius (°C) (50 to 60 Fahrenheit (°F)) (Petty *et al.* 2017, p. 3). Sexual maturity of males occurs at the end of the first year of life, while sexual maturity of females occurs at the end of their second year of life (Page 1978, p. 663; Petty *et al.* 2017, p. 3). Females produce up to 355 eggs per clutch, which hatch in 21 days at an average stream temperature of 10 °C (50 °F) (Etnier and Starnes 1993, p. 576). The incubation period is likely shorter (about 2 weeks) when stream temperatures are higher (Service 2020b, p. 1). The larvae move up and down in the water column and presumably feed on zooplankton and other small macroinvertebrates after depleting yolk sac nutrients (Etnier and Starnes 1993, p. 576; Petty *et al.* 2017, p. 3). After about 30 days, the larvae move to the stream bottom (Petty *et al.* 2017, p. 3) where they mature. Except for their late winter movements from pools to riffles for spawning, no information is available on the movement behavior of the sickle darter. However, studies of two closely related species in the genus

Percina (longhead darter and frecklebelly darter) indicate that the sickle darter likely exhibits seasonal upstream and downstream movements (Eisenhour *et al.* 2011, p. 15; Eisenhour and Washburn 2016, pp. 19–24).

Sickle darters feed primarily on larval mayflies and midges; minor prey items include riffle beetles, caddisflies, dragonflies, and several other groups of aquatic macroinvertebrates (Page and Near 2007, pp. 609–610; Alford 2019, p. 10). Crayfishes have been reported as a common food item for the closely related longhead darter (Page 1978, p. 663), but have not been observed in the sickle darter's diet (Alford 2019, p. 10).

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an ''endangered species'' or a ''threatened species.'' The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an ''endangered species'' or a ''threatened species'' because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Services can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent a decision by the Service on whether the species should be proposed for listing as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS–R4–ES–2020–0094 on *http://www.regulations.gov.*

To assess sickle darter viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the species' ability to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years), redundancy supports the species' ability to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the species' ability to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the individual species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all stages, we used the best available information to characterize viability as

the ability of a species to sustain populations in the wild over time.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability.

For sickle darter populations to be resilient, the needs of individuals (slow-flowing pools, substrate, food availability, water quality, and aquatic vegetation or large woody debris) must be met at a larger scale. Stream reaches with suitable habitat must be large enough to support an appropriate number of individuals to avoid negative effects associated with small population size, such as inbreeding depression and the Allee effect (whereby low population density reduces the probability of encountering mates for spawning). Connectivity of stream reaches allows for immigration and emigration between populations and increases the likelihood of recolonization should a population be lost. At the species level, the sickle darter needs a sufficient number and distribution of healthy populations to withstand environmental stochasticity (resiliency) and catastrophes (redundancy) and adapt to biological and physical changes in its environment (representation). To evaluate the current and future viability of the sickle darter, we assessed a range of conditions to allow us to consider the species' resiliency, representation, and redundancy.

We delineated analytical units (populations) using the tributary systems the sickle darter historically occupied. Each population represents demographically linked interbreeding individuals; however, these populations are currently separated by long distances or isolated by impoundments. We identified 10 historical populations across the range of the sickle darter: Emory River, Clinch River, Powell River, Little River, French Broad River, North Fork Holston River, Middle Fork Holston River, South Fork Holston River, Watauga River, and Sequatchie River.

To assess resiliency, we evaluated six components that broadly relate to the species' physical environment or its population demography. Each population's physical environment was assessed by averaging three components determined to have the most influence on the species: Physical habitat quality, connectivity, and water quality. The three components describing population demography were reproduction, occurrence extent (total length of occupied streams compared to historical range), and occupied stream length. Parameters for each component's condition category were established by evaluating the range of existing data and separating those data into categories based on our understanding of the species' demographics and habitat. Using the demographic and habitat parameters, we then categorized the overall condition of each population. We weighted each of the six components equally and determined the average score to describe each population's current condition (see Table 1, below).

Due to a limited amount of species-specific genetic information for the sickle darter, we based our evaluation of the species' representation on the extent and variability of environmental diversity (habitat diversity) across the species' geographical range. Additionally, we assessed sickle darter redundancy (ability of species to withstand catastrophic events) by evaluating the number and distribution of resilient populations throughout the species' range. Highly resilient populations, coupled with a relatively broad distribution, have a positive relationship to species-level redundancy.

TABLE 1—COMPONENT CONDITIONS USED TO ASSESS RESILIENCY FOR SICKLE DARTER POPULATIONS

Component	Condition			
	High	Moderate	Low	0
Physical Habitat	Slow-flowing pools abundant (ample cover in pools); silt deposition low; no extensive or significant habitat alteration such as recent channelization or riparian clearing; > 75% of available habitat suitable for the species.	Slow-flowing pools present but not abundant (some pools with cover); silt deposition moderate; habitat alteration at moderate level such that channelization or other habitat disturbance more widespread; 25–75% of available habitat suitable for the species.	Slow-flowing pools scarce (few pools with cover); silt deposition extensive; habitat severely altered and recognized as impacting the species; < 25% of habitats suitable for the species.	Habitat unsuitable.
Connectivity	High immigration potential between populations (no dams or other barriers separating populations).	Moderate immigration potential between populations (populations separated by 1 low-head dam, and other partial barriers, such as narrow culverts, may be present).	Low immigration potential between populations (populations separated by ≥ 2 low-head dams or other barriers).	No connectivity (populations isolated; no immigration potential due to the presence of large reservoirs).
Water Quality	Minimal or no known water quality issues (i.e., no 303(d) streams* impacting the species, area sparsely populated, few roads).	Water quality issues recognized that may impact species (i.e., some 303(d) streams*, unpaved roads more common, moderate levels of developed land use).	Water quality issues prevalent within system, likely impacting populations (i.e., numerous 303(d) streams*).	Water quality unsuitable.
Reproduction	Clear evidence of reproduction, with multiple age classes present.	Clear evidence of reproduction, juveniles present, but multiple age classes not detected.	No direct evidence of reproduction (only adults present).	Extirpated.
Occurrence Extent	<10% decline from historical range	10–50% decline from historical range.	>50% decline from historical range	Extirpated.
Occupied Stream Length (Continuity).	≥22.5 km (≥ 14 mi)	11.3–22.5 km (7–14 mi)	<11.3 km (< 7 mi)	Extirpated.

* A 303(d) stream is a stream listed under section 303(d) of the Clean Water Act of 1972 (33 U.S.C. 1251 *et seq.*) as a water body impaired by pollutants.

Current Condition of Sickle Darter

Currently, the sickle darter is known from six tributary systems in the upper Tennessee River drainage: Emory River, Little River, Clinch River, North Fork Holston River, Middle Fork Holston River, and Sequatchie River. Historical populations in the Powell River, French Broad River, South Fork Holston River,

and Watauga River systems are extirpated, including the species' only population within the Blue Ridge ecoregion. Impoundments and water pollution in the upper Tennessee River drainage were major factors in the decline of the sickle darter and several other fishes during the early to mid-20th century (Etnier and Starnes 1993, pp. 15, 576). Current factors affecting the condition of sickle darter populations include habitat and water quality degradation, low connectivity, and small population size (*e.g.,* Clinch River). The Emory River and Little River populations exhibit moderate resiliency, as evidenced by the species' persistence within these systems for over 45 years, recent and repeated evidence of reproduction and recruitment, a relatively long occupied reach in each system (more than 22.5 kilometers (km) (14 miles (mi))), and the physical habitat condition and water quality in both systems. The remaining four populations exhibit low resiliency. They are represented by fewer documented occurrences, no evidence of recruitment, shorter occupied reaches, and occur in areas with limited habitat and water quality.

The species' adaptive potential (representation) is low because of its reduced range (and presumably associated reduction in genetic diversity), and the loss of connectivity caused by dam construction. The sickle darter occupies only two of three historical ecoregions (Ridge and Valley and Southwestern Appalachians), likely reducing its ability to adapt to changing environmental conditions over time.

We assessed the number and distribution of resilient populations across the sickle darter's range as a measure of its redundancy. Construction of dams across the upper Tennessee River drainage has eliminated connectivity between extant populations. However, within the currently occupied streams, large barriers are absent, although some small barriers that hamper movement are present (*e.g.,* defunct low-head mill dams, low-water bridges, narrow or partially blocked culverts). As such, there is connectivity within each occupied stream and opportunity for movement of individuals, decreasing the effect of localized stochastic events. Overall, the sickle darter exhibits a low degree of redundancy based on the number of resilient populations and the amount of isolation observed across the species' range, increasing the species' vulnerability to catastrophic events.

Risk Factors for Sickle Darter

Habitat loss and degradation (Factor A) resulting from impoundments, siltation, and water quality degradation, pose the largest risk to the current and future viability of the sickle darter and are the primary contributors to the species' reduced range, population fragmentation, and population loss. Climate change (Factor E) is a potential stressor that may impact the sickle darter in the future. We find the species does not face significant threats from overutilization (Factor B), disease or predation (Factor C), or invasive species (Factor E). A brief summary of relevant stressors is presented below; for a full description, refer to chapter 3 of the SSA report (Service 2020a, entire).

Siltation

Siltation is characterized by excess sediments suspended or deposited in a stream. Excessive levels of sediment accumulate and cover the stream bottom, filling the interstitial spaces with finer substrates and homogenizing and decreasing the available habitat for fishes. In severe cases, sediment can bury large substrate particles such as cobble and boulders. Siltation can affect fishes through abrasion of gill tissues, suffocation of eggs or larvae, reductions in disease tolerance, degradation of spawning habitats, modification of migration patterns, and reductions in food availability (Berkman and Rabeni 1987, pp. 285–294; Waters 1995, pp. 5–7; Wood and Armitage 1997, pp. 211–212; Meyer and Sutherland 2005, pp. 2–3). The sickle darter is considered to be intolerant of siltation (Etnier and Starnes 1993, p. 576). Pool habitat, which is the area in streams most often occupied by sickle darters, is affected by sediment deposition earlier and more readily than habitats with faster moving water (Eisenhour et al. 2009, p. 11). However, the sickle darter is occasionally observed in areas with at least low to moderate levels of siltation on some substrates, as in the Emory River (Service 2020b, p. 3).

Siltation continues to be one of the primary stressors of streams in the upper Tennessee River drainage (TDEC 2010, pp. 43–45; TDEC 2014, pp. 48–50; TDEC 2017, pp. 51–128; VDEQ 2018, pp. 89–91). Sediments can originate from a variety of sources, but State agencies continue to cite land use practices associated with agriculture, land development, and resource extraction (*e.g.,* coal mining) as primary sediment sources within the current and historical range of the sickle darter (TDEC 2010, pp. 56–65; TDEC 2014, pp. 62–69; VDEQ 2018 (Appendix 5), pp. 2313–2531). Unrestricted livestock access occurs on many streams in the range of the sickle darter and has the potential to cause siltation and other habitat disturbance (Fraley and Ahlstedt 2000, pp. 193–194). Grazing may reduce water infiltration rates and increase stormwater runoff; trampling and vegetation removal increases the probability of erosion and siltation (Brim Box and Mossa 1999, p. 103). Other sources of siltation in the species' range include croplands, stream channelization, and removal of riparian (streamside) vegetation, which have the potential to contribute large sediment loads during storm events, thereby causing increased siltation and potentially introducing agricultural pollutants such as herbicides and pesticides carried on or with sediment particles that wash into streams.

Surface coal mining, oil and gas drilling, and logging may also contribute to siltation of stream habitats in the upper Tennessee River drainage, especially the upper Clinch and Powell River systems (TDEC 2017, pp. 94–97; Zipper et al. 2016, pp. 609–610; VDEQ 2018, pp. 2313–2531). Land clearing, road construction, and excavation associated with these land use practices produce new road networks and large areas of bare soil that can contribute large amounts of sediment if best management practices (BMPs) are not used. Siltation from surface coal mining activities, such as the placement of valley fills, forest clearing, and road construction, has affected the sickle darter's historical range in the mainstem Clinch and Powell Rivers. Over the last decade, forestry BMP implementation rates, to control erosion, runoff, and siltation, have increased within the upper Tennessee River drainage (Clatterbuck et al. 2017, pp. 8–12; VDOF 2014, pp. 1–5); however, siltation continues to impact aquatic habitats in those areas where BMP use is lacking.

Water Quality Degradation (Pollution)

Information is lacking on the sickle darter's tolerance to specific pollutants, but overall the species is likely to have low tolerance experienced by other species in its genus. A review of species tolerances to pollution classified five species in the sickle darter genus *Percina* as intolerant, moderately intolerant, or having intermediate tolerance (Grabarkiewicz and Davis 2008, p. 64). None of these five species were classified as moderately tolerant or tolerant of pollution. A variety of pollutants that may impact the sickle darter continue to degrade stream water quality within the upper Tennessee River drainage (Locke et al. 2006, pp.

197, 202–203; TDEC 2010, pp. 42–48; TDEC 2014, pp. 47–53; Zipper et al. 2016, p. 604; TDEC 2017, pp. 51–106; VDEQ 2018 (Appendix 5), pp. 2313–2531). Major pollutants within the upper Tennessee River drainage include pathogens, domestic sewage, animal waste, nutrients, metals, and toxic organic compounds.

Pathogens (fecal indicator bacteria) are a leading cause of stream pollution across the sickle darter's range (Hampson et al. 2000, p. 7; TDEC 2014a, pp. 47–53, TDEC 2017, pp. 51–106; VDEQ 2018 (Appendix 5), pp. 2313–2531). The effect of high bacterial levels on the sickle darter is unknown, but high bacterial concentrations are one indicator of degraded stream conditions, including low dissolved oxygen that negatively affects fish or that may indicate the presence of other pollutants of concern that could harm the species. In the upper Tennessee River drainage, livestock waste is the primary source of bacterial contamination in rural areas, while deteriorating and leaky sewage systems, faulty sewage treatment plants, urban runoff, and combined sewer overflow (CSO) systems are the primary sources of bacterial contamination in urban streams (Hampson et al. 2000, p. 7). Elevated nutrient concentrations of phosphorus, nitrite/nitrate, and ammonia are another leading cause of stream pollution in the upper Tennessee River drainage (Hampson et al. 2000, p. 8; Price et al. 2011, pp. III–1, IV–1; TDEC 2014, p. 50; TDEC 2017, pp. 51–106; VDEQ 2018, pp. 89–91). Primary sources include wastewater treatment facilities, urban and industrial stormwater systems, and agricultural runoff (*i.e.,* livestock waste and synthetic fertilizers) (Hampson et al. 2000, p. 9; TDEC 2014, p. 50).

Other stream pollutants in the upper Tennessee River drainage include organic compounds (*e.g.,* polychlorinated biphenyls (PCBs), dioxins), metals (*e.g.,* mercury, iron, manganese), and pesticides (Hampson et al. 2000, pp. 14–19; Soucek et al. 2000, entire; Soucek et al. 2003, entire; Locke et al. 2006, pp. 200–203; Price et al. 2011, p. VI–1; TDEC 2014, pp. 51–53). Industrial development and coal mining activities prior to the passage of the Clean Water Act of 1972 (CWA; 33 U.S.C. 1251 *et seq.*) and the Surface Mining Control and Reclamation Act of 1977 (SMCRA; 30 U.S.C. 1201 *et seq.*) have left a legacy of contaminated sediment and polluted waters that continue to affect streams in portions of the upper Tennessee River drainage (Hampson et al. 2000, p. 19). Coal mining activity has decreased in the Clinch and Powell River systems in recent years; however, current and previous mining activities continue to impact portions of these stream systems in Tennessee and Virginia (TDEC 2014, p. 51; Ahlstedt et al. 2016, pp. 13–14; Zipper et al. 2016, pp. 604–612; TDEC 2017, pp. 94–97). Insecticides, herbicides, and fungicides are widely used in the upper Tennessee River drainage to control insects, fungi, weeds, and other undesirable organisms (Hampson et al. 2000, pp. 14–18). The compounds vary in their toxicity, persistence in the environment, and transport characteristics, but often become widely distributed in the environment and can pose hazards to non-target organisms such as the sickle darter.

Impoundments and Their Effects—Habitat Fragmentation and Loss

Impoundments are a threat to the sickle darter and a major factor influencing the species' current distribution within the upper Tennessee River drainage (Etnier and Starnes 1993, p. 576; Jenkins and Burkhead 1993, pp. 101–106; Service 2020a, p. 3). From 1912 to 1963, Tennessee Valley Authority constructed 12 dams, impounding waters in each of the sickle darter's historical tributary systems in Tennessee and Virginia (Miller and Reidinger 1998, pp. 35–37). Two dams were constructed on the Tennessee River mainstem, while the remaining 10 dams were built on tributaries (Clinch River, French Broad River, Holston River, South Fork Holston River, and Watauga River), creating 10 impoundments or reservoirs. Physical, chemical, and biological changes to these systems have been dramatic. Alterations to flow and temperature in the impounded reaches behind the dams and the tailwaters that extend several miles below the dams render these reaches uninhabitable for stream fishes such as the sickle darter. Additionally these dams have diminished and, in some cases, eliminated connectivity of sickle darter populations.

Population Fragmentation and Isolation

As a result of the loss of populations throughout the historical range, the sickle darter's remaining range is limited. The remaining populations are localized and geographically isolated from one another due to impoundments and other habitat degradation, leaving them vulnerable to localized extinctions from toxic chemical spills, habitat modification, progressive degradation from runoff (non-point source pollutants), natural catastrophic changes to their habitat (*e.g.,* flood scour, drought), other stochastic disturbances, and decreased fitness from reduced genetic diversity.

Species that have incurred reductions in range and population size are more likely to suffer loss of genetic diversity due to genetic drift, potentially increasing their susceptibility to inbreeding depression, decreasing their ability to adapt to environmental changes, and reducing the fitness of individuals (Soulé 1980, pp. 157–158; Hunter 2002, pp. 97–101; Allendorf and Luikart 2007, pp. 117–146). Some small sickle darter populations (*e.g.,* Middle Fork Holston River) may be below the effective population size required to maintain long-term genetic and population viability (Soulé 1980, pp. 162–164; Hunter 2002, pp. 105–107). The long-term viability of a species depends on the conservation of numerous local populations throughout its geographic range (Harris 1984, pp. 93–104). These separate populations are essential for the species to recover and adapt to environmental changes (Harris 1984, pp. 93–104; Noss and Cooperrider 1994, pp. 264–297). The level of isolation of sickle darter populations makes recolonization following localized extirpations virtually impossible without human intervention.

Climate Change

Changing climate conditions can influence sickle darter viability through changes in water temperature and precipitation patterns that result in increased flooding, prolonged droughts, or reduced stream flows (McLaughlin et al. 2002, pp. 6060–6074; Cook et al. 2004, pp. 1015–1018; Thomas et al. 2004, pp. 145–148; p. 2065; IPCC 2014, pp. 58–83). The species' early spawning period (February–March) makes it vulnerable to warming temperatures and higher flows—conditions that could interrupt or prevent successful spawning in a given year (Service 2020b, p. 3). Stream temperatures in the Southeast have increased roughly 0.2 to 0.4 °C (0.4 to 0.7 °F) per decade over the past 30 years (Kaushal et al. 2010, p. 463), although the extent to which the increase in temperatures has affected the sickle darter in unknown. Predicted impacts of climate change on fishes include disruptions to their physiology, such as temperature tolerance, dissolved oxygen needs, and metabolic rates; life history, such as timing of reproduction and growth rate; and distribution, including range shifts and migration of new predators (Jackson and Mandrak 2002, pp. 89–98; Heino et al. 2009, pp. 41–51; Strayer and Dudgeon 2010, pp. 350–351; Comte et al. 2013, pp. 627–636).

Data on recent trends and predicted changes for the upper Tennessee River drainage allow evaluation of the potential impacts of climate change to the sickle darter in the future. Different emission scenarios were used to estimate average annual increases in maximum and minimum air temperature, precipitation, snowfall, and other variables (Alder and Hostetler 2017, entire). Depending on the chosen model and emission scenario (Representative Concentration Pathway (RCP) 4.5 vs. 8.5), annual mean maximum air temperatures for the upper Tennessee River drainage are expected to increase by 2.1 to 3.1 °C (3.8 to 5.6 °F) by 2074, while precipitation models predict that the upper Tennessee River drainage will experience a slight increase in annual mean precipitation (0.2 in per month) through 2074 (Girvetz et al. 2009, pp. 1–19; Alder and Hostetler 2016, pp. 1–9). Because stream temperature is broadly driven by air temperature (Webb and Nobilis 2007, p. 82), water temperatures in the current and historical range of the sickle darter are expected to increase in the future under both RCP 4.5 and RCP 8.5.

The upper thermal limits of the sickle darter are unknown, but the species' occurrence in streams ranging in size from large creeks to medium-sized rivers suggests that it may have some tolerance to a variety of water conditions. The species may be less vulnerable to droughts, compared to species occurring in smaller or headwater streams. Relative to other fishes, sickle darter may have some resilience to the effects of climate change. Among more than 700 species in the Appalachian region, six other darter species in the genus *Percina* are ranked as moderately vulnerable to the effects of climate change (Appalachian Landscape Conservation Cooperative 2017, unpaginated). Moderately vulnerable is defined as abundance and/or range extent within geographical area assessed likely to decrease by 2050. The sickle darter may have some of the same vulnerabilities due to its similar ecology, life history, and small range.

Conservation Efforts

The sickle darter is listed as threatened by Tennessee (Tennessee Wildlife Resources Commission (TWRC) 2016, p. 3) and Virginia (VDGIF 2018, p. 1), making it unlawful to take the species or damage its habitat without a State permit. Additionally, the sickle darter is identified as a species of greatest conservation need in the Tennessee and Virginia Wildlife Action Plans, which outline actions to promote species conservation. A propagation effort for the sickle darter was initiated in 2015, producing 25 juveniles that were released to the wild. The status of the released fish is unknown, but the effort demonstrates that propagation may be a useful conservation tool to augment sickle darter populations or reintroduce the species to historical localities in the future.

Future Scenarios

In our SSA report (Service 2020a, entire), we defined viability as the ability of the species to sustain populations in the wild over time. To help address uncertainty associated with the degree and extent of potential future stressors and their impacts on the species' needs, the concepts of resiliency, redundancy, and representation were assessed using three plausible future scenarios. We devised these scenarios by identifying information on the following primary threats anticipated to affect sickle darter in the future: Land cover, urbanization, climate change, and conservation activity. The three scenarios capture the range of uncertainty in the changing landscape and how sickle darter will respond to the changing conditions (see Table 2, below). We used the best available data and models to project out 50 years into the future (*i.e.,* 2070), a timeframe where we were reasonably certain the land use change, urbanization, and climate models that we used could forecast patterns in the species' range relevant to the sickle darter and its habitat given the species' life span. For more information on the models and their projections, please see the SSA report (Service 2020a, pp. 54–67).

Under Scenario 1 (continuation of current trend), no significant increases or decreases are expected with respect to land cover, urbanization, or habitat conditions, and habitat restoration efforts (*e.g.,* livestock fencing, riparian plantings, streambank restoration) by the Service and its partners are projected to continue at current levels. In addition, climate change would track RCP 4.5. Three of six extant sickle darter populations are projected to maintain their resiliency categories at current levels. Three extant populations, Clinch River, Middle Fork Holston River, and North Fork Holston River, are projected to become extirpated within 30 years. The species' redundancy and representation are expected to remain at low levels.

Under Scenario 2 (improving trend), habitat conditions throughout the upper Tennessee River drainage are projected to improve due to increased conservation efforts and improving land use practices (*e.g.,* greater forest cover and reduced agricultural and development effects). Based on these factors, resiliency of all extant populations would remain at current levels or increase, and the species may be rediscovered or will be reintroduced into portions of the Powell River system and French Broad River system. The species' redundancy would increase to a low-moderate level and representation would remain at a low level because populations will be reintroduced or rediscovered in two historically occupied river systems, increasing the number of extant populations (our measure of redundancy) from 6 to 8. In spite of the two added populations, representation would remain low because individuals would have the same genetic composition of parental stock in the rivers from which they were sourced, or will be founded from very small, previously undetected populations.

Under Scenario 3 (worsening trend), habitat conditions are projected to decline within the upper Tennessee River drainage due to reductions in forest cover, increased urbanization and agricultural activities, and a climate trend that tracks RCP 8.5. Combined with reduced conservation efforts, these factors will have a negative effect on population resiliency, with projected extirpations of the Clinch River, North Fork Holston River, Middle Fork Holston River, and Sequatchie River populations. Loss of these populations would reduce redundancy and representation, with overall species' redundancy and representation remaining at low levels.

One of our plausible scenarios (improving trends) projected improving conditions characterized by an increased percentage of forested land cover and a reduced percentage of pasture and hay land cover. In this scenario, urbanization and climate change rates of increase would be reduced relative to current trends (Service 2020a, pp. 72–73) and additional conservation actions would be implemented. There was greater uncertainty regarding future species' status and conservation action implementation than in the other two future scenarios. For example, the improving trends scenario projected reintroduction and successful establishment of two populations in the species' historical range, but successful establishment of viable populations of sickle darters has not yet been proven, and funding for this type of conservation, as well as other conservation actions such as easements

for land restoration, is uncertain. Therefore, we did not rely on the improving trends scenario to assess the likelihood of the species becoming in danger of extinction in the foreseeable future. (see *Status Throughout All of Its Range,* below)

TABLE 2—FUTURE CONDITION OF THE SICKLE DARTER BY THE YEAR 2070 UNDER THREE FUTURE SCENARIOS

Analytical unit (population)	Current condition	Scenario 1: Current trend	Scenario 2: Improving trend	Scenario 3: Worsening trend
Emory River	Moderate	Moderate	Moderate	Low.
Clinch River	Low	Likely Extirpated	Low	Likely Extirpated.
Powell River	Extirpated	Likely Extirpated	Low*	Likely Extirpated.
Little River	Moderate	Low	Moderate	Low.
French Broad River	Extirpated	Likely Extirpated	Low*	Likely Extirpated.
Middle Fork Holston River	Low	Likely Extirpated	Low	Likely Extirpated.
North Fork Holston River	Low	Likely Extirpated	Low	Likely Extirpated.
South Fork Holston River	Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated.
Sequatchie River	Low	Low	Low	Likely Extirpated.
Watauga	Extirpated	Likely Extirpated	Likely Extirpated	Likely Extirpated.

*Scenario 2 anticipates successful reintroduction or rediscovery of the species in two river systems.

Cumulative Effects of Threats

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the species, but have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. Our assessment of the current and future conditions encompasses and incorporates the threats individually and cumulatively. Our current and future condition assessment is iterative because it accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Determination of Sickle Darter Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines ''endangered species'' as a species in danger of extinction throughout all or a significant portion of its range, and ''threatened species'' as a species likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of ''endangered species'' or ''threatened species'' because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Status Throughout All of Its Range

The current conditions as assessed in the sickle darter SSA report show that the species exists in six populations, in six tributary systems in two ecoregions. Two populations, Little River and Emory River, have moderate resiliency, and four populations have low resiliency. Although there are six separate populations distributed within the upper Tennessee River drainage, redundancy is low because four have low resiliency. Representation is currently low because genetic variation has likely been reduced over time as populations became disconnected, isolated, and reduced in size. Further, representation has been diminished with the loss of the species from the Blue Ridge ecoregion. While current resiliency, redundancy, and representation are far from optimal, it is unlikely that the sickle darter is in danger of extinction from a near-term catastrophic event. The occurrence in separate rivers of two populations, which are both in moderate condition and regularly recruiting new age classes (generations), greatly diminishes the possibility that such an event would simultaneously cause extirpation of the two populations, nor is it likely that such an event would simultaneously have the same level of impact on the other four populations in low condition.

After evaluating threats to the species and assessing the cumulative effect of the threats under the section 4(a)(1) factors, we conclude that the risk factors acting on the sickle darter and its habitat, either singly or in combination, are not of sufficient imminence, intensity, or magnitude to indicate that the species is in danger of extinction now (an endangered species) throughout all of its range.

Our analysis of the sickle darter's future conditions shows that the population and habitat factors used to determine resiliency, representation, and redundancy will continue to decline. The primary threats are currently acting on the species and are likely to continue into the future. We selected 50 years as ''foreseeable'' in this case because it includes projections from available models for urbanization, land use, and climate change, threats which will affect the status of the species over that timeframe.

The range of plausible future scenarios of the sickle darter's habitat conditions and water quality factors portend reduced viability into the future. Under the current trend scenario, resiliency is low in two populations and or moderate in one population, and three populations are likely extirpated so that redundancy and representation are reduced. Under the worsening trend scenario, resiliency is low in two populations, and four populations are likely extirpated so that redundancy and representation are substantially reduced. This expected reduction in both the number and distribution of resilient populations is likely to make the species vulnerable to catastrophic disturbance. Thus, after assessing the best available information, we conclude that the sickle darter is not currently in danger of extinction but is likely to become in danger of extinction within the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020) (*Center for Biological Diversity*), vacated the aspect of our Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014) that provided that the Service does not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range. Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant, and (2) the species is in danger of extinction in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Center for Biological Diversity,* we now consider whether there are any significant portions of the species' range where the species is in danger of extinction now (*i.e.,* endangered). In undertaking this analysis for sickle darter, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered.

For the sickle darter, we considered whether the threats are geographically concentrated in any portion of the species' range at a biologically meaningful scale. We examined the following threats currently acting on the species: Habitat loss and degradation through siltation, water quality degradation, and impoundments and their effects and the associated effects of the species' reduced range. We also examined the cumulative effects of these threats. Our analysis revealed that these threats are likely to continue into the foreseeable future, or approximately 50 years. Siltation and water quality degradation resulting from nutrients, pathogens, municipal and residential development, agriculture, and logging are present in all watersheds where the sickle darter occurs. Land use changes associated with extraction of energy resources (coal, oil, and gas) are restricted to the Clinch (including Emory River) and Powell River systems, but the stressors associated with these activities, including sedimentation and water quality degradation, also come from sources (*e.g.,* urbanization, grazing, logging) that are common to all watersheds where the species occurs.

Isolation as a result of habitat fragmentation affects all sickle darter populations similarly, and all populations will experience the effects of changing climate conditions. Additionally, resiliency of the remaining populations would decline, while our continuing trends and worsening trends future scenarios respectively projected three or four of the six extant populations would become extirpated. The Little River watershed has the highest amount of land affected by urbanization (development) currently, and that is projected to continue in the future (Service 2020a, pp. 86–87). However, current land use and future rates of land use change are not substantially different among the watersheds occupied by the six populations.

Overall, the current threats acting on the species and its habitat are expected to continue, and there are no indications that these threats would lessen or that declining populations trends would be reverted. After assessing the best available information, we found no concentration of threats in any portion of the sickle darter's range at a biologically meaningful scale. Thus, there are no portions of the species' range where the species has a different status from its rangewide status. Therefore, no portion of the species' range provides a basis for determining that the species is in danger of extinction in a significant portion of its range, and we determine that the species is likely to become in danger of extinction within the foreseeable future throughout all of its range. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that the sickle darter meets the Act's definition of a ''threatened species.'' Therefore, we propose to list the sickle darter as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

Recovery Planning

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning consists of preparing draft and final recovery plans, beginning with the development of a recovery outline and making it available to the public within 30 days of a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened (''downlisting'') or removal from protected status (''delisting''), and methods for monitoring recovery progress. Recovery plans also establish

a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (*http://www.fws.gov/endangered*), or from our Kentucky Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of North Carolina, Tennessee, and Virginia would be eligible for Federal funds to implement management actions that promote the protection or recovery of the sickle darter. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although the sickle darter is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered, or on private lands seeking funding, by Federal agencies, which may include, but are not limited to, the Tennessee Valley Authority, U.S. Department of Agriculture (USDA) U.S. Forest Service, USDA Farm Service Agency, USDA Natural Resources Conservation Service, and Federal Emergency Management Agency; issuance of section 404 CWA permits by the U.S. Army Corps of Engineers; and construction and maintenance of roads or highways by the Federal Highway Administration.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. The discussion below regarding protective regulations under section 4(d) of the Act complies with our policy.

Critical Habitat

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

As discussed earlier in this document, there is currently no imminent threat of collection or vandalism identified under Factor B for this species, and identification and mapping of critical habitat is not expected to initiate any such threat. In our SSA and proposed listing determination for the sickle darter, we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to the sickle darter and that those threats in some way can be addressed by section 7(a)(2) consultation measures. The species occurs wholly in the jurisdiction of the United States, and we are able to identify areas that meet the definition of critical habitat. Therefore, because none of the circumstances enumerated in our regulations at 50 CFR 424.12(a)(1) have been met and because there are no other circumstances the Secretary has identified for which this designation of critical habitat would be not prudent, we have determined that the designation of critical habitat is prudent for the sickle darter.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the sickle darter is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Data sufficient to perform required analyses are lacking, or

(ii) The biological needs of the species are not sufficiently well known to

identify any area that meets the definition of ''critical habitat.''

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

For the sickle darter, the species' needs are sufficiently well known, but a careful assessment of the economic impacts that may occur due to a critical habitat designation is ongoing. Until these efforts are complete, information sufficient to perform a required analysis of the impacts of the designation is lacking, and, therefore, we find designation of critical habitat for the sickle darter to be not determinable at this time. We plan to publish a proposed rule to designate critical habitat for the sickle darter concurrent with the availability of a draft economic analysis of the proposed designation.

II. Proposed Rule Issued Under Section 4(d) of the Act

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the Secretary of the Interior (Secretary) shall issue such regulations as he deems necessary and advisable to provide for the conservation of species listed as threatened. The U.S. Supreme Court has noted that statutory language like ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Additionally, the second sentence of section 4(d) of the Act states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9 of the Act.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a particular species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife, or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to him with regard to the permitted activities for those species. He may, for example, permit taking, but not importation of such species, or he may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising this authority under section 4(d), we have developed a proposed rule that is designed to address the sickle darter's specific threats and conservation needs. Although the statute does not require us to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the sickle darter. As discussed above under Summary of Biological Status and Threats, we have concluded that the sickle darter is likely to become in danger of extinction within the foreseeable future primarily due to habitat degradation or loss stemming from hydrologic alterations by impoundments, including dams and other barriers; land development that does not incorporate BMPs; and diminished water quality from point and nonpoint source pollution and siltation. These threats contribute to the negative effects associated with the species' habitat fragmentation and isolation and potential effects of climate change. The provisions of this proposed 4(d) rule would promote conservation of the sickle darter by encouraging management of the landscape in ways that meet both watershed and riparian management considerations and the species' conservation needs. The provisions of this proposed rule are one of many tools that we would use to promote the conservation of the sickle darter. This proposed 4(d) rule would apply only if and when we make final the listing of the sickle darter as a threatened species.

Provisions of the Proposed 4(d) Rule

This proposed 4(d) rule would provide for the conservation of the sickle darter by prohibiting the following activities, except as otherwise authorized or permitted: Import or export; take; possession and other acts with unlawfully taken specimens; delivery, receipt, transport, or shipment in interstate or foreign commerce in the course of commercial activity; or sale or offer for sale in interstate or foreign commerce.

Threats to the species are noted above and described in detail under Summary of Biological Status and Threats. The most significant threat expected to affect the species in the foreseeable future is loss and fragmentation of habitat from siltation, water quality degradation, and impoundments and their effects. A range of activities have the potential to affect the sickle darter, including commercial activities, agriculture, resource extraction, and land development. Regulating these activities would help preserve the sickle darter's remaining populations, slow the rate of population decline, and decrease synergistic, negative effects from other stressors. Therefore, regulating activities that increase siltation, diminish water quality, alter stream flow, or reduce fish passage would help preserve and potentially provide for expansion of remaining populations and decrease synergistic, negative effects from other threats.

Under the Act, ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Some of these provisions have been further defined in regulations at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or incidentally. Regulating incidental and intentional take would help the species maintain population size and resiliency.

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance propagation or survival, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act.

There are also certain statutory exceptions from the prohibitions, which are found in sections 9 and 10 of the Act, and other standard exceptions from the prohibitions, which are found in our regulations at 50 CFR part 17, subparts C and D. Below, we describe these exceptions to the prohibitions that we are proposing for the sickle darter.

Under our proposed 4(d) rule, take of the sickle darter would not be prohibited in the following instances:

- Take is authorized by a permit issued in accordance with 50 CFR 17.32;
- Take results from actions of an employee or agent of one of the Services or of a State conservation agency that is operating under a conservation program pursuant to the terms of a cooperative agreement with the Service;
- Take is in defense of human life; and
- Take results from actions taken by representatives of one of the Services or of a State conservation agency to aid a sick specimen or to dispose of, salvage, or remove a dead specimen that is reported to the Office of Law Enforcement.

We also propose to allow Federal and State law enforcement officers to possess, deliver, carry, transport, or ship any sickle darters taken in violation of the Act as necessary in performing their official duties.

In part, these exceptions to the prohibitions recognize the special and unique relationship with our State natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist the Services in implementing all aspects of the Act. In this regard, section 6 of the Act provides that the Service shall cooperate to the maximum extent practicable with the State in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, would be able to conduct activities designed to conserve the sickle darter that may result in otherwise prohibited take for wildlife without additional authorization.

In addition to the exceptions to the prohibitions described above, we propose certain species-specific exceptions to the prohibitions to provide for the conservation of the sickle darter. Consistent with all of the proposed exceptions and based on the best available information, our proposed 4(d) rule identifies the following activities, which are unlikely to result in take of the sickle darter in violation of section 9 if carried out in accordance with existing regulations and permit requirements and outside the February through March spawning season:

These 4(d) rule exceptions cover actions that improve or restore sickle darter habitat, including channel restoration and streambank stabilization, bridge and culvert replacement (including transportation projects that enhance fish passage), as well as low-head dam removal. To encourage protection of streams occupied by the sickle darter, we have included in the exceptions silvicultural activities that implement State best management practices. Within each occupied river system, these actions will promote expansion of the population's range and reduce the population's fragmentation and isolation. Additionally, these actions can reduce stressors that impact the sickle darter, including runoff of siltation and pollution, and may (through riparian reforestation) mediate local water temperatures expected to increase with climate change.

Habitat restoration actions and silvicultural activities excepted by the 4(d) rule may result in some minimal level of harm or temporary disturbance to the sickle darter. For example, a culvert replacement project would likely elevate suspended sediments for several hours and the darters would need to move out of the sediment plume to resume normal feeding behavior. Because the 4(d) rule exceptions do not apply during the sickle darter's two-month spawning period, a critical phase of the species' life history, the potential for take is further minimized. Overall, these activities benefit the species by expanding suitable habitat and reducing within-population fragmentation, contributing to conservation and recovery.

Based on the best available information, the following activities may potentially result in violation of section 9 of the Act; this list is not comprehensive:

(1) Unauthorized handling, collecting, possessing, selling, delivering, carrying, or transporting of the sickle darter, including interstate transportation across State lines and import or export across international boundaries.

(2) Destruction or alteration of the species' habitat by discharge of fill material, draining, ditching, tiling, pond construction, stream channelization or diversion, or diversion or alteration of surface or ground water flow into or out of the stream (*i.e.,* due to roads, impoundments, discharge pipes, stormwater detention basins, etc.).

(3) Introduction of nonnative species that compete with or prey upon the sickle darter.

(4) Discharge of chemicals or fill material into any waters in which the sickle darter is known to occur.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Kentucky Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Nothing in this proposed 4(d) rule would change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of the sickle darter. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service, where appropriate. We ask the public, particularly State agencies and other interested stakeholders that may be affected by the proposed 4(d) rule, to provide comments and suggestions regarding additional guidance and methods that the Service could provide or use, respectively, to streamline the implementation of this proposed 4(d) rule (see Information Requested, above).

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too

long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 *et seq.*)

It is our position that we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with listing a species as an endangered or threatened species under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have determined that no Tribal lands fall within the range of the sickle darter, so no Tribal lands would be affected by the proposed rule.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *http://www.regulations.gov* and upon request from the Kentucky Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Kentucky Ecological Services Field Office.

Signing Authority

The Director, U.S. Fish and Wildlife Service, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the U.S. Fish and Wildlife Service. Aurelia Skipwith, Director, U.S. Fish and Wildlife Service, approved this document on October 30, 2020, for publication.

Dated: October 30, 2020.

Madonna Baucum,

Regulations and Policy Chief, Division of Policy, Economics, Risk Management, and Analytics, Joint Administrative Operations, U.S. Fish and Wildlife Service.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by adding an entry for ''Darter, sickle'' to the List of Endangered and Threatened Wildlife in alphabetical order under FISHES to read as set forth below:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
FISHES				
*	*	*	*	*
Darter, sickle	*Percina williamsi*	Wherever found	T	[**Federal Register** citation when published as a final rule]; 50 CFR 17.44(ff).[4d]
*	*	*	*	*

■ 3. Amend § 17.44 by adding a paragraph (ff) to read as set forth below:

§ 17.44 Special rules—fishes.

* * * * *

(ff) Sickle darter (*Percina williamsi*).

(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the sickle darter. Except as provided under paragraph (ff)(2) of this section and §§ 17.4 and 17.5, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

(i) Import or export, as set forth at § 17.21(b) for endangered wildlife.

(ii) Take, as set forth at § 17.21(c)(1) for endangered wildlife.

(iii) Possession and other acts with unlawfully taken specimens, as set forth at § 17.21(d)(1) for endangered wildlife.

(iv) Interstate or foreign commerce in the course of commercial activity, as set forth at § 17.21(e) for endangered wildlife.

(v) Sale or offer for sale, as set forth at § 17.21(f) for endangered wildlife.

(2) *Exceptions from prohibitions.* In regard to this species, you may:

(i) Conduct activities as authorized by a permit under § 17.32.

(ii) Take, as set forth at § 17.21(c)(2) through (c)(4) for endangered wildlife.

(iii) Take as set forth at § 17.31(b).

(iv) Take incidental to an otherwise lawful activity caused by:

(A) Channel restoration projects that create natural, physically stable, ecologically functioning streams (or stream and wetland systems) and that take place between April 1 and January 31. These projects can be accomplished using a variety of methods, but the desired outcome is a natural channel with low shear stress (force of water moving against the channel); bank heights that enable reconnection to the floodplain; a connection of surface and groundwater systems, contributing to

perennial flows in the channel; riffles and pools composed of existing soil, rock, and wood instead of large imported materials; low compaction of soils within adjacent riparian areas; and inclusion of riparian wetlands.

(B) Streambank stabilization projects that use bioengineering methods to replace pre-existing, bare, eroding stream banks with vegetated, stable stream banks, thereby reducing bank erosion and instream sedimentation and improving habitat conditions for the species, that take place between April 1 and January 31. Stream banks may be stabilized using live stakes (live, vegetative cuttings inserted or tamped into the ground in a manner that allows the stake to take root and grow), live fascines (live branch cuttings, usually willows, bound together into long, cigar-shaped bundles), or brush layering (cuttings or branches of easily rooted tree species layered between successive lifts of soil fill). Stream banks must not be stabilized solely through the use of quarried rock (rip-rap) or the use of rock baskets or gabion structures.

(C) Bridge and culvert replacement/removal projects or low head dam removal projects that remove migration barriers or generally allow for improved upstream and downstream movements of sickle darters while maintaining normal stream flows, preventing bed and bank erosion, and improving habitat conditions for the species, and that take place between April 1 and January 31.

(D) Silviculture practices and forest management activities that:

(*1*) Implement State best management practices, particularly for Streamside Management Zones and stream crossings; and

(*2*) When such activities involve sickle darter spawning habitat, are carried out between April 1 and January 31.

(E) Transportation projects that provide for fish passage at stream crossings.

(v) Possess and engage in other acts with unlawfully taken wildlife, as set forth at § 17.21(d)(2) for endangered wildlife.

* * * * *

[FR Doc. 2020–24471 Filed 11–10–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No.: 201103–0288]

RIN 0648–BK05

Fisheries of the Northeastern United States; Omnibus Framework Adjustment To Modify the Mid-Atlantic Fishery Management Council's Risk Policy

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to approve and implement changes to the Mid-Atlantic Fishery Management Council's Risk Policy. The purpose of this action is to adjust the Council's risk policy by accepting a higher level of risk for stocks at or above biomass targets. These adjustments could lead to increases in catch limits for healthy fisheries managed by the Council.

DATES: Comments must be received by November 26, 2020.

ADDRESSES: The Mid-Atlantic Fishery Management Council has prepared a draft environmental assessment (EA) for this action that describes and analyzes the proposed measures and other considered alternatives. Copies of the draft Risk Policy Omnibus Framework Adjustment (framework), including the EA and information on the economic impacts of this proposed rulemaking, are available upon request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. These documents are also accessible via the internet at *http://www.mafmc.org.*

You may submit comments on this document, identified by NOAA–NMFS–2020–0143, by the following method:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal.

- Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0143;*
- Click the ''Comment Now!'' icon, complete the required fields; and
- Enter or attach your comments.

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).

FOR FURTHER INFORMATION CONTACT: Shannah Jaburek, Fishery Management Specialist, 978–282–8456.

SUPPLEMENTARY INFORMATION:

Background

In 2011, the Mid-Atlantic Fishery Management Council implemented its current risk policy. The risk policy specifies the Council's acceptable tolerance of risk for its managed resources. The risk policy also works in conjunction with the Scientific and Statistical Committee's application of the Council's acceptable biological catch (ABC) control rule to account for scientific uncertainty to determine an ABC for a specific stock. Five years after implementation, the Council conducted a review of its risk policy to determine if any modifications were necessary to meet the Council's goals and objectives for its managed fisheries. From this review, the Council determined there were two elements of the current policy that warranted modifications. The Council took final action on this framework to modify its risk policy in December 2019 and submitted the action to us in early August 2020.

Proposed Action

The purpose of this action is to adjust the Council's risk policy by accepting a higher level of risk (*i.e.,* the probability of overfishing, P*) for stocks that are healthy and either at or above biomass targets. For stocks not subject to a rebuilding plan that have a ratio of biomass (B) to biomass at maximum sustainable yield (B_{MSY}) of 1.0 or lower, the maximum P* as informed by the overfishing limit (OFL) distribution would decrease linearly from a maximum value of 45 percent until the P* becomes zero at a B/B_{MSY} ratio of 0.10. For stocks with biomass that exceeds B_{MSY} and the B/B_{MSY} ratio is greater than 1.0, the P* would increase linearly from 45 percent to a maximum of 49 percent when the B/B_{MSY} ratio is equal to 1.5 or greater. Under the current risk policy, the maximum allowed P* is capped at 40 percent for stocks with a B/B_{MSY} ratio of 1.0 or higher, with this probability decreasing

linearly until P* becomes zero at the B/B_{MSY} ratio of 0.10. The Council made no adjustments for stocks under a rebuilding plan or stocks with no OFL or proxy OFL. The increased tolerance of risk could lead to increases in ABC allocations for healthy fisheries the Council manages. The Council and its Scientific and Statistical Committee used this modified risk policy in recommending ABCs for scup and black sea bass for the 2021 fishing year that begins on January 1, 2021.

This action would also remove the typical/atypical species designation when applied to the current risk policy. This designation was intended to provide for less risk to those species whose life histories make them more vulnerable to over-exploitation; however, it has rarely been used and is currently only applied to ocean quahog. This would allow the Council to better use improvements in stock assessment and modeling approaches that can more appropriately account for and address such vulnerability.

Classification

Pursuant to section 304 (b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator has determined that this proposed rule is consistent with all applicable Fishery Management Plans that the Council manages, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

This proposed rule is expected to be an Executive Order 13771 deregulatory action.

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.

The Council evaluated the potential socioeconomic impacts of the proposed measures as part of the EA. As noted in the EA, according to the ownership database, 1,462 affiliate firms landed 1 or more of the managed resources during the 2016–2018 period, with 1,451 of those business affiliates categorized as small business and 11 categorized as large business. During this time period in the commercial fishery, for all small entities, managed resources revenues contributed approximately 25 percent of the total gross receipts, and managed resources revenues contributed approximately 17 percent of the total gross receipts of the large entities. For the recreational fishery, 336 affiliate firms, all of which are categorized as small businesses, held a for-hire Federal permit for one or more of the managed resources and generated revenues from recreational fishing for these managed resources during 2016–2018. It is not possible to derive what proportion of the overall revenues for these for-hire firms came from fishing activities for an individual species. Nevertheless, given the popularity of the managed resources as recreational species in the Mid-Atlantic and New England, revenues generated from these managed resources are likely to be important for many of these firms at certain times of the year.

No immediate direct economic impacts are expected from the actions proposed in this framework, because these actions are not expected to result in changes to the manner in which Council-managed commercial and recreational (for-hire) fisheries operate. The adjustments proposed in this framework are largely administrative in nature, and, as such, are not expected to directly impact the landings levels, fishery distribution or fishing methods and practices of Council-managed fisheries. However, these actions may have indirect positive impacts on Council-managed fisheries. This action proposes to change the Council's risk policy to meet the objectives of continuing to prevent overfishing and minimize the risks of a stock declining to low levels, while, at the same time, increasing fishery yield across all stock biomass levels, where possible, with the resulting economic benefits. Specifically, this proposed rule would allow for increased risk under very high stock biomass conditions, which would provide increased access and fishing opportunities for robust stocks, leading to economic benefits associated with increased fishery yield. Thus, indirect impacts of this proposed rule are likely to lead to positive economic benefits for all fishery participants, including small entities. Because this proposed rule is administrative in nature, having no direct impacts on fisheries, and because indirect impacts are likely to lead to positive economic benefits for fishery participants, we have concluded that that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: November 3, 2020.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.21, revise paragraphs (b)(1) and (2) and (c)(1) to read as follows:

§ 648.21 Mid-Atlantic Fishery Management Council risk policy.

* * * * *

(b) * * *

(1) For stocks with a ratio of biomass (B) to biomass at MSY (B_{MSY}) of 1.0 or lower, the maximum probability of overfishing as informed by the OFL distribution shall decrease linearly from a maximum value of 45 percent until the probability of overfishing becomes zero at a B/B_{MSY} ratio of 0.10.

(2) For stocks with biomass that exceeds B_{MSY} and the B/B_{MSY} ratio is greater than 1.0, the probability of overfishing shall increase linearly from a probability of overfishing of 45 percent to a maximum probability of overfishing of 49 percent when the B/B_{MSY} ratio is equal to 1.5 or greater.

(c) * * *

(1) Unless otherwise allowed in paragraph (c)(2) of this section, for instances in which the application of the risk policy approaches in paragraph (b) of this section using OFL distribution results in a more restrictive ABC recommendation than the calculation of ABC derived from the use of $F_{REBUILD}$ at the MAFMC-specified overfishing risk level as outlined in paragraph (a) of this section, the SSC shall recommend to the MAFMC the lower of the ABC values.

* * * * *

[FR Doc. 2020–24944 Filed 11–10–20; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 85, No. 219

Thursday, November 12, 2020

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

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0097]

Pioneer Hi-Bred International, Inc.; Availability of a Request and Plant Pest Risk Similarity Assessment for an Extension of Determination of Nonregulated Status for Maize for Use in the Seed Production Technology for Africa Process

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has received a request to extend our determination of nonregulated status of Pioneer Hi-Bred International, Inc.'s (Pioneer's) DP–32138–1 SPT maintainer maize to maize MS44 maintainer line DP56113 for use in the Seed Production Technology for Africa (SPTA) process (hereafter DP56113 SPTA maintainer maize). DP56113 SPTA maintainer maize has been genetically engineered for maintenance and recovery of male-sterile maize breeding lines using the same construct and method of transformation as DP–32138–1 SPT maintainer maize. We are making available for public comment the request and our plant pest risk similarity assessment and preliminary determination of nonregulated status.

DATES: We will consider all comments that we receive on or before December 14, 2020.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0097*.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0097, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

The Pioneer extension request, our plant pest risk similarity assessment and preliminary determination of nonregulated status, and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0097* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 7997039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Eck, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3892; email: *cynthia.a.eck@usda.gov*.

SUPPLEMENTARY INFORMATION: Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, ''Movement of Organisms Modified or Produced Through Genetic Engineering,'' regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such organisms and products are considered regulated articles.

Pursuant to the terms set forth in a final rule published in the **Federal Register** on May 18, 2020 (85 FR 29790–29838, Docket No. APHIS–2018–0034),[1] any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340, or that APHIS extend a determination of nonregulated status to other organisms. Such an extension request must include information to establish the similarity of the antecedent organism and the regulated article in question.

On June 28, 2011,[2] APHIS announced its determination of nonregulated status of Pioneer Hi-Bred International, Inc.'s (Pioneer's) DP–32138–1 SPT maintainer maize, which was genetically engineered for maintenance and recovery of male-sterile maize breeding lines. APHIS has received a request for an extension of that determination of nonregulated status of DP–32138–1 SPT maintainer maize to maintainer maize designated as MS44 maintainer line maize event DP-Ø56113–9 and referred to as DP56113 SPTA maintainer maize (APHIS Petition Number 20–043–01.ext), also from Pioneer. DP56113 SPTA maintainer maize has also been genetically engineered for maintenance and recovery of male-sterile maize breeding lines. In its request, Pioneer stated that this maintainer maize is similar to the antecedent organism DP–32138–1 SPT maintainer maize and, based on the similarity to the antecedent organism, is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the extension request, DP56113 SPTA maintainer maize was developed using the same constructs and method of transformation as DP–32138–1 SPT maintainer maize. Based on the information in the request, we have concluded that DP56113 SPTA maintainer maize is similar to DP–32138–1 SPT maintainer maize. DP56113 SPTA maintainer maize is currently regulated under 7 CFR part 340.

As part of our decision-making process regarding a GE organism's regulatory status, APHIS evaluates the plant pest risk of the article. In section 403 of the PPA, ''plant pest'' is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS has prepared a plant pest risk similarity assessment (PPRSA) to compare DP56113 SPTA maintainer maize to the antecedent. As described in the PPRSA, the same genetic constructs used in DP56113 SPTA maintainer maize were previously used in DP–32138–1 SPT maintainer maize, and APHIS has concluded that DP56113 SPTA maintainer maize is unlikely to

[1] To view the final rule, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0034*.

[2] *https://www.regulations.gov/document?D=APHIS-2010-0041-0057*.

pose a plant health risk. Therefore, based on the similarity between DP56113 SPTA maintainer maize and DP–32138–1 SPT maintainer maize as described in the PPRSA, APHIS has concluded that DP56113 SPTA maintainer maize is no more likely to pose a plant pest risk than DP–32138–1 SPT maintainer maize.

APHIS has analyzed information submitted by Pioneer, references provided in the extension request, peer-reviewed publications, and supporting documentation prepared for the antecedent organism. Based on APHIS' analysis of this information and the similarity of DP56113 SPTA maintainer maize to the antecedent organism DP–32138–1 SPT maintainer maize, APHIS has determined that DP56113 SPTA maintainer maize is unlikely to pose a plant pest risk. We have therefore reached a preliminary decision to approve the request to extend the determination of nonregulated status of DP–32138–1 SPT maintainer maize to DP56113 SPTA maintainer maize, whereby DP56113 SPTA maintainer maize would no longer be subject to our regulations governing the introduction of certain genetically engineered organisms.

We are therefore publishing this notice to make available our evaluation and inform the public of our preliminary decision to extend the determination of nonregulated status of DP–32138–1 SPT maintainer maize to DP56113 SPTA maintainer maize.

APHIS will accept written comments on the request for extension, PPRSA, and our preliminary determination for DP56113 SPTA maintainer maize for 30 days. These documents are available for public review as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above. Copies of these documents may also be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments will be available for public review. After reviewing and evaluating the comments, if APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our website at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status*. APHIS will also furnish a response to the petitioner regarding our final regulatory determination. No further **Federal Register** notice will be published announcing the final regulatory determination regarding DP56113 SPTA maintainer maize.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 6th day of November 2020.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020–25037 Filed 11–10–20; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection: Collaborative Forest Landscape Restoration Program

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the U.S. Forest Service (USFS) is seeking comments from all interested individuals and organizations on the renewal and revision of the information collection, *Collaborative Forest Landscape Restoration Program*.

DATES: Comments must be received in writing on or before January 11, 2021 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Lindsay Buchanan, Collaborative Forest Landscape Restoration Program Coordinator, 1220 SW 3rd Ave., Portland, Oregon 97204. Comments may also be submitted by email to: *lindsay.buchanan@usda.gov*. The public may inspect comments received at 1220 SW 3rd Ave., Portland, Oregon 97204, during normal business hours. Visitors are encouraged to call ahead to 503–808–2810 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Lindsay Buchanan, Collaborative Forest Landscape Restoration Program Coordinator, Forest Management, Range Management, and Vegetation Ecology, can be reached by phone at 503–808–2810, or by email at *lindsay.buchanan@usda.gov*. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Collaborative Forest Landscape Restoration Program.

OMB Number: 0596–0245.

Expiration Date of Approval: January 31, 2021.

Type of Request: Renewal with Revisions.

Abstract: The Collaborative Forest Landscape Restoration Program (CFLRP) is a USFS program started in 2010 to encourage collaborative groups of neighboring landowners, to work with the Forest Service to find common ground pertaining to forest restoration. Such collaborative neighboring landowners include State, local, and Tribal government representatives, businesses, interest groups, and non-profit organizations. Partners work with the USFS to implement restoration work and multi-party monitoring of landscape restoration treatments.

The Forest Landscape Restoration Act (FLRA) of 2009 (16 U.S.C. 7303), which enabled the CFLRP, requires monitoring ''to assess the positive or negative ecological, social, and economic effects of projects implementing a selected proposal for not less than 15 years after project implementation commences.'' This Information Collection Request (ICR) will help meet the obligation for monitoring the social impacts on residents and stakeholders of activities conducted under the CFLRP. The scope of the ICR includes residents of communities within and adjacent to the CFLRP landscapes and collaborative participants.

Gaining information from individuals who work or live in the geographic area of the CFLRP projects provides valuable information to partners and land management decision makers. To ensure the USFS is informed about the opinions of participants of collaborative processes and public members living in or around the CFLRP project, the USFS seeks to obtain approval by the Office of Management and Budget (OMB) of an ICR to collect both qualitative and quantitative feedback from stakeholders on management decisions, forest restoration work, monitoring activities, and land management planning. The information will be collected through a census survey of participants and a mail-in, on-line, and hard copy survey of residents. Through the collection of this information, managers and planners will obtain valuable information to inform future decisions. USFS public affairs staff, social scientists, and economists may also use this information, and USFS, academic, and other researchers may use or cite the results or data collected in publications.

Without the collection of this information, the USFS will be unable to determine whether it is meeting the requirements of the Forest Landscape Restoration Act, nor if they are fully incorporating partner and public input into forest project, implementation, monitoring and/or planning processes as required by law.

Type of Respondents: Residents within the Selected CFLRP landscapes in Forest Service Regions 1, 2, 3, 4, 5, 6, 8, and 9.

Estimated Annual Number of Respondents: 5,250.

Estimated Annual Number of Responses per Respondent: 7.

Estimated Total Annual Burden Hours on Respondents: 2,700 hours.

Comment is Invited: Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden 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 to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request for OMB approval.

Paul Strong,

Acting Director, Forest Management, Range and Vegetation Ecology, National Forest System.

[FR Doc. 2020–24997 Filed 11–10–20; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

International Trade Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Annual Report From Foreign-Trade Zones

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 August 31, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Department of Commerce.

Title: Annual Report from Foreign-Trade Zones.

OMB Control Number: 0625–0109.

Form Number(s): ITA–359P.

Type of Request: Regular submission, extension of a current information collection.

Number of Respondents: 261.

Average Hours per Response: 1 to 76 hours.

Burden Hours: 5,979 hours.

Needs and Uses: The annual reports are used by Congress and the Department to determine the economic effect of the Foreign-Trade Zone program as well as by the Foreign-Trade Zones Board and other trade policy officials to determine whether zone activity is consistent with U.S. international trade policy.

Affected Public: State. Local, tribal governments, or not-for-profit institutions that have been granted foreign-trade zone authority.

Frequency: Annually.

Respondent's Obligation: Mandatory.

Legal Authority: 19 U.S.C. 81(p).

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 0625–0109.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–25017 Filed 11–10–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–943, C–570–944]

Oil Country Tubular Goods From the People's Republic of China: Self-Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

Summary

The Department of Commerce (Commerce) is self-initiating country-wide anti-circumvention inquiries to determine whether imports of welded oil country tubular goods (OCTG) completed in Brunei and the Philippines (collectively, third countries) using inputs manufactured in the People's Republic of China (China) are circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on OCTG from China.

DATES: Applicable November 12, 2020.

FOR FURTHER INFORMATION CONTACT: Dana Mermelstein at (202) 482–1391, AD/CVD Operations, Office VI or Justin Enck at (202) 482–1614, Office of Policy, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On April 8, 2009, Evraz Rocky Mountain Steel, Maverick Tube Corporation, TMK IPSCO, United States Steel Corporation, V&M Star LP, V&M Tubular Corporation of America, Wheatland Tube Corp., and the United Steel, Paper, and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO–CLC filed petitions seeking the imposition of antidumping and countervailing duties on imports of OCTG from China.[1] Following Commerce's affirmative determinations of dumping and countervailable subsidies,[2] and the U.S.

[1] *See Oil Country Tubular Goods from the People's Republic of China: Initiation of Antidumping Duty Investigation,* 74 FR 20671 (May 5, 2009); *Certain Oil Country Tubular Goods from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 74 FR 20678 (May 5, 2009).

[2] *See Certain Oil Country Tubular Goods from the People's Republic of China: Final Determination of Sales at Less Than Fair Value, Affirmative Final Determination of Critical Circumstances and Final Determination of Targeted Dumping,* 75 FR 20335

Continued

International Trade Commission's (ITC) finding of material injury,[3] Commerce issued AD and CVD orders on imports of OCTG from China.[4]

Section 781(b)(1) of the Tariff Act of 1930, as amended (the Act), provides that Commerce may find circumvention of an AD or CVD order when merchandise of the same class or kind subject to the order is completed or assembled in a foreign country other than the country to which the order applies. In conducting anti-circumvention inquiries, under section 781(b)(1) of the Act, Commerce relies on the following criteria: (A) Merchandise imported into the United States is of the same class or kind as any merchandise produced in a foreign country that is the subject of an antidumping or countervailing duty order or finding, (B) before importation into the United States, such imported merchandise is completed or assembled in another foreign country from merchandise which is subject to the order or merchandise which is produced in the foreign country that is subject to the order, (C) the process of assembly or completion in the foreign country referred to in section (B) is minor or insignificant, (D) the value of the merchandise produced in the foreign country to which the AD or CVD order applies is a significant portion of the total value of the merchandise exported to the United States, and (E) the administering authority determines that action is appropriate to prevent evasion of such order or finding.

In determining whether or not the process of assembly or completion in a third country is minor or insignificant under section 781(b)(1)(C) of the Act, section 781(b)(2) of the Act directs Commerce to consider: (A) The level of investment in the foreign country, (B) the level of research and development in the foreign country, (C) the nature of the production process in the foreign country, (D) the extent of production facilities in the foreign country, and (E) whether or not the value of processing performed in the foreign country represents a small proportion of the value of the merchandise imported into the United States. However, no single factor, by itself, controls Commerce's determination of whether the process of assembly or completion in a third country is minor or insignificant.[5] Accordingly, it is Commerce's practice to evaluate each of these five factors as they exist in the third country, depending on the totality of the circumstances of the particular anti-circumvention inquiry.[6]

Furthermore, section 781(b)(3) of the Act sets forth additional factors to consider in determining whether to include merchandise assembled or completed in a third country within the scope of an AD and/or CVD order. Specifically, Commerce shall take into account such factors as: (A) The pattern of trade, including sourcing patterns; (B) whether the manufacturer or exporter of the merchandise is affiliated with the person who, in the third country, uses the merchandise to complete or assemble the merchandise which is subsequently imported into the United States; and (C) whether imports of the merchandise into the third country have increased after the initiation of the investigation that resulted in the issuance of such order or finding.

Scope of the Orders

The products covered by the *Orders* are certain hollow steel products of circular cross-section, including oil well casing and tubing, of iron (other than cast iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish. For a full description of the scope of these orders, *see* the ''Scope of the Orders,'' in the Appendix to this notice.

Merchandise Subject to the Anti-Circumvention Inquiries

These anti-circumvention inquiries cover welded OCTG completed in the third countries using inputs manufactured in China and subsequently exported from the third countries to the United States.

Initiation of Anti-Circumvention Inquiries

Through its regular monitoring of trade data, Commerce has gathered information indicating that hot-rolled steel sheet and strip from China may be exported to Brunei and the Philippines for minor processing, and then exported to the United States as welded OCTG, in circumvention of the *Orders.* Based on this information, we determine, pursuant to section 781(b) of the Act and 19 CFR 351.225(b) and (h), that self-initiation of anti-circumvention inquiries is warranted to determine whether certain imports of welded OCTG, completed in Brunei and the Philippines using inputs manufactured in China, are circumventing the *Orders.* For a full discussion of the basis for our decision to initiate these anti-circumvention inquiries, *see* the Anti-Circumvention Initiation Memo.[7]

As explained in the Anti-Circumvention Initiation Memo, the available information warrants initiating these anti-circumvention inquiries on a country-wide basis. Commerce has taken this approach in prior anti-circumvention inquiries, where the facts warranted.[8]

Consistent with the approach in the prior anti-circumvention inquiries that were initiated on a country-wide basis, Commerce intends to issue questionnaires to solicit information from producers and exporters in each of the third countries concerning their shipments of OCTG to the United States and the origin of any imported inputs being processed into OCTG. A

(April 19, 2010); and *Certain Oil Country Tubular Goods from the People's Republic of China: Final Affirmative Countervailing Duty Determination, Final Negative Critical Circumstances Determination,* 74 FR 64045 (December 7, 2009).

[3] *See Certain Oil Country Tubular Goods from the People's Republic of China; Determination,* 75 FR 28058 (May 19, 2010) and *Certain Oil Country Tubular Goods from the People's Republic of China,* 75 FR 3248 (January 20, 2010); *see also Certain Oil Country Tubular Goods from China,* Inv. No. 731–TA–1159, USITC Pub. 4152 (May 2010) (Final) and *Certain Oil Country Tubular Goods from China,* Inv. No. 701–TA–463, USITC Pub. 4124 (January 2010) (Final).

[4] *See Certain Oil Country Tubular Goods from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 75 FR 28551 (May 21, 2010) (*AD Order*)*; Certain Oil Country Tubular Goods From the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 75 FR 3203 (January 20, 2010) (*CVD Order*) (collectively, *Orders*).

[5] *See* Statement of Administrative Action accompanying the Uruguay Round Agreements Act (SAA), H.R. Doc. No. 103–316 (1994) at 893.

[6] *See Uncovered Innerspring Units from the People's Republic of China: Final Affirmative Determination of Circumvention of the Antidumping Duty Order,* 83 FR 65626 (December 21, 2018), and accompanying Issues and Decision Memorandum at 4.

[7] *See* Memorandum, ''Oil Country Tubular Goods from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders'' (Anti-Circumvention Initiation Memo). This memo is a public document that is dated concurrently with, and hereby adopted by, this notice and on file electronically via ACCESS.

[8] *See, e.g., Stainless Steel Sheet and Strip From the People's Republic of China: Initiation of Anti-Circumvention and Scope Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 85 FR 29401, 29402 (May 15, 2020); *see also Certain Corrosion-Resistant Steel Products from the Republic of Korea and Taiwan: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 83 FR 37785 (August 2, 2018); *Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China: Initiation of Anti-Circumvention Inquiry on the Antidumping Duty Order,* 82 FR 40556, 40560 (August 25, 2017) (stating at initiation that Commerce would evaluate the extent to which a country-wide finding applicable to all exports might be warranted); *Certain Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 81 FR 79454, 79458 (November 14, 2016) (stating at initiation that Commerce would evaluate the extent to which a country-wide finding applicable to all exports might be warranted).

company's failure to respond completely to Commerce's requests for information may result in the application of partial or total facts available, pursuant to section 776(a) of the Act, which may include adverse inferences, pursuant to section 776(b) of the Act.

Notification to Interested Parties

In accordance with 19 CFR 351.225(b), Commerce determines that available information warrants initiating these anti-circumvention inquiries to determine whether certain imports of welded OCTG, completed in Brunei and the Philippines using inputs manufactured in China, are circumventing the *Orders.* Accordingly, Commerce hereby notifies all parties on Commerce's scope service list of the initiation of these anti-circumvention inquiries. In addition, in accordance with 19 CFR 351.225(f)(1)(i) and (ii), in this notice of initiation issued under 19 CFR 351.225(b), we have included a description of the product that is the subject of these anti-circumvention inquiries (*i.e.,* OCTG completed in the third countries using inputs manufactured in China), and an explanation of the reasons for Commerce's decision to initiate these anti-circumvention inquiries, as provided above. Commerce will establish a schedule for questionnaires and comments on the issues in these inquiries.

In accordance with 19 CFR 351.225(l)(2), if Commerce issues preliminary affirmative determinations, we will then instruct U.S. Customs and Border Protection to suspend liquidation and require a cash deposit of estimated antidumping and countervailing duties, at the applicable rate, for each unliquidated entry of the merchandise at issue, entered or withdrawn from warehouse for consumption on or after the date of initiation of the inquiries. Commerce intends to issue its final determinations within 300 days of the date of publication of this initiation, in accordance with section 781(f) of the Act and 19 CFR 351.225(f)(5).

This notice is published in accordance with section 781(b) of the Act and 19 CFR 351.225(f).

Dated: November 3, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—Scope of the *Orders*

The scope of these *Orders* consists of certain OCTG, which are hollow steel products of circular cross-section, including oil well casing and tubing, of iron (other than cast iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish (*e.g.,* whether or not plain end, threaded, or threaded and coupled) whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished (including limited service OCTG products) or unfinished (including green tubes and limited service OCTG products), whether or not thread protectors are attached. The scope of the *Orders* also covers OCTG coupling stock. Excluded from the scope of the *Orders* are casing or tubing containing 10.5 percent or more by weight of chromium; drill pipe; unattached couplings; and unattached thread protectors.

The merchandise covered by the *Orders* is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7304.29.10.10, 7304.29.10.20, 7304.29.10.30, 7304.29.10.40, 7304.29.10.50, 7304.29.10.60, 7304.29.10.80, 7304.29.20.10, 7304.29.20.20, 7304.29.20.30, 7304.29.20.40, 7304.29.20.50, 7304.29.20.60, 7304.29.20.80, 7304.29.31.10, 7304.29.31.20, 7304.29.31.30, 7304.29.31.40, 7304.29.31.50, 7304.29.31.60, 7304.29.31.80, 7304.29.41.10, 7304.29.41.20, 7304.29.41.30, 7304.29.41.40, 7304.29.41.50, 7304.29.41.60, 7304.29.41.80, 7304.29.50.15, 7304.29.50.30, 7304.29.50.45, 7304.29.50.60, 7304.29.50.75, 7304.29.61.15, 7304.29.61.30, 7304.29.61.45, 7304.29.61.60, 7304.29.61.75, 7305.20.20.00, 7305.20.40.00, 7305.20.60.00, 7305.20.80.00, 7306.29.10.30, 7306.29.10.90, 7306.29.20.00, 7306.29.31.00, 7306.29.41.00, 7306.29.60.10, 7306.29.60.50, 7306.29.81.10, and 7306.29.81.50.

The OCTG coupling stock covered by the *Orders* may also enter under the following HTSUS item numbers: 7304.39.00.24, 7304.39.00.28, 7304.39.00.32, 7304.39.00.36, 7304.39.00.40, 7304.39.00.44, 7304.39.00.48, 7304.39.00.52, 7304.39.00.56, 7304.39.00.62, 7304.39.00.68, 7304.39.00.72, 7304.39.00.76, 7304.39.00.80, 7304.59.60.00, 7304.59.80.15, 7304.59.80.20, 7304.59.80.25, 7304.59.80.30, 7304.59.80.35, 7304.59.80.40, 7304.59.80.45, 7304.59.80.50, 7304.59.80.55, 7304.59.80.60, 7304.59.80.65, 7304.59.80.70, and 7304.59.80.80.

The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of the *Orders* is dispositive.

[FR Doc. 2020–24993 Filed 11–10–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–854]

Certain Tin Mill Products From Japan: Rescission of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the antidumping duty order on certain tin mill products from Japan for the period August 1, 2019, through July 31, 2020, based on the timely withdrawal of the request for review.

DATES: Applicable November 12, 2020.

FOR FURTHER INFORMATION CONTACT: Glenn T. Bass Jr., 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) 482–8338.

Background

On August 4, 2020, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on certain tin mill products from Japan for the period August 1, 2019, through July 31, 2020.[1] On August 31, 2020, United States Steel Corporation (the petitioner), filed a timely request for review, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b).[2] Pursuant to this request and in accordance with section 751(a) of the Act and 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the nine companies named by the petitioner in their request for review.[3] No other requests for review were received. On October 28, 2020, the petitioner timely withdrew their request for an administrative review with respect to all nine companies.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the party that requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. As noted above, the petitioner, the only party to file a request for review, withdrew this request by the 90-day deadline. Accordingly, we are rescinding, in its entirety, the administrative review of the antidumping duty order on certain tin mill products from Japan covering the period August 1, 2019, through July 31, 2020.

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 85 FR 47167 (August 4, 2020).

[2] *See* Letter from the petitioner, ''Tin Mill Products from Japan: Request for Administrative Review of Antidumping Duty Order,'' dated August 31, 2020.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 63081 (October 6, 2020).

[4] *See* Letter from the petitioner, ''Tin Mill Products from Japan: Withdrawal of Request for Administrative Review of Antidumping Duty Order,'' dated October 28, 2020.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of certain tin mill products from Japan. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to all 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. 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 violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: November 5, 2020.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2020–24994 Filed 11–10–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Highly Migratory Species Vessel Logbooks and Cost-Earnings Data Reports

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on July 23, 2020, (85 FR 44520) during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Highly Migratory Species (HMS) Vessel Logbooks and Cost-Earnings Data Reports.

OMB Control Number: 0648–0371.

Form Number(s): 88–191.

Type of Request: Regular.

Number of Respondents: 5,513.

Average Hours per Response: 10 minutes for cost/earnings summaries attached to logbook reports, 30 minutes for annual expenditure forms, 12 minutes for logbook catch trip and set reports, 2 minutes for negative logbook catch reports.

Burden Hours: 21,304.

Needs and Uses: NMFS collects information via vessel logbooks to monitor the U.S. catch of Atlantic swordfish, sharks, billfish, and tunas in relation to the quotas, thereby ensuring that the United States complies with its domestic and international obligations. The HMS logbook program, OMB Control No. 0648–0371, was specifically designed to collect the vessel level information needed for the management of Atlantic HMS, and includes set forms, trip forms, negative reports, and cost-earning requirements for both commercial and recreational vessels. The information supplied through the HMS logbook program provides the catch and effort data on a per-set or per-trip level of resolution for both directed and incidental species. In addition to HMS fisheries, the HMS logbook program is also used to report catches of dolphin and wahoo by commercial and charter/headboat fisheries by vessels that do not possess other federal permits. Additionally, the HMS logbook collects data on incidental species, including sea turtles, which is necessary to evaluate the fisheries in terms of bycatch and encounters with protected species. While most HMS fishermen use the HMS logbook program, HMS can also be reported as part of several other logbook collections including the Northeast Region Fishing Vessel Trip Reports (0648–0212) and Southeast Region Coastal Logbook (0648–0016).

These data are necessary to assess the status of HMS, dolphin, and wahoo in each fishery. International stock assessments for tunas, swordfish, billfish, and some species of sharks are conducted through ICCAT's Standing Committee on Research and Statistics periodically and provide, in part, the basis for ICCAT management recommendations which become binding on member nations. Domestic stock assessments for most species of sharks and for dolphin and wahoo are used as the basis of managing these species.

Supplementary information on fishing costs and earnings has been collected via the HMS logbook program. This economic information enables NMFS to assess the economic impacts of regulatory programs on small businesses and fishing communities, consistent with the National Environmental Policy Act (NEPA), Executive Order 12866, the Regulatory Flexibility Act, and other domestic laws.

Atlantic HMS fisheries are managed under the dual authority of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) and the Atlantic Tunas Conservation Act (ATCA). Under the MSA, management measures must be consistent with ten National Standards, and fisheries must be managed to maintain optimum yield, rebuild overfished fisheries, and prevent overfishing. Under ATCA, the Secretary of Commerce shall promulgate regulations, as necessary and appropriate, to implement measures adopted by the International Commission for the Conservation of Atlantic Tunas (ICCAT).

Affected Public: Businesses or other for-profit organizations (vessel owners).

Frequency: Trip summary reports are submitted within 7 days following the completion of each fishing trip, trip cost-earnings reports are due within 30 days of trip completion, no catch/

fishing reports are due at the end of each month in which no fishing occurs, and annual expenditure reports are submitted annually.

Respondent's Obligation: Mandatory.

Legal Authority: Under the provisions of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), the National Marine Fisheries Service (NMFS) is responsible for management of the Nation's marine fisheries. NMFS must also promulgate regulations, as necessary and appropriate, to carry out obligations the United States (U.S.) undertakes internationally regarding tuna management through the Atlantic Tunas Convention Act (ATCA, 16 U.S.C. 971 *et seq.*).

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

Written comments and recommendations for the proposed information collection should be 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 0648–0371.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–25041 Filed 11–10–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA605]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Site Characterization Surveys Off of Coastal Virginia

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

ACTION: Notice; modification of an incidental harassment authorization; request for comments.

SUMMARY: NMFS received a request from Dominion Energy Virginia (Dominion) on September 29, 2020, for a modification to the incidental harassment authorization (IHA) that was issued on August 28, 2020. This initial IHA allowed Dominion to take nine species of marine mammals, by Level B harassment, incidental to marine site characterization surveys conducted in the areas of the Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS) Offshore Virginia (Lease No. OCS–A–0483) as well as in coastal waters where an export cable corridor will be established in support of the Coastal Virginia Offshore Wind Commercial (CVOW Commercial) Project. Dominion was recording take of Atlantic spotted dolphin (*Stenella frontalis*) by Level B harassment at a rate that would exceed the authorized limit on this species and therefore, NMFS is proposing to modify the IHA to increase authorized take by Level B harassment of spotted dolphin. The mitigation, monitoring, and reporting measures remain the same as prescribed in the initial IHA and no additional take was requested for other species. NMFS will consider public comments on the requested modification prior to making any final decision and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than November 27, 2020.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Written comments should be submitted via email to *ITP.pauline@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. Attachments to comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://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: Robert Pauline, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the original application and supporting documents (including NMFS **Federal Register** notices of the original proposed and final authorizations, and the previous IHA), as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* 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 issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization may be 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 such 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 such takings are set forth.

History of Request

On February 7, 2020, NMFS received a request from Dominion for an IHA to take marine mammals incidental to marine site characterization surveys in the areas of the Commercial Lease of Submerged Lands for Renewable Energy Development on the OCS Offshore Virginia (Lease No. OCS–A–0483) as well as in coastal waters where an export cable corridor will be established in support of the offshore wind project. Dominion's planned marine site characterization surveys include high-

resolution geophysical (HRG) and geotechnical survey activities. Geophysical and shallow geotechnical survey activities are anticipated to be supported by up to four vessels. The vessels will transit a combined estimated total of 121.54 kilometers (km) of survey lines per day. Dominion's request was for incidental take of a small number of nine marine mammal species by Level B harassment only. The application was deemed adequate and complete on May 12, 2020. We published a notice of proposed IHA and request for comments in the **Federal Register** on June 17, 2020 (85 FR 36562). We subsequently published the final notice of our issuance of the IHA in the **Federal Register** on September 8, 2020 (85 FR 55415), with effective dates from August 28, 2020, to August 27, 2021. The specified activities were expected to result in the take by Level B harassment of 9 species (10 stocks) of marine mammals including bottlenose dolphin (*Tursiops truncatus*), pilot whale (*Globicephala spp.*), common dolphin (*Delphinus delphis*), Atlantic white sided dolphin (*Lagenorhynchus acutus*), Atlantic spotted dolphin (*Stenella frontalis*), Risso's dolphin (*Grampus griseus*), harbor porpoise (*Phocoena phocoena*), harbor seal (*Phoca vitulina*), and gray seal (*Halichoerus grypus*),

On September 29, 2020, NMFS received a request from Dominion for a modification to the IHA that was issued on August 28, 2020 (85 FR 55415; September 8, 2020). Since the issuance of the initial IHA, Dominion has been recording large pods of Atlantic spotted dolphin within the Level B harassment zone such that they were approaching the authorized take limit for this species. Dominion felt that without an increase in authorized take of spotted dolphins they would be forced to repeatedly shut down whenever animals entered into specified Level B harassment zones. This would likely prolong the duration of survey and add increased costs to the project. Therefore, Dominion is requesting, and NMFS is proposing to modify the IHA to increase authorized take of spotted dolphin by Level B harassment. The mitigation, monitoring, and reporting measures remain the same as prescribed in the initial IHA and no additional take is requested or proposed for species other than spotted dolphin. Moreover, the IHA would still expire on August 27, 2021.

Description of the Proposed Activity and Anticipated Impacts

The modified IHA would include the same HRG and geotechnical surveys in the same locations that were described in the initial IHA. The mitigation, monitoring, and reporting measures remain the same as prescribed in the initial IHA. NMFS refers the reader to the documents related to the initial IHA issued on August 28, 2020, for more detailed description of the project activities. These previous documents include the notice of proposed IHA and request for comments (85 FR 36562; June 17, 2020) and notice of our issuance of the IHA in the **Federal Register** (85 FR 55415; September 8, 2020).

Detailed Description of the Action

A detailed description of the survey activities is found in these previous documents. The location, timing, and nature of the activities, including the types of HRG equipment planned for use, daily trackline distances and number of survey vessels (four) are identical to those described in the previous notices.

Description of Marine Mammals

A description of the marine mammals in the area of the activities is found in these previous documents, which remains applicable to this modified IHA as well. In addition, NMFS has reviewed recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and recent scientific literature, and determined that no new information affects our original analysis of impacts under the initial IHA.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

A description of the potential effects of the specified activities on marine mammals and their habitat may be found in the documents supporting the initial IHA, which remains applicable to the issuance of this modified IHA. There is no new information on potential effects.

Estimated Take

A detailed description of the methods and inputs used to estimate take for the specified activity are found in the notice of IHA for the initial authorization (85 FR 55415; September 8, 2020). The HRG equipment that may result in take, as well as the source levels, marine mammal stocks taken, marine mammal density data and the methods of take estimation applicable to this authorization remain unchanged from the previously issued IHA. The proposed number of authorized takes is also identical with the exception of spotted dolphin.

During the one month period from the effective date of the initial IHA (August 28, 2020) through September 29, 2020, a total of 19 spotted dolphins had been observed within the Level B harassment zone distances and recorded as takes. This was largely due to a single pod of 15 dolphins sighted in the zone. Another 24 dolphins were observed over three survey days but they were not located in the Level B harassment zone. Prior to the issuance of the initial IHA, Dominion operated only during daylight hours under a Letter of Concurrence (LoC) issued by NMFS. As such, Dominion committed to shutting down whenever a marine mammal approached or entered a Level B harassment zone in order to avoid all incidental take. In the weeks prior to the issuance of the initial IHA, Dominion had observed pods containing up to 17 individuals in the Level B harassment zone. However, these pods were not recorded as incidental takes since mitigation measures were employed, *i.e.,* the acoustic source was shut down and the animals were not exposed to source levels associated with harassment. The estimated take in the initial IHA was based on the best available density data from Roberts *et al.* (2016, 2017, 2018), however, the multiple occurrences of the large pod in the vicinity of the survey was unexpected and not reflected in the take estimate. Table 1 shows spotted dolphin detection events when Dominion was operating under both the LoC (before August 28, 2020) as well as the initial IHA (on or after August 28, 2020).

TABLE 1—ATLANTIC SPOTTED DOLPHIN OBSERVATIONS DURING DOMINION ENERGY HRG SURVEY ACTIVITIES

Vessel name	Date of detection	Number of animals observed in the group	Level B takes accumulated
Sarah Bordelon	9/16/2020	15	15
Marcelle Bordelon	9/9/2020	4	4
Marcelle Bordelon	9/7/2020	6	

TABLE 1—ATLANTIC SPOTTED DOLPHIN OBSERVATIONS DURING DOMINION ENERGY HRG SURVEY ACTIVITIES—Continued

Vessel name	Date of detection	Number of animals observed in the group	Level B takes accumulated
Sarah Bordelon	9/4/2020	7	
Sarah Bordelon	9/4/2020	11	
Marcelle Bordelon	8/23/2020	5	
Sarah Bordelon	8/17/2020	17	

Given that large pods of spotted dolphin were recorded on multiple occasions, Dominion became concerned that the authorized number of takes by Level B harassment would be exceeded, necessitating the frequent shutdown of HRG survey equipment to avoid additional take of this species. On October 3, 2020, Dominion reached the authorized take amount for spotted dolphins. Since that time, they have been shutting down whenever spotted dolphins are sighted approaching or entering the harassment zone. Dominion now requests that NMFS authorize additional take of this species to conservatively allow 20 authorized takes per day. NMFS concurs that this take amount is reasonable in case observed dolphin pods are larger than what has been recorded to date. While NMFS does not expect that larger spotted dolphin pods would occur every day, it cannot be ruled out. With approximately 120 survey days remaining, NMFS is proposing to increase authorized spotted dolphin take by Level B harassment from 27 to 2,427 ((20 animals/day * 120 survey days) + initial 27 authorized takes). This represents 4.38 percent of the western North Atlantic stock of spotted dolphin. Take by Level A harassment was not requested, nor does NMFS anticipate it. NMFS did not authorize Level A harassment in the initial IHA and is not proposing to do so in this modified IHA.

The total numbers of incidental takes by Level B harassment, including proposed updated spotted dolphin takes, and as a percentage of population, is shown in Table 2 below.

TABLE 2—TOTAL NUMBERS OF AUTHORIZED TAKES BY LEVEL B HARASSMENT AND AS A PERCENTAGE OF POPULATION

Species	Totals	
	Take authorization (No.)	Instances of take as percentage of population [1]
Short-finned pilot whale	12	0.06
Bottlenose dolphin (Offshore)	511	0.81
Bottlenose dolphin (Southern Migratory Coastal)	224	6.5
Common dolphin	68	0.08
Atlantic white-sided dolphin	44	0.12
Spotted dolphin (adjusted)	2,427	4.38
Risso's dolphin	6	0.08
Harbor porpoise	39	0.09
Harbor seal [2]	35	0.02
Gray Seal [2]		0.06

[1] Calculations of percentage of stock taken are based on the best available abundance estimate as shown in Table 2 in **Federal Register** final notice of issuance of the IHA (85 FR 55415; September 8, 2020). In most cases the best available abundance estimate is provided by Roberts *et al.* (2016, 2017, 2018), when available, to maintain consistency with density estimates derived from Roberts *et al.* (2016, 2017, 2018. For bottlenose dolphins, Roberts *et al.* (2016, 2017, 2018) provides only a single abundance estimate and does not provide abundance estimates at the stock or species level (respectively), so abundance estimates used to estimate percentage of stock taken for bottlenose dolphins are derived from NMFS SARs (Hayes *et al.* 2019).

[2] Pinniped density values reported as "seals" and not species-specific.

Description of Mitigation, Monitoring and Reporting Measures

The mitigation, monitoring, and reporting measures described here are identical to those included in the **Federal Register** notice announcing the initial IHA and the discussion of the least practicable adverse impact included in that document remains accurate (85 FR 55415; September 8, 2020).

Establishment of Exclusion Zones (EZs)—Marine mammal EZs must be established around the HRG survey equipment and monitored by protected species observers (PSOs) during HRG surveys as follows:

- 500-m EZ is required for North Atlantic right whales;
- During use of the GeoMarine Dual 400 Sparker 800J, a 100-m EZ is required for all other marine mammals except delphinid(s) from the genera *Delphinus, Lagenorhynchus, Stenella* or *Tursiops* and seals; and
- When only the Triple Plate Boomer 1000J is in use, a 25-m EZ is required for all other marine mammals except delphinid(s) from the genera *Delphinus, Lagenorhynchus, Stenella* or *Tursiops* and seals; 200-m buffer zone is required for all marine mammals except those species otherwise excluded (*i.e.,* North Atlantic right whale).

If a marine mammal is detected approaching or entering the EZs during the survey, the vessel operator must adhere to the shutdown procedures described below. In addition to the EZs described above, PSOs must visually monitor a 200-m buffer zone for the purposes of pre-clearance. During use of acoustic sources with the potential to result in marine mammal harassment (*i.e.,* anytime the acoustic source is active, including ramp-up), occurrences of marine mammals within the monitoring zone (but outside the EZs) must be communicated to the vessel operator to prepare for potential shutdown of the acoustic source. The buffer zone is not applicable when the

EZ is greater than 100 m. PSOs are also required to observe a 500-m monitoring zone and record the presence of all marine mammals within this zone.

Visual Monitoring—Monitoring must be conducted by qualified protected PSOs who are trained biologists, with minimum qualifications described in the **Federal Register** notice of the issuance of the initial IHA (85 FR 55415; September 8, 2020). Dominion must have one PSO on duty during the day and has committed that a minimum of two NMFS-approved PSOs must be on duty and conducting visual observations when HRG equipment is in use at night. Visual monitoring must begin no less than 30 minutes prior to ramp-up of HRG equipment and continue until 30 minutes after use of the acoustic source. PSOs must establish and monitor the applicable EZs, Buffer Zone and Monitoring Zone as described above. PSOs must coordinate to ensure 360° visual coverage around the vessel from the most appropriate observation posts, and must conduct observations while free from distractions and in a consistent, systematic, and diligent manner. PSOs are required to estimate distances to observed marine mammals. It is the responsibility of the Lead PSO on duty to communicate the presence of marine mammals as well as to communicate action(s) that are necessary to ensure mitigation and monitoring requirements are implemented as appropriate.

Pre-Clearance of the Exclusion Zones—Prior to initiating HRG survey activities, Dominion must implement a 30-minute pre-clearance period. During pre-clearance monitoring (*i.e.,* before ramp-up of HRG equipment begins), the Buffer Zone also acts as an extension of the 100-m EZ in that observations of marine mammals within the 200-m Buffer Zone would also preclude HRG operations from beginning. During this period, PSOs must ensure that no marine mammals are observed within 200 m of the survey equipment (500 m in the case of North Atlantic right whales). HRG equipment must not start up until this 200-m zone (or, 500-m zone in the case of North Atlantic right whales) is clear of marine mammals for at least 30 minutes. The vessel operator must notify a designated PSO of the proposed start of HRG survey equipment as agreed upon with the lead PSO; the notification time must not be less than 30 minutes prior to the planned initiation of HRG equipment in order to allow the PSOs time to monitor the EZs and Buffer Zone for the 30 minutes of pre-clearance.

If a marine mammal is observed within the relevant EZs or Buffer Zone during the pre-clearance period, initiation of HRG survey equipment must not begin until the animal(s) has been observed exiting the respective EZ or Buffer Zone, or, until an additional time period has elapsed with no further sighting (*i.e.,* minimum 15 minutes for porpoises, and 30 minutes for all other species). The pre-clearance requirement includes small delphinoids. PSOs must also continue to monitor the zone for 30 minutes after survey equipment is shut down or survey activity has concluded.

Ramp-Up of Survey Equipment—When technically feasible, a ramp-up procedure must be used for geophysical survey equipment capable of adjusting energy levels at the start or re-start of survey activities. The ramp-up procedure must be used at the beginning of HRG survey activities in order to provide additional protection to marine mammals near the Survey Area by allowing them to detect the presence of the survey and vacate the area prior to the commencement of survey equipment operation at full power. Ramp-up of the survey equipment must not begin until the relevant EZs and Buffer Zone has been cleared by the PSOs, as described above. HRG equipment must be initiated at their lowest power output and would be incrementally increased to full power. If any marine mammals are detected within the EZs or Buffer Zone prior to or during ramp-up, the HRG equipment must be shut down (as described below).

Shutdown Procedures—If an HRG source is active and a marine mammal is observed within or entering a relevant EZ (as described above) an immediate shutdown of the HRG survey equipment is required. When shutdown is called for by a PSO, the acoustic source must be immediately deactivated and any dispute resolved only following deactivation. Any PSO on duty has the authority to delay the start of survey operations or to call for shutdown of the acoustic source if a marine mammal is detected within the applicable EZ. The vessel operator must establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the HRG source(s) to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch. Subsequent restart of the HRG equipment must only occur after the marine mammal has either been observed exiting the relevant EZ, or, until an additional time period has elapsed with no further sighting of the animal within the relevant EZ.

Upon implementation of shutdown, the HRG source may be reactivated after the marine mammal that triggered the shutdown has been observed exiting the applicable EZ (*i.e.,* the animal is not required to fully exit the Buffer Zone where applicable) or, following a clearance period of 15 minutes for small odontocetes and seals and 30 minutes for all other species with no further observation of the marine mammal(s) within the relevant EZ. If the HRG equipment shuts down for brief periods (*i.e.,* less than 30 minutes) for reasons other than mitigation (*e.g.,* mechanical or electronic failure) the equipment may be re-activated as soon as is practicable at full operational level, without 30 minutes of pre-clearance, only if PSOs have maintained constant visual observation during the shutdown and no visual detections of marine mammals occurred within the applicable EZs and Buffer Zone during that time. For a shutdown of 30 minutes or longer, or if visual observation was not continued diligently during the pause, pre-clearance observation is required, as described above.

The shutdown requirement is waived for certain genera of small delphinids (*i.e., Delphinus, Lagenorhynchus, Stenella (which includes Atlantic spotted dolphins),* or *Tursiops)* under certain circumstances. If a delphinid(s) from these genera is visually detected within the EZ shutdown would not be required. If there is uncertainty regarding identification of a marine mammal species (*i.e.,* whether the observed marine mammal(s) belongs to one of the delphinid genera for which shutdown is waived), PSOs must use best professional judgment in making the decision to call for a shutdown.

If a species for which authorization has not been granted, or a species for which authorization has been granted but the authorized number of takes have been met, approaches or is observed within the area encompassing the Level B harassment isopleth (100 m or 25 m), shutdown must occur.

Vessel Strike Avoidance—Dominion must comply with vessel strike avoidance measures as described in the **Federal Register** notice of the issuance of the initial IHA (85 FR 55415; September 8, 2020).

Seasonal Operating Requirements—Dominion will conduct HRG survey activities in the vicinity of the North Atlantic right whale Mid-Atlantic seasonal management area (SMA) near Norfolk and the mouth of the Chesapeake Bay. Activities conducted prior to May 1 must comply with the seasonal mandatory speed restriction period for this SMA (November 1 through April 30) for any survey work or transit within this area.

Throughout all phases of the survey activities, Dominion must monitor NOAA Fisheries North Atlantic right whale reporting systems for the establishment of a dynamic management area (DMA). If NMFS establishes a DMA in the Lease Area or cable route corridor being surveyed, within 24 hours of the establishment of the DMA, Dominion is required to work with NMFS to shut down and/or alter activities to avoid the DMA.

Training—Project-specific training is required for all vessel crew prior to the start of survey activities. Confirmation of the training and understanding of the requirements must be documented on a training course log sheet. Signing the log sheet will certify that the crew members understand and will comply with the necessary requirements throughout the survey activities.

Reporting—PSOs must record specific information on the sighting forms as described in the **Federal Register** notice of the issuance of the initial IHA (85 FR 55415; September 8, 2020). Within 90 days after completion of survey activities, Dominion must provide NMFS with a monitoring report which includes summaries of recorded takes and estimates of the number of marine mammals that may have been harassed.

In the event of a ship strike or discovery of an injured or dead marine mammal, Dominion must report the incident to the Office of Protected Resources, NMFS and to the New England/Mid-Atlantic Regional Stranding Coordinator as soon as feasible. The report must include the information listed in the **Federal Register** notice of the issuance of the initial IHA (85 FR 55415; September 8, 2020).

Based on our evaluation of the applicant's measures in consideration of the increased estimated take for spotted dolphins, NMFS has re-affirmed the determination that the required mitigation measures provide the means effecting the least practicable impact on spotted dolphins and their habitat.

Preliminary Determinations

Dominion's HRG survey activities and the mitigation, monitoring, and reporting requirements are unchanged from those covered in the initial IHA. The effects of the activity, taking into consideration the mitigation and related monitoring measures, remain unchanged from those stated in the initial IHA, notwithstanding the increase to the authorized amount of spotted dolphin take. Specifically, the Level B harassment authorized for spotted dolphins is expected to be of lower severity, predominantly in the form of avoidance of the sound source and potential occasional interruption of foraging. With approximately 120 survey days remaining, NMFS is proposing to increase authorized spotted dolphin take by Level B harassment to 2,427. Even in consideration of the increased estimated numbers of take by Level B harassment, the impacts of these lower severity exposures are not expected to accrue to the degree that the fitness of any individuals is impacted, and, therefore no impacts on annual rates of recruitment or survival will result. Further, and separately, the proposed take amount of spotted dolphin would be of small numbers of spotted dolphins relative to the population size (less than 5 percent), as take that is less than one third of the species or stock abundance is considered by NMFS to be small numbers. In conclusion, there is no new information suggesting that our effects analysis or negligible impact finding for Atlantic spotted dolphins should change.

Based on the information contained here and in the referenced documents, NMFS has preliminarily reaffirmed the following: (1) The required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the proposed authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the proposed authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) Dominion's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action, and (5) appropriate monitoring and reporting requirements are included.

Endangered Species Act (ESA)

No incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

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 modification of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the modified IHA qualifies to be categorically excluded from further NEPA review.

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.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to modify the IHA to Dominion for conducting marine site characterization surveys in the areas of the Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf Offshore Virginia (Lease No. OCS–A–0483) as well as in coastal waters where an export cable corridor will be established in support of the CVOW Commercial Project effective until August 27, 2021. The only change is an increase in the authorized take of Atlantic spotted dolphins from 27 to 2,427. A draft of the proposed modified IHA can be found at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable.*

Request for Public Comments

We request comment on our proposed modification of the IHA for Dominion's marine site characterization surveys. We also request comment on the potential for renewal of this modified IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform our final decision on the request for MMPA authorization or 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, or nearly identical, activities as described in the Description of the Proposed Activity and Anticipated Impacts section of this notice is planned or (2) the activities as described in the Description of the Proposed Activity and Anticipated Impacts 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 those described previously in 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: November 6, 2020.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2020–25034 Filed 11–10–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Gulf of Alaska Catcher Vessel and Processor Trawl (CVPT) Economic Data Report (EDR)

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on July 23, 2020 (85 FR 44523), during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Gulf of Alaska Catcher Vessel and Processor Trawl (CVPT) Economic Data Report (EDR).

OMB Control Number: 0648–0700.

Form Number(s): None.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 117.

Average Hours per Response: Annual Trawl Catcher Vessel EDR, 15 hours; Annual Shoreside Processor EDR, 15 hours.

Total Annual Burden Hours: 1,755 hours.

Needs and Uses: The National Marine Fisheries Services (NMFS), Alaska Regional Office, is requesting extension of the currently approved information collection for the Annual Trawl Catcher Vessel Economic Data Report (EDR) and the Annual Shoreside Processor EDR.

The EDRs collect economic data on the information for the Gulf of Alaska Trawl Groundfish Economic Data Report Program (GOA Trawl EDR Program). The Gulf of Alaska Trawl Groundfish Economic Data Report Program evaluates the economic effects of current and future groundfish management measures for Gulf of Alaska (GOA) trawl fisheries. This program provides NMFS and the North Pacific Fishery Management Council with baseline information on affected harvesters, crew, processors, and communities in the GOA. Data collected through the EDRs include labor information, revenues received, capital and operational expenses, and other operational or financial data. NMFS and the Council use this information to assess the impacts of major changes in the groundfish management regime, including catch share program implementation.

The Trawl Catcher Vessel EDR is submitted annually by owners or leaseholders of catcher vessels that harvest groundfish using trawl gear from the GOA or parallel fisheries. This EDR focuses on vessel identifiers, employment data, and variable cost data (associated with fuel usage and gear purchases). The Shoreside Processor EDR is submitted annually by owners or leaseholders of shoreside processors or stationary floating processors that receive deliveries from vessels that harvest groundfish using trawl gear from the GOA or parallel fisheries. This EDR focuses on employment and labor costs and for processors located in Kodiak, utility consumption and cost.

Requirements for the EDRS are located at 50 CFR 679.110.

Affected Public: Individuals or households; Business or other for-profit organizations; Not-for-profit institutions.

Frequency: Annually.

Respondent's Obligation: Mandatory.

Legal Authority: Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*).

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

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0700.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–25040 Filed 11–10–20; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2020–0035]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (Bureau) is publishing this notice seeking comment on a Generic Information Collection titled, ''Payday Loan Disclosure Testing'' under the Generic Information Collection Plan entitled, ''Generic Information Collection Plan for the

Development and Testing of Disclosures and Related Materials'' prior to requesting the Office of Management and Budget's (OMB's) approval of this collection.

DATES: Written comments are encouraged and must be received on or before December 14, 2020 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PRA_Comments@cfpb.gov.* Include Docket No. CFPB–2020–0035 in the subject line of the message.
- *Mail/Hand Delivery/Courier:* Comment intake, Bureau of Consumer Financial Protection (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552.

Please note that due to circumstances associated with the COVID–19 pandemic, the Bureau discourages the submission of comments by mail, hand delivery, or courier. Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to Suzan Muslu, Data Governance Program Manager, at (202) 435 –9267, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION: *Title of Collection:* Payday Loan Disclosure Testing.

OMB Control Number: 3170–0022.

Type of Review: Request for approval of a generic information collection under an existing Generic Information Collection Plan.

Affected Public: Individuals and Households.

Estimated Number of Respondents: 400.

Estimated Total Annual Burden Hours: 74.

Abstract: The Bureau has hired a contractor to conduct one-on-one consumer interviews with participants to evaluate and refine potential options for a Bureau-designed payday loan disclosure.

Through this research effort, the Bureau aims to build upon previous academic research on payday disclosures and create disclosures that present key information clearly and effectively. The Bureau will collect information on how consumers locate, comprehend, and use information in the disclosures. Respondents will review disclosure forms and be asked questions about their impressions of the form, comprehension of information presented, usability, and decision making. Usability questions will focus on the impressions consumers take away from the form given the content and layout of the form. Decision making questions will focus on how participants use the information given to assess the cost, payment, and timing of the loan.

The results of this testing (estimated to conclude September 2021) may be used, along with other Bureau considerations, to inform the decision-making process around whether to move forward with a rulemaking related to payday loan disclosures.

Request for Comments: The Bureau is publishing this notice and soliciting comments on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be submitted to OMB as part of its review of this request. All comments will become a matter of public record.

Dated: November 5, 2020.

Suzan Muslu,

Data Governance Program Manager, Bureau of Consumer Financial Protection.

[FR Doc. 2020–24995 Filed 11–10–20; 8:45 am]

BILLING CODE 4810–AM–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Package for Disaster Response Cooperative Agreement

AGENCY: Corporation for National and Community Service (CNCS).

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, CNCS is proposing to renew an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 11, 2021.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, Attention: Luke Wigle, 250 E Street SW, Washington, DC 20525.

(2) By hand delivery or by courier to the CNCS mailroom at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except federal holidays.

(3) Electronically through *www.regulations.gov.*

Comments submitted in response to this notice may be made available to the public through *regulations.gov.* For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Luke Wigle, 202–409–4791, or by email at *lwigle@cns.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Application Package for Renewal of the Disaster Response Cooperative Agreement.

OMB Control Number: 3045–0133.

Type of Review: Renewal.

Respondents/Affected Public: Businesses and Organizations.

Total Estimated Number of Annual Responses: 100.

Total Estimated Number of Annual Burden Hours: 3,960.

Abstract: CNCS, operating as AmeriCorps, seeks renewal of the current information collection pursuant to the Domestic Volunteer Service Act of 1973 (42 U.S.C. 4950 *et seq.*) and the National and Community Service Act of 1990 (42 U.S.C. 12501 *et seq.*) The information collected will be used to help CNCS more effectively utilize its deployable resources to meet the needs of disaster affected communities. A better understanding of the participating programs will allow CNCS to match the capabilities of the programs to the needs of the communities and will allow better asset mapping and resource typing. Additionally, the information collected will allow CNCS to conduct better outreach to interested programs by providing them with more information about CNCS disaster procedures, reimbursement requirements, and support services offered.

The revisions are intended to streamline the application process and ensure interested programs meet the appropriate programmatic and fiscal requirements to successfully execute disaster response activities. Additionally, the supporting forms will help CNCS identify and deploy programs more effectively and efficiently, matching the capabilities of the programs to the needs of the communities requesting assistance. The additional tools and forms under the DRCA will allow for effective information collection during a disaster event as well as assess the capacity of all DRCA programs throughout the year. Information will be collected electronically through completion of the forms and emailed to CNCS. The information collection will otherwise be used in the same manner as the existing application.

CNCS also seeks to continue using the current application until the revised application is approved by OMB. The current application is due to expire on March 30, 2021.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on *regulations.gov.*

Dated: October 28, 2020.

Jacob Sgambati,

Acting Deputy Director, AmeriCorps NCCC.

[FR Doc. 2020–24945 Filed 11–10–20; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Extension of Public Comment Period for the Interim Report for the Buffalo Bayou and Tributaries, Texas Resiliency Study

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

ACTION: Notice of extension.

SUMMARY: A notice of availability was published in the **Federal Register** by the U.S. Army Corps of Engineers (USACE) on October 2, 2020 for the Buffalo Bayou and Tributaries, Texas Resiliency Study (BBTRS) notifying the public an Interim Report was available for review and comment. The notice indicated the review period was to conclude on November 2, 2020. Four virtual public meetings were held in October 2020 in an effort to provide the public with an overview of Interim Report and answer questions about the study and alternatives considered. In response to several requests for extension, this notice announces an extension of the public comment period to November 20, 2020. No additional public meetings have been scheduled during the extension period.

DATES: This notice announces an 18-day extension of the public comment period. Written comments on the Interim Report must be received by email or post-marked by November 20, 2020.

ADDRESSES: The Interim Report and additional pertinent information about the study can be found at: *https://www.swg.usace.army.mil/Missions/Projects/BBTRS/.* Written comments may be mailed to USACE, Galveston District, ATTN: BBTRS, P.O. Box 1229, Galveston, TX, 77553–1229 or submitted electronically by email to *BBTRS@usace.army.mil.*

FOR FURTHER INFORMATION CONTACT: Ms. Shelby Scego, USACE, Regional Planning and Environmental Center, at 918–669–7423 or *BBTRS@usace.army.mil.*

SUPPLEMENTARY INFORMATION:

1. *Background.* USACE, in partnership with the Harris County Flood Control District (HCFCD), as the non-Federal sponsor, began a feasibility study in 2018 to identify, evaluate, and recommend actions to reduce flood risks along Buffalo Bayou and its tributaries, both upstream and downstream of Addicks and Barker dams. The study will also complete a Dam Safety Modification Evaluation on Addicks and Barker dams. The BBTRS is authorized under Section 216 of the Flood Control Act of 1970 (Pub. L. 91–611) and existing project authority. Section 216 authorizes USACE to review a completed navigation, flood risk reduction, water supply, or related project due to significantly changed physical or economic conditions, and to report to Congress with recommendations regarding modification of the project's structures or operation, and for improving the quality of the environment in the overall public interest.

2. *Interim Report.* On October 2, 2020, the USACE released an Interim Report for the study. The Interim Report presents alternatives that could reduce the risk of flooding in the Buffalo Bayou, Addicks Reservoir, Barker Reservoir, and upper Cypress Creek watersheds in Harris, Fort Bend, and Waller counties, Texas. The report also evaluates alternatives for dam safety modifications to the Addicks and Barker dams. The report does not identify a preferred alternative nor does it make any recommendations or decisions.

The Interim Report is an added step to the feasibility study process and is intended to explain updated

information, present the focused array of alternatives, and seek public feedback that will inform the next level of evaluation to identify a Tentatively Selected Plan (TSP). The TSP may be a single alternative or comprised of several alternatives from the focused array under consideration.

Note: This is not a Notice of Extension associated with the release of a Draft Environmental Impact Statement (EIS) in accordance with the National Environmental Policy Act. This is an interim step intended to gather public feedback before a Draft EIS is released.

3. *Solicitation of Comments:* The USACE is soliciting comments on the Interim Report from the public, Federal, State, and local agencies, elected officials, Tribal Nations, and other interested parties. The public comment period initially began on October 2, 2020, but has been extended to November 20, 2020. Public comments may be submitted by email or through postal mail at the addresses provided above.

4. *Public Participation and Meetings:* Four virtual public meetings were held in October 2020. Over 450 people participated in the virtual meetings, which included an overview of the alternatives being considered and a question and answer session. No additional public meetings are scheduled during the extension period.

5. *Identification of Tentatively Selected Plan and Availability of Draft EIS.* Depending on input received on the Interim Report, USACE estimates issuing a Draft Feasibility Report and Draft Environmental Impact Statement for public review and comment in early 2021. At that time, USACE will provide a 45-day public review period, in accordance with the National Environmental Policy Act (NEPA). USACE will notify all interested agencies, organizations, and individuals of the availability of the draft document at that time.

Pete G. Perez,

Director, Programs Directorate.

[FR Doc. 2020–24969 Filed 11–10–20; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the U.S. Naval Academy Board of Visitors

AGENCY: Department of the Navy, U.S. Department of Defense (DoD).

ACTION: Notice of partially closed meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the U.S. Naval Academy Board of Visitors, hereafter ''Board,'' will take place.

DATES: Open to the public, December 7, 2020, from 9 a.m. to 11 a.m. Closed to the public, December 7, 2020, from 11 a.m. to noon (12 p.m.).

ADDRESSES: This meeting will be held at the United States Naval Academy in Annapolis, MD. The meeting will be handicap accessible. Escort is required.

FOR FURTHER INFORMATION CONTACT: Major Raphael Thalakottur, USMC, Executive Secretary to the Board of Visitors, Office of the Superintendent, U.S. Naval Academy, Annapolis, MD 21402–5000, 410–293–1503, *thalakot@usna.edu,* or visit *https://www.usna.edu/PAO/Superintendent/bov.php.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), the General Services Administration's (GSA) Federal Advisory Committee Management Final Rule (41 CFR part 102–3).

Purpose of Meeting: The U.S. Naval Academy Board of Visitors will meet to make such inquiry, as the Board deems necessary, into the state of morale and discipline, the curriculum, instruction, physical equipment, fiscal affairs, and academic methods of the Naval Academy.

Agenda: Proposed meeting agenda for December 7, 2020.

0830–0900 Assemble
0900 Call to Order
0900–1055 Business Session
1055–1100 Break
1100–1200 Executive Session (Closed to Public)

Current details on the board of visitors may be found at *https://www.usna.edu/PAO/Superintendent/bov.php.*

The executive session of the meeting from 11:00 a.m. to 12:00 p.m. on December 7, 2020, will consist of discussions of new and pending administrative or minor disciplinary infractions and non-judicial punishments involving midshipmen attending the Naval Academy, to include but not limited to, individual honor or conduct violations within the Brigade, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. For this reason, the executive session of this meeting will be closed to the public, as the discussion of such information cannot be adequately segregated from other topics, which precludes opening the executive session of this meeting to the public. Accordingly, the Secretary of the Navy, in consultation with the Department of the Navy General Counsel, has determined in writing that the meeting shall be partially closed to the public because the discussions during the executive session from 11 a.m. to noon (12 p.m.) will be concerned with matters protected under sections 552b(c) (5), (6), and (7) of title 5, United States Code.

Authority: 5 U.S.C. 552b.

Meeting Accessibility: Pursuant to FACA and 41 CFR 102–3.140, this meeting is open to the public. Any public attendance at the meeting will be governed by prevailing health directives at the United States Naval Academy. Please contact the Executive Secretary five business days prior the meeting to coordinate required medical screenings and access to the meeting.

Written Statements: Per Section 10(a)(3) of the FACA and 41 CFR 102–3.105(j) and 102–3.140, interested persons may submit a written statement for consideration at any time, but should be received by the Designated Federal Officer at least 15 business days prior to the meeting date so that the comments may be made available to the Board for their consideration prior to the meeting. Written statements should be submitted via mail to 121 Blake Rd., Annapolis, MD 21402. Please note that since the Board operates under the provisions of the FACA, as amended, all submitted comments and public presentations will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the board website.

Dated: November 5, 2020.

K.R. Callan,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2020–24959 Filed 11–10–20; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0174]

Agency Information Collection Activities; Comment Request; Work Colleges Expenditure Report

AGENCY: Department of Education (ED), Federal Student Aid.

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 January 11, 2021.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0174. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, (202) 337–4018.

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: Work Colleges Expenditure Report.

OMB Control Number: 1845–0152.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 10.

Total Estimated Number of Annual Burden Hours: 20.

Abstract: The Higher Education Opportunity Act, Public Law 110–315 includes provisions for the Higher Education Act of 1965, as amended, in section 448 that promotes the use of comprehensive work-learning-service programs as a valuable education approach when it is an integral part of the institution's education program and a part of a financial plan which decreases reliance on grants and loans. Work Colleges participants are required to report expenditure of funds annually. The data collected is in this report is used by the Department to monitor program effectiveness and accountability of fund expenditures. The data is used in conjunction with institutional program reviews to assess the administrative capability and compliance of the applicant. There are no other resources for collecting this data.

Dated: November 6, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2020–24992 Filed 11–10–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG21–20–000.
Applicants: Beowawe Power, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Beowawe Power, LLC.
Filed Date: 11/5/20.
Accession Number: 20201105–5071.
Comments Due: 5 p.m. ET 11/27/20.

Docket Numbers: EG21–21–000.
Applicants: Cameron Ridge, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Cameron Ridge, LLC.
Filed Date: 11/5/20.
Accession Number: 20201105–5078.
Comments Due: 5 p.m. ET 11/27/20.

Docket Numbers: EG21–22–000.
Applicants: Cameron Ridge II, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Cameron Ridge II, LLC.
Filed Date: 11/5/20.
Accession Number: 20201105–5096.
Comments Due: 5 p.m. ET 11/27/20.

Docket Numbers: EG21–23–000.
Applicants: DifWind Farms LTD VI.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of DifWind Farms LTD VI.
Filed Date: 11/5/20.
Accession Number: 20201105–5099.
Comments Due: 5 p.m. ET 11/27/20.

Docket Numbers: EG21–24–000.
Applicants: Terra-Gen Dixie Valley, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Terra-Gen Dixie Valley, LLC.
Filed Date: 11/5/20.
Accession Number: 20201105–5100.
Comments Due: 5 p.m. ET 11/27/20.

Docket Numbers: EG21–25–000.
Applicants: Garnet Wind, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Garnet Wind, LLC.
Filed Date: 11/5/20.
Accession Number: 20201105–5103.
Comments Due: 5 p.m. ET 11/27/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER03–1001–003.
Applicants: Galt Power, Inc.
Description: Notice of Change in Status of Galt Power, Inc.
Filed Date: 10/30/20.
Accession Number: 20201030–5467.
Comments Due: 5 p.m. ET 11/20/20.

Docket Numbers: ER17–105–007; ER09–1196–003; ER10–1362–007; ER11–3959–009; ER12–2639–010; ER12–726–008; ER15–1019–008; ER17–104–007; ER17–556–005; ER18–2158–002.
Applicants: Broadview Energy JN, LLC, Broadview Energy KW, LLC, Grady

Wind Energy Center, LLC, Fowler Ridge IV Wind Farm LLC, Hatchet Ridge Wind, LLC, Spring Valley Wind LLC, Ocotillo Express LLC, Lost Creek Wind, LLC, Post Rock Wind Power Project, LLC, Stillwater Wind, LLC.

Description: Notice of Change in Status of Broadview Energy JN, LLC, et. al.

Filed Date: 10/30/20.

Accession Number: 20201030–5466.

Comments Due: 5 p.m. ET 11/20/20.

Docket Numbers: ER19–1781–001.

Applicants: MeterGenius, Inc.

Description: Notice of Change in Status of MeterGenius, Inc.

Filed Date: 10/30/20.

Accession Number: 20201030–5468.

Comments Due: 5 p.m. ET 11/20/20.

Docket Numbers: ER21–317–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original WMPA 5845; Queue No. AF1–300 to be effective 10/7/2020.

Filed Date: 11/4/20.

Accession Number: 20201104–5075.

Comments Due: 5 p.m. ET 11/25/20.

Docket Numbers: ER21–318–000.

Applicants: Morgantown Steam, LLC.

Description: § 205(d) Rate Filing: Supplemental Notice of Succession to be effective 8/4/2020.

Filed Date: 11/4/20.

Accession Number: 20201104–5078.

Comments Due: 5 p.m. ET 11/25/20.

Docket Numbers: ER21–319–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original ISA No. 5822; Queue No. AE1–143 to be effective 10/7/2020.

Filed Date: 11/4/20.

Accession Number: 20201104–5085.

Comments Due: 5 p.m. ET 11/25/20.

Docket Numbers: ER21–320–000.

Applicants: San Diego Gas & Electric Company.

Description: Informational Filing of Transmission Owner Rate Appendix XII [Cycle 3] of San Diego Gas & Electric Company.

Filed Date: 10/30/20.

Accession Number: 20201030–5458.

Comments Due: 5 p.m. ET 11/20/20.

Docket Numbers: ER21–322–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original WMPA, Service Agreement No. 5835; Queue No. AF2–288 to be effective 10/6/2020.

Filed Date: 11/5/20.

Accession Number: 20201105–5033.

Comments Due: 5 p.m. ET 11/27/20.

Docket Numbers: ER21–323–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original WMPA SA No. 5842; Queue No. AF2–286 to be effective 10/6/2020.

Filed Date: 11/5/20.

Accession Number: 20201105–5066.

Comments Due: 5 p.m. ET 11/27/20.

Docket Numbers: ER21–324–000.

Applicants: Public Service Company of New Mexico.

Description: Compliance filing: Refund Report in response to Audit in Docket No. PA18–1–000 to be effective N/A.

Filed Date: 11/5/20.

Accession Number: 20201105–5070.

Comments Due: 5 p.m. ET 11/27/20.

Docket Numbers: ER21–325–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original WMPA SA No. 5843; Queue No. AF2–287 to be effective 10/6/2020.

Filed Date: 11/5/20.

Accession Number: 20201105–5072.

Comments Due: 5 p.m. ET 11/27/20.

Docket Numbers: ER21–326–000.

Applicants: Direct Energy Business Marketing, LLC.

Description: Compliance filing: Report Regarding a Spot Market Sale of Electric in WECC to be effective N/A.

Filed Date: 11/5/20.

Accession Number: 20201105–5091.

Comments Due: 5 p.m. ET 11/27/20.

Docket Numbers: ER21–327–000.

Applicants: Commonwealth Edison Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: ComEd submits IA No. 5742 to be effective 10/29/2020.

Filed Date: 11/5/20.

Accession Number: 20201105–5097.

Comments Due: 5 p.m. ET 11/27/20.

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: November 5, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–25002 Filed 11–10–20; 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:

Docket Numbers: RP21–196–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: TETLP Cleanup Filing—LINK URL Conversion to be effective 12/4/2020.

Filed Date: 11/4/20.

Accession Number: 20201104–5022.

Comments Due: 5 p.m. ET 11/16/20.

Docket Numbers: RP21–197–000.

Applicants: Rover Pipeline LLC.

Description: § 4(d) Rate Filing: Summary of Negotiated Rate Capacity Release Agreements on 11–4–20 to be effective 11/4/2020.

Filed Date: 11/4/20.

Accession Number: 20201104–5032.

Comments Due: 5 p.m. ET 11/16/20.

Docket Numbers: RP21–198–000.

Applicants: Natural Gas Pipeline Company of America.

Description: § 4(d) Rate Filing: Filing-Amendment to a Negotiated Rate Agreement—Tenaska Marketing Ventures to be effective 11/5/2020.

Filed Date: 11/4/20.

Accession Number: 20201104–5084.

Comments Due: 5 p.m. ET 11/16/20.

Docket Numbers: RP21–199–000.

Applicants: NEXUS Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—DTE to Eco-Energy 961275 eff 11–05–20 to be effective 11/5/2020.

Filed Date: 11/4/20.

Accession Number: 20201104–5086.

Comments Due: 5 p.m. ET 11/16/20.

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 date(s). Protests may be considered, but intervention is

necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 5, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–25005 Filed 11–10–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–14–000]

NextEra Energy, Inc.; American Electric Power Company, Inc.; Evergy, Inc.; Exelon Corporation; Xcel Energy Services Inc.; Notice of Petition for Declaratory Order

Take notice that on October 30, 2020, NextEra Energy, Inc., American Electric Power Company, Inc., Evergy, Inc., Exelon Corporation, and Xcel Energy Services Inc. (Petitioners) submitted a petition for declaratory order seeking to resolve two issues arising in the wake of Order Nos. 860 and 860–A,[1] as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

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://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 Eergency 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.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern time on November 30, 2020.

Dated: November 5, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–25001 Filed 11–10–20; 8:45 am]

BILLING CODE 6717–01–P

[1] *Data Collection for Analytics & Surveillance & Mkt.-Based Rate Purposes,* Order No. 860, 168 FERC 61,039 (2019), *order on reh'g and clarification,* Order No. 860–A, 170 FERC 61,129 (2020).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2020–0521; FRL–10016–49–OLEM]

Proposed Information Collection Request; Comment Request; Survey of State Emergency Response Commissions (SERCs)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), ''Survey of State Emergency Response Commissions (SERCs)'' (EPA ICR No. 2660.01, OMB Control No. 2050-new) 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 request for approval of a new collection. 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 January 11, 2021.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OLEM–2020–0521, 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: Sicy Jacob, Regulations Implementation Division, Office of Emergency Management, Mail Code 5104A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–8019; email address: *jacob.sicy@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 information collection request (ICR). The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate 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: The EPA's Office of Emergency Management is conducting a survey of the State Emergency Response Commissions (SERCs) of each State and territories of the U.S. The SERCs were created under the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986. The purpose of this survey is to gather information on how EPCRA is being implemented, best practices, challenges, and gaps in meeting the requirements. After the survey is completed, EPA is planning to publish the results of the survey, including success stories and lessons learned to share with all states and territories.

EPCRA established State Emergency Response Commissions (SERCs) and Local Emergency Planning Committees (LEPCs) and assigned implementation responsibilities to these state and local agencies. EPCRA required SERCs to appoint LEPCs [1] within a few months after the enactment of EPCRA and to supervise their activities. Importantly, SERCs should ensure that LEPCs develop local emergency response plans for their community, review the plans, and make suggestions to coordinate the plans with neighboring LEPCs. In addition, SERCs are required to collect and manage hazardous chemical information from facilities and to provide access to the public on the presence of hazardous chemicals in the community.

In response to the deadly explosion at a fertilizer distribution facility in West Texas, Executive Order (E.O.) 13650 was signed, which directed the federal government to improve the safety and security of chemical facilities and reduce the risks of hazardous chemicals to workers and communities. One of the key components of the E.O. was to strengthen the state and local infrastructure created by EPCRA for emergency planning and preparedness. EPA published additional guidance documents, and developed on-line training for states, tribes and local agencies to implement EPCRA to protect their community and first responders.

As part of the America's Water Infrastructure Act (AWIA),[2] promulgated in October 2018, additional coordination and provision of information responsibilities were established for SERCs and LEPCs under EPCRA. Specifically, these EPCRA amendments establish notification and information coordination with State Drinking Water Agency and Community Water Systems to ensure that these agencies prepare and protect the community from contamination of their water.

The data collected in this survey will inform the Agency about how SERCs are fulfilling the requirements of the law, specifically in sharing key information among all appropriate State organizations and managing LEPCs and their activities. Additionally, the results of the survey will help to identify areas where SERCs are having difficulty meeting their requirements, the specific challenges they are facing, and will identify areas where EPA can better assist SERCs and LEPCs in implementing EPCRA and its amendments under AWIA.

Form Numbers: None.

Respondents/affected entities: Respondents to this voluntary ICR are State Emergency Response Commissions (SERCs).

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: Approximately 56 (total).

Frequency of response: Once.

Total estimated burden: 4 Hours/respondent, 224 hours total. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $284/respondent, $15,904 total, includes $0 annualized capital or operation & maintenance costs.

Reggie Cheatham,

Director, Office of Emergency Management.

[FR Doc. 2020–24998 Filed 11–10–20; 8:45 am]

BILLING CODE 6560–50–P

[1] Approximately, 3,000 LEPCs were established within few months after the enactment of EPCRA.

[2] The America's Water Infrastructure Act (AWIA) amended the emergency release notification and the hazardous chemical inventory provisions of the 1986 legislation. The amendments require the SERCs to provide immediate notification to the State Drinking Water Primacy Agency or the Community Water Systems where there is no primacy agency. The amendment to the hazardous chemical inventory provisions require the SERCs and LEPCs to provide access to the ''Tier II'' information upon request by the community water systems.

FARM CREDIT ADMINISTRATION

Sunshine Act Meeting; Farm Credit Administration Board

AGENCY: Farm Credit Administration.

ACTION: Notice, regular meeting.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act, of the forthcoming regular meeting of the Farm Credit Administration Board.

DATES: *Date and Time:* The regular meeting of the Board will be held November 19, 2020, from 9:00 a.m. until such time as the Board may conclude its business. *Note: Because of the COVID–19 pandemic, we will conduct the board meeting virtually. If you would like to observe the open portion of the virtual meeting, see instructions below for board meeting visitors.*

Attendance: To observe the virtual meeting, go to FCA.gov, select ''Newsroom,'' then ''Events.'' There you will find a description of the meeting and a link to ''Instructions for board meeting visitors.'' See **SUPPLEMENTARY INFORMATION** for further information about attendance requests.

Contact: Dale Aultman, Secretary to the Farm Credit Administration Board (703) 883–4009. TTY is (703) 883–4056.

SUPPLEMENTARY INFORMATION: This meeting of the Board will be open to the public. If you wish to observe, follow the instructions above in the ''Attendance'' section at least 24 hours before the meeting. If you need assistance for accessibility reasons or if you have any questions, contact Dale Aultman, Secretary to the Farm Credit Administration Board, at (703) 883–4009. The matters to be considered at the meeting are as follows:

Open Session

A. *Approval of Minutes*

- October 8, 2020

B. *Reports*

- Funding Corporation Activities
- USDA's Beginning Farmers and Ranchers Lending Summit

New Business

- Farm Credit System Building Association 2021 Budget and Assessments

Dated: November 9, 2020.

Dale Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2020–25120 Filed 11–9–20; 4:15 pm]

BILLING CODE 6705–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FRS 17226]

Federal Advisory Committee Act; Communications Security, Reliability, and Interoperability Council

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC or Commission) Communications Security, Reliability, and Interoperability Council (CSRIC) VII will hold its seventh meeting via live internet link.

DATES: December 9, 2020.

ADDRESSES: The Meeting will be held via conference call and available to the public via WebEx at *http://www.fcc.gov/live.*

FOR FURTHER INFORMATION CONTACT: Suzon Cameron, Designated Federal Officer, (202) 418–1916 (voice) or *CSRIC@fcc.gov* (email); or, Kurian Jacob, Deputy Designated Federal Officer, (202) 418–2040 (voice) or *CSRIC@fcc.gov* (email).

SUPPLEMENTARY INFORMATION: The meeting on December 9, 2020, from 1:00 p.m. EDT to 5:00 p.m. EST will be held electronically only and may be viewed live, by the public, at *http://www.fcc.gov/live.* Any questions that arise during the meeting should be sent to *CSRIC@fcc.gov* and will be answered at a later date. The meeting is being held in a wholly electronic format in light of travel and gathering restrictions related to COVID–19 in place in Washington, DC, and the larger U.S., which affect members of CSRIC and the FCC.

The CSRIC is a Federal Advisory Committee that will provide recommendations to the FCC to improve the security, reliability, and interoperability of communications systems. On March 15, 2019, the FCC, pursuant to the Federal Advisory Committee Act, renewed the charter for CSRIC VII for a period of two years through March 14, 2021. The meeting on December 9, 2020, will be the seventh meeting of CSRIC VII under the current charter.

The Commission will provide audio and/or video coverage of the meeting over the internet from the FCC's web page at *http://www.fcc.gov/live.* The public may submit written comments before the meeting to Suzon Cameron, CSRIC VII Designated Federal Officer, by email to *CSRIC@fcc.gov.*

Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (tty). Such requests should include a detailed description of the accommodation needed. In addition, please include a way the FCC can contact you if it needs more information. Please allow at least five days' advance notice; last-minute requests will be accepted but may be impossible to fill.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2020–25015 Filed 11–10–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 20–1269; FRS 17229]

Media Bureau Lifts Freeze on the Filing of Television Station Minor Modification Applications and Rulemaking Petitions

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces that, effective [insert date], the Media Bureau is lifting the freezes on petitions for rulemaking to change channels in the DTV Table of Allotments, petitions for rulemaking for new DTV allotments, petitions for rulemaking to change communities of license, including changes in technical parameters, and modification applications that increase a full power or Class A station's service area beyond an area that is already served..

DATES: The filing freezes will be lifted effective November 12, 2020.

FOR FURTHER INFORMATION CONTACT: Joyce L. Bernstein, Video Division, Media Bureau, Federal Communications Commission, *Joyce.Bernstein@fcc.gov,* (202) 418–1645.

SUPPLEMENTARY INFORMATION: The Media Bureau announces that, effective fifteen days after publication of this Public Notice, it is lifting the freezes it imposed in 2004, in connection with the DTV Transition, on the filing of certain full power and Class A television station minor modification applications and full power television station rulemaking petitions to amend the DTV Table Allotments. Over the course of the following years, the Bureau extended the freezes to further ensure its database remained stable in connection with the incentive auction and repacking process. With the 2009 completion of the DTV transition and the July 13, 2020 completion of the post-incentive auction transition period, these freezes are no longer required. Accordingly, the Media Bureau deems it appropriate to lift the freezes on petitions for rulemaking to change channels in the DTV Table of Allotments, petitions for rulemaking for new DTV allotments, petitions for rulemaking to change communities of license, including changes in technical parameters, and modification applications that increase a full power or Class A station's service area beyond an area that is already served. The Public Notice also includes filing instructions for interested parties.

The freeze on the filing of applications for new LPTV/translator digital stations and major changes remains in effect.

This action is taken by the Chief, Video Division, Media Bureau pursuant to authority delegated by 47 CFR 0.283 of the Commission's rules.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

[FR Doc. 2020–24996 Filed 11–10–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FRS 17223]

Radio Broadcasting Services; AM or FM Proposals To Change The Community of License

AGENCY: Federal Communications Commission.

ACTION: Notice.

DATES: The agency must receive comments on or before January 11, 2021.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, 202–418–2054.

SUPPLEMENTARY INFORMATION: The following applicants filed AM or FM proposals to change the community of license: ALEXANDER BROADCASTING, INC., WRCR(AM), Fac. ID No. 64556, FROM: RAMAPO, NY, TO: HAVERSTRAW, NY, BP–20200813AAK; BUSTOS MEDIA

HOLDINGS, LLC, KZTM(FM), Fac. ID No. 33829, FROM: CENTRALIA, WA, TO: MCKENNA, WA, File No. 0000121551; FAMILY LIFE MINISTRIES, INC., WCGT(FM), Fac. ID No. 172665, FROM: TIDIOUTE, PA, TO: CLINTONVILLE, PA, File No. 0000124533; FAMILY LIFE MINISTRIES, INC., WCOT(FM), Fac. ID No. 20653, FROM: JAMESTOWN, NY, TO: TIDIOUTE, PA, File No. 0000124532; PRAISE COMMUNICATIONS, INC, WTUA(FM), Fac. ID No. 23895, FROM: PINOPOLIS, SC, TO: ST. STEPHEN, SC, File No. 0000125220, and OMNI BROADCASTING, LLC, WTKP(FM), Fac. ID No. 67579, FROM: PORT ST. JOE, FL, TO: YOUNGSTOWN, FL, File No. 0000124529. The full text of these applications is available electronically via the Media Bureau's Consolidated Data Base System, *https://licensing.fcc.gov/prod/cdbs/pubacc/prod/app_sear.htm* or Licensing and Management System (LMS), *https://apps2int.fcc.gov/dataentry/public/tv/publicAppSearch.html.*

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 2020–24961 Filed 11–10–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments 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 November 27, 2020.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Laurie Lewis Saunders, John T. Saunders III, Steve C. Lewis, Richard S. Lewis II, A.J. Lewis III, A.J. Lewis, IV, Frances M. Lewis, and Sallie W. Lewis, all of San Antonio, Texas; all individually, and as trustee or voting appointee for one or more of the following trusts:* the Laurie Lewis Saunders Family 2007 Trust One, the Laurie Lewis Saunders Family 2007 Trust Two, the A.J. Lewis Jr. Trust FBO Laurie Lewis Saunders, the Peggy W. Lewis Article III GST Exempt Trust FBO Laurie Lewis Saunders, the Christina M. Saunders Trust, the John T. Saunders III Trust, the Virginia G. Saunders Trust, the Steve C. Lewis Family 2007 Trust One, the Steve C. Lewis Family 2007 Trust Two, the A.J. Lewis, Jr. Trust FBO Steve C. Lewis, the Peggy W. Lewis Article III GST Exempt Trust FBO Steve C. Lewis, the Barclay C. Adams Grantor Trust, the Richard S. Lewis II Grantor Trust, the Adams Family 2019 GST—Exempt Trust, the Richard S. Lewis 11 Family 2018 Trust, the A.J. Lewis III Family 2007 Trust One, the A.J. Lewis III Family Trust Two, the A.J. Lewis, Jr. Trust FBO A.J. Lewis III, the Peggy W. Lewis Article III GST Exempt Trust FBO A.J. Lewis III, the Frances Marguerite Lewis Grantor Trust, the A.J. Lewis IV Grantor Trust, the Sallie Wolff Lewis Grantor Trust, the A.J. Lewis IV Family Trust One, the A.J. Lewis IV Family Trust Two, the Frances M. Lewis Family Trust One, the Frances M. Lewis Family Trust Two, the Sallie W. Lewis Family Trust One, the Sallie W. Lewis Family Trust Two, all of San Antonio Texas, and

Susan C. Lewis, Christina M. Saunders, Barclay C. Adams, all of San Antonio, Texas; and Kenneth S. Adams IV, Nashville, Tennessee; to become members of the Lewis Family Group, a group acting in concert, to retain the voting shares of Jefferson Bancshares, Inc., and thereby indirectly retain the voting shares of Jefferson Bank, both of San Antonio, Texas.

2. *Paul E. McSween III, Linda Lewis McSween, Juliet McSween Zacher, Jennifer McSween Canavan, Linda McSween Satel, all of San Antonio, Texas; all individually, and as grantor, trustee, or voting appointee for one or more of the following trusts:* the Paul E. McSween III Family 2011 Trust One, the Paul E. McSween III Family 2011 Trust Two, the Paul E. McSween IV Grantor Trust, the Thomas D. McSween Grantor Trust, the Benjamin Lewis McSween Grantor Trust, the Linda Lewis McSween Trust, the Jennifer McSween Canavan Family 2011 Trust One, Jennifer McSween Canavan Family 2011 Trust Two, the Jennifer McSween Canavan Management Trust, the Juliet W. McSween Zacher Family 2011 Trust One, Juliet W. McSween Zacher Family 2011 Trust Two, the Juliet McSween Zacher Management Trust, the Linda G. McSween Satel Family 2011 Trust One, the Linda G. McSween Satel Family 2011 Trust Two, the Linda McSween Satel Management Trust, the Katherine Ann Satel Grantor Trust, the Emily Grace Satel Grantor Trust, and the Caroline McSween Satel Grantor Trust, all of San Antonio, Texas; and

Caroline M. Satel, Katherine Ann Satel, Emily Grace Satel, Joseph S. Satel, Jr., Paul E. McSween IV, Thomas D. McSween, Benjamin Lewis McSween, Crain McSween Canavan, William Jackson Canavan, Josephine Grace Canavan, Walker Cole Canavan, August Andrew Zacher, Annabelle McSween Zacher, and the Richard Spencer Lewis Memorial Foundation, all of San Antonio, Texas; to become members of the McSween Family Control Group, a group acting in concert, to retain the voting shares of Jefferson Bancshares, Inc., and thereby indirectly retain the voting shares of Jefferson Bank, both of San Antonio, Texas.

Board of Governors of the Federal Reserve System, November 6, 2020.

Ann Misback,

Secretary of the Board.

[FR Doc. 2020–25010 Filed 11–10–20; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

[File No. 191–0182]

Pfizer Inc. and Mylan N.V.; Analysis of Agreement Containing Consent Orders To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied

in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before December 14, 2020.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: ''Pfizer Inc. and Mylan N.V.; File No. 191 0182'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jasmine Rosner (202–326–3558), Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis of Agreement Containing Consent Orders to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC website at this web address: *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 14, 2020. Write ''Pfizer Inc. and Mylan N.V.; File No. 191 0182'' 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.

Due to the public health emergency in response to the COVID–19 outbreak and 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.

If you prefer to file your comment on paper, write ''Pfizer Inc. and Mylan N.V.; File No. 191 0182'' 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 D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include 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 sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by 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). 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 on *https://www.regulations.gov*—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, 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 at *http://www.ftc.gov* to read this Notice and the news release describing this matter. 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 that it receives on or before December 14, 2020. 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.*

Analysis of Consent Orders To Aid Public Comment

The Federal Trade Commission (''Commission''has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Pfizer Inc., Upjohn Inc., Viatris Inc., Mylan N.V., and Utah Acquisition Sub Inc., that is designed to remedy the anticompetitive effects resulting from the proposed combination of Upjohn and Mylan. Under the terms of the Consent Agreement, the parties are required to divest Upjohn's generic drug rights and assets related to six products to Prasco, LLC. The Consent Agreement also requires the parties to divest Mylan's rights and assets related to eplerenone tablets to Prasco. Further, the Consent Agreement requires prior Commission approval before Upjohn, Mylan, or Viatris may gain an interest in or exercise control over any third party's rights to (1) levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets.

The Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw the Consent Agreement, modify it, or make final the proposed Decision and Order (''Order'').

Pursuant to agreements dated July 29, 2019, Pfizer proposes to spin off its Upjohn business, which includes legacy Pfizer branded products and the authorized generic business,

Greenstone, LLC. Upjohn will combine with Mylan to form a new entity, Viatris (''Proposed Combination''). The Commission alleges in its Complaint that the Proposed Combination, if consummated, would violate Section 7 of the Clayton Act, 15 U.S.C. 18, as amended, and Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, as amended, by lessening current competition in the following seven U.S. markets: (1) Amlodipine besylate/atorvastatin calcium tablets, (2) eplerenone tablets, (3) gatifloxacin ophthalmic solution, (4) medroxyprogesterone acetate injectable solution, (5) phenytoin chewable tablets, (6) prazosin hydrochloride (''HCl'') capsules, and (7) spironolactone hydrochlorothiazide (''HCTZ'') tablets. The Commission also alleges that the Proposed Combination would violate the aforementioned statutes by lessening future competition in the markets for: (1) Levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Combination.

I. The Products and Structure of the Markets

In human pharmaceutical markets, price generally decreases as the number of generic competitors increases. Prices continue to decrease incrementally with the entry of the second, third, fourth, and even fifth generic competitor. And in markets prone to supply shortages, additional entry after the fifth generic competitor continues to affect price and ensures more stable supply. Accordingly, the reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Combination would reduce current competition in the markets for seven products where Greenstone distributes the authorized generic version of the branded drug:

- Amlodipine besylate/atorvastatin calcium tablets combine a calcium channel blocker to treat hypertension with a lipid-lowering agent to treat high cholesterol. Only four companies sell generic amlodipine besylate/atorvastatin calcium tablets: Greenstone, Mylan, Dr. Reddy's Laboratories Ltd., and Apotex Inc.
- Eplerenone is a diuretic that is prescribed as an adjunctive therapy when treating hypertension or congestive heart failure after a heart attack. Significant sellers of eplerenone include Greenstone, Mylan, Breckenridge Pharmaceutical, Inc., and Accord Healthcare Inc.
- Gatifloxacin ophthalmic solution is an eye drop that treats bacterial conjunctivitis caused by susceptible strains of certain bacteria. The market for gatifloxacin has faced historical supply disruptions. Five companies supply this product today: Greenstone, Mylan, Sandoz International GmbH, Akorn, Inc., and Lupin Ltd.
- Medroxyprogesterone acetate is an injectable solution used to treat certain types of dysfunctional uterine bleeding. Injectable products, such as medroxyprogesterone acetate, have recently experienced shortages and supply disruptions. Greenstone, Mylan, Amphastar Pharmaceuticals, Inc., Teva Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Ltd. currently supply medroxyprogesterone acetate.
- Phenytoin chewable tablets are an anti-epileptic drug that slows down impulses in the brain that cause seizures. Only three suppliers provide phenytoin chewable tablets today: Greenstone, Mylan, and Taro Pharmaceutical Industries Ltd.
- Prazosin HCl capsules are an alpha-adrenergic blocker that treats hypertension by relaxing the veins and arteries so that blood can more easily pass. The market for prazosin HCl capsules is supplied by four companies: Greenstone, Mylan, Teva, and Novitium Pharma LLC.
- Spironolactone HCTZ tablets are a diuretic used to treat hypertension. Only three suppliers provide spironolactone HCTZ tablets: Greenstone, Mylan, and Sun.

The Proposed Combination also would reduce future competition in the following generic markets:

- Levothyroxine sodium tablets are offered in a host of strengths and are prescribed to treat hypothyroidism or as an adjunct therapy for patients undergoing treatment for thyroid cancer. Suppliers for levothyroxine sodium tablets vary by strength. Should Upjohn or Greenstone launch an authorized generic of Pfizer's levothyroxine sodium branded product (Levoxyl®), the Proposed Combination likely would reduce the number of independent suppliers from three to two in some strengths.
- Sucralfate tablets are used to treat and prevent ulcers in the small intestines. Three companies sold sucralfate tablets historically: Greenstone, Mylan, and Teva. Mylan recently discontinued sales of sucralfate. The Proposed Combination likely alters Mylan's incentives to relaunch sucralfate tablets and would reduce the number of firms capable of selling sucralfate tablets from three to two.
- Varenicline tartrate tablets are a smoking cessation aid offered under Pfizer's brand Chantix®. Currently, only branded Chantix® is available in the market. Mylan is one of a limited number of companies likely to share the Hatch-Waxman 180-day exclusivity period when the generic market forms. Should Upjohn or Greenstone launch an authorized generic of Pfizer's Chantix®, the Proposed Combination would significantly reduce the number of independent generic suppliers.

II. Entry

Entry into the markets at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Combination. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and time-consuming.

III. Competitive Effects

The Proposed Combination would likely cause significant anticompetitive harm to consumers in the relevant generic pharmaceutical markets by eliminating current and/or future competition in concentrated existing generic markets or in future generic markets. In generic pharmaceuticals markets, price is heavily influenced by the number of participants with sufficient supply. Market participants consistently characterize generic drug markets as commodity markets in which the number of generic suppliers has a direct impact on pricing. Customers and competitors alike have confirmed that the prices of the generic pharmaceutical products at issue continue to decrease with new entry even after a number of suppliers have entered these generic markets.

The evidence shows anticompetitive effects are likely because the Proposed Combination will reduce the number of independent competitors in the markets at issue. In each of the current generic drug markets, industry participants have indicated that the presence of Greenstone and Mylan as independent competitors has allowed them to negotiate lower prices and, in some markets, has improved surety of supply.

In five of the markets where Upjohn and Mylan currently compete (amlodipine besylate/atorvastatin calcium tablets, eplerenone tablets, phenytoin chewable tablets, prazosin HCl capsules, and spironolactone HCTZ tablets), the Proposed Combination likely would reduce competition by combining two of only four or fewer

current suppliers, likely leading to higher prices. In two of the markets where Upjohn and Mylan currently compete and where significant product shortages have occurred (gatifloxacin ophthalmic solution and medroxyprogesterone acetate injectable solution), the Proposed Combination would eliminate an independent supplier. Customers have indicated that preserving competition between Upjohn and Mylan, particularly in markets prone to shortages, is important to maintaining adequate supplies and competitive prices.

In addition, the Proposed Combination likely would delay or forego the introduction of beneficial competition, and subsequent price decreases, by eliminating future competition in the markets for generic levothyroxine sodium tablets, sucralfate tablets, and varenicline tartrate tablets.

Absent the Consent Agreement, the Proposed Combination would eliminate significant current and future competition between the parties and likely cause U.S. consumers to pay higher prices for the aforementioned generic pharmaceutical products.

IV. The Consent Agreement and Order

The proposed Order effectively remedies the competitive concerns raised by the Proposed Combination for the ten generic pharmaceutical product areas at issue. Pursuant to the proposed Order, the parties are required to divest to Prasco Upjohn's authorized generic rights and assets related to six products. The proposed Order also requires the parties to divest Mylan's rights and assets related to eplerenone tablets to Prasco. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Proposed Combination is consummated. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products.

Further, the proposed Order requires prior Commission approval before Upjohn, Mylan, or Viatris may gain an interest in, or exercise control over, any third party's rights to the following products: (1) Levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Combination. Prasco is a capable purchaser with management and employees who have experience marketing and distributing generic pharmaceutical products. It will be able to replicate the competition otherwise lost from the Proposed Combination.

The proposed Order contains several provisions to help ensure that the divestitures are successful. As to the products and rights being divested to Prasco, generic drug manufacturing will continue to be performed by the same entity as prior to the Proposed Combination, reducing the risk of any interruption in supply to Prasco. In some instances, Pfizer—which will be an independent entity, separate from Viatris after the Proposed Combination—will serve as Prasco's contract manufacturer, allowing Prasco to step into the shoes of Upjohn/Greenstone. Should Prasco decide to move manufacturing to another contract manufacturer, the proposed Order requires the parties to provide transitional services to assist Prasco or its designated contract manufacturer in establishing manufacturing capabilities and securing all necessary FDA approvals. These transitional services include technical assistance to manufacture the currently marketed products in substantially the same manner and quality employed or achieved by the parties. To the extent that Pfizer will manufacture relevant products on behalf of both Viatris and Prasco, the proposed Order requires that supply to Prasco is provided at a pre-determined cost and is prioritized over supply to Viatris. For amlodipine besylate/atorvastatin calcium tablets, Viatris will provide the active pharmaceutical ingredient (''API'') used in Prasco's product. The proposed Order requires that Viatris provide Prasco with API at a pre-determined cost and that it prioritizes Prasco's use of API over its own. Moreover, the proposed Order requires a firewall between Viatris's API business and its commercial business to prevent the sharing of commercially sensitive information. Under the proposed Order, the Commission also will appoint two Monitors.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission, Commissioner Chopra and Commissioner Slaughter dissenting.

April J. Tabor,

Acting Secretary.

Statement of Commissioner Christine S. Wilson

Today, the Commission announces that it has voted 3–2 to issue a complaint and accept a settlement to remedy the threats to competition arising from Mylan's proposed acquisition of Pfizer's off-patent drug business.

The experienced staff of the Federal Trade Commission thoroughly investigated all cognizable theories of harm to competition during more than a year of review. Their extensive investigation put to rest some concerns and produced grounds for other concerns. Staff negotiated comprehensive remedies to address the potential anticompetitive effects identified during their exhaustive investigation—as they have done in many transactions in the pharmaceutical sector, including Bristol-Myers Squibb/Celgene and AbbVie/Allergan. Yet, as Commissioners Slaughter and Chopra did in those merger reviews, they are again opposing the settlement of this enforcement action.

Prices for pharmaceuticals and biologics deserve the attention of the American public and the federal government. As I stated in connection with the announcement of the FTC's settlement with Bristol-Myers and Celgene, within its limited civil authority as a competition agency, the Commission vigorously pursues a comprehensive agenda to address anticompetitive mergers and unlawful conduct in the pharmaceutical industry.[1] I continue to encourage those government entities with the appropriate mandates to fix the many problems in this sector that lie beyond our jurisdiction.

Dissenting Statement of Commissioner Rohit Chopra Joined by Commissioner Rebecca Kelly Slaughter

Summary

- The FTC's record when it comes to reviewing pharmaceutical mergers suggests that the agency will simply never seek to block a merger. Instead, the agency's approach is to strike narrow settlements. This encourages market actors to propose even more unlawful mergers.
- Both Pfizer and Mylan have been accused of collusion in the generic drug business. We must assess whether this merger will enhance their ability to conspire and collude.
- Rajiv Malik, who will be president of the merged entity, is currently a defendant charged with antitrust

[1] Statement of Commissioner Christine S. Wilson, *In the Matter of Bristol-Myers Squibb Company/Celgene Corporation,* File No. 191–0061, Nov. 15, 2019, available at *https://www.ftc.gov/system/files/documents/public_statements/1554278/bms-celgene-wilson-statement.pdf.*

misconduct. The Commission's silence about his role is deeply problematic.

Drug prices are out of control, and in too many instances, are out of reach for patients who depend on them. Competition from generic drugs pushes down high prices. That's why it's critical to combat abuse of intellectual property that allows branded drug makers to block generic entry. But we should also be deeply concerned that patients can't reap the full benefits from generic competition, given the alleged collusion in the generic drug industry to drive up prices. Any investigation of massive mergers in the generic business must take this into account.

Today, the Federal Trade Commission has voted to settle allegations that Mylan's (NASDAQ: MYL) proposed $12 billion acquisition of Pfizer's (NYSE: PFE) generic drug business is unlawful.[1] The combined firm would become the largest generic pharmaceutical firm in the world and offer approximately 3,000 drug products that treat a broad range of diseases and conditions.[2] The FTC's proposed settlement requires divestiture of seven individual products, as well as other provisions.

When it comes to pharmaceutical mergers, I am unable to identify a single instance in recent history where the agency has filed a complaint in federal court seeking to halt a prescription drug company merger. This lack of litigation creates the strong impression that the FTC simply looks to strike settlement deals involving individual product divestitures. Virtually every market participant I have spoken to in this industry believes that there is simply no risk of the FTC blocking an unlawful pharmaceutical merger outright.

I respectfully disagree with the status quo approach the Commission applied to this pharmaceutical merger. The use here is especially concerning, since both firms and two of Mylan's top executives have been accused of a wide-ranging price fixing and market allocation conspiracy in the generic drug industry.[3] With an expanded empire of generic drug products, these alleged antitrust crimes may be even easier to perpetrate by the new entity.[4]

In this statement, I focus on how mergers involving companies competing across a large number of product lines can exacerbate the risk of collusive conspiracies, particularly in industries where middlemen may not have an incentive to keep prices low.[5] I also focus on issues we must always confront. For example, the Commission should always look to testimony from top executives at companies proposing to merge in order to fully understand the range of potential effects on competition. The Commission can only make a conclusion about the risk of collusion and any impacts on competition when it has a full range of data and evidence.

Conditions for Collusion

When competitors enter into agreements to fix prices, rig bids, and divvy up markets, they can face civil and criminal charges. Pfizer and Mylan are defendants in several state attorneys general and private plaintiff lawsuits alleging market allocation and price fixing in the generic drug industry.[6] They are also under investigation for criminal market allocation and price fixing by the Department of Justice.[7] Over thirty additional generic drug companies are defendants in the same state attorneys general suits, including well-known drug firms Sandoz, Actavis, Teva, and Allergan, among others. Patients have allegedly paid many billions of dollars in overcharges for the generic drugs involved, causing a significant negative impact on our national health and economy.[8]

Typically, collusion is easier to pull off when a market has only a few big players, since coordination is more difficult with more actors.[9] However, there are many generic drug companies that operate in the United States. So why might there be widespread misconduct?

One potential explanation is that these companies compete with each other in multiple different product markets. The enormous profit potential for these firms from collusion likely contributes to their incentives to engage in mutually beneficial coordination. By trading favorable competitive terms in one market for favorable competitive terms in another market, it may be easier for competing firms to reach mutually beneficial terms of trade and punish each other for any deviations.[10]

Pfizer and Mylan allegedly did just that.[11] In addition to colluding within individual generic drug product markets, Pfizer's Greenstone division, Mylan, and others are charged with trading customers across *different* drug markets.[12] They allegedly allowed price increases on generic drugs without competing, based on a quid pro quo from competitors on different drug products.[13] Given these allegations, it is important that we closely investigate how this transaction could increase the ability of the merged entity to engage in similar—or even more harmful—collusive conduct. For example, the merged entity would become the top supplier of generic drugs by global revenues, with an enormous number of

[1] Pfizer, Press Release, Mylan and Upjohn, a Division of Pfizer, to Combine, Creating a New Champion for Global Health Uniquely Positioned to Fulfill the World's Need for Medicine (July 29, 2019, 2:45 a.m.), *https://www.pfizer.com/news/pressrelease/pressreleasedetail/mylan_and_upjohn_a_division_of_pfizer_to_combine_creating_a_new_champion_for_global_health_uniquely_positioned to fulfill the worlds need for medicine.*

[2] *See* Mylan & Upjohn Investor Presentation, A New Champion for Global Health at 17 (July 29, 2019), *https://www.championforglobalhealth.com/media/championforglobalhealth/pdf/mylanupjohninvestorpresentation072919.pdf; see also* Mylan & Upjohn Fact Sheet, A New Champion for Global Health (n.d.a.), *https://www.championforglobalhealth.com/media/championforglobalhealth/pdf/MylanUpjohnFactsheet072919.pdf.*

[3] *See* Compl., *Connecticut* v. *Teva Pharms. USA, Inc.,* Case No. 3:19–cv–00710 (D. Conn. filed May 10, 2019) ¶ 50; *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34, Civ. Action No. 17–3768 (E.D. Pa. filed June 15, 2018).

[4] The Department of Justice also charged Teva with criminally conspiring to fix prices, rig bids, and allocate customers for generic drugs. Five previous corporate cases were resolved by deferred prosecution agreements; Teva and its co-conspirator Glenmark are awaiting trial. Four executives have also been charged; three have entered guilty pleas, and one is awaiting trial. *See* Press Release, Dep't. of Just., Seventh Generic Drug Manufacturer Is Charged In Ongoing Criminal Antitrust Investigation (Aug. 25, 2020), *https://www.justice.gov/opa/pr/seventh-generic-drug-manufacturer-charged-ongoing-criminal-antitrustinvestigation.*

[5] Most generic drugs are sold by their manufacturers to group purchasing organizations and large retail purchasers, who negotiate pricing contracts for their members that ultimately purchase the products. These contracts typically have inflation-based provisions that allow for potentially greater compensation when prices are higher. *See In re Generic Pharms. Pricing Antitrust Litig.* ¶ 74.

[6] *See e.g.,* Pl. States' Consol. Am. Compl., *In re Generic Pharms. Pricing Antitrust Litig.;* Compl., *Connecticut* v. *Teva Pharms.;* Compl., *Connecticut* v. *Sandoz, Inc.,* Civ. Action No. 3:20–cv–802 (D. Conn. filed June 10, 2020).

[7] *See* Pfizer Inc., Current Report (Form 8–K) (Aug. 6, 2020) at 175; Mylan N.V., Annual Report (Form 10–K) (Dec. 31, 2019) at 153.

[8] Compl., *Connecticut* v. *Teva Pharms. USA, Inc.* ¶ 5.

[9] This concept is reflected in the FTC's Horizontal Merger Guidelines. U.S. DEP'T OF JUST. & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 7.2 (Aug. 19, 2010), *https://www.justice.gov/sites/default/files/atr/legacy/2010/08/19/hmg-2010.pdf.*

[10] *See* Federico Ciliberto & Jonathan W. Williams, Does multimarket contact facilitate tacit collusion? Inference on conduct parameters in the airline industry, 45 RAND J. OF ECON. 764–791 (2014) (noting that such multimarket contact facilitates tacit collusion in the U.S. airline industry).

[11] Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶¶ 103–105 (describing Defendant Malik's willingness to ''play fair'' and give up two large customers to Heritage because Heritage had previously allowed Mylan to enter another market without competition); *see also* Compl., *Connecticut* v. *Sandoz, Inc.* ¶ 1299.

[12] *Id.*

[13] Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 101; *see also* Compl., *Connecticut* v. *Teva Pharms* ¶ 12.

products and a broad range of competitors with which to engage in quid pro quo collusive arrangements.[14] With more generic drugs in the hands of one competitor, it may be easier to form a cartel and punish those who don't adhere to its terms. Despite this risk, the Commission's analysis is silent with respect to the alleged price fixing conduct.[15]

The FTC often acts without the benefit of the experience of other law enforcement partners.[16] In all matters, the Commission should avoid a go-it-alone approach and collaborate with other agencies to help shed light on the mechanisms involved in the allegations. Together, we should closely assess whether the likelihood of harm increases post-merger.

Investigating Executives

In any matter where a company has a history of potential wrongdoing, a key method to determine the motivations for a merger and to predict how it will affect competition is to seek sworn testimony from key executives. This is especially critical to understand how sales, pricing, and market forces are working. This evidence is also helpful if the agency must prepare a lawsuit.

While filings submitted by merging parties shed light on many aspects of a transaction, they do not always provide a complete picture of the deal rationale, pricing models, and boardroom behavior. The state allegations of price fixing and market allocation make clear that individual executives play a key role in sales and price setting, so it is critical that we fully understand this element of the competitive process. For example, what is their involvement in developing a pricing model? Do they approve deviations from this pricing model? How do they decide which new markets to enter? In what contexts do they interact with their competitors? There are a long list of questions that are absolutely essential in an inquiry like this.

In this transaction, one of the alleged masterminds of the ongoing price fixing and market allocation schemes is Rajiv Malik, Mylan's current president, who is a named defendant in one of the state lawsuits.[17] A second Mylan executive, Vice President of Sales James Nesta, is also a named defendant in one of the cases.[18] The merging parties have publicly announced that Mr. Malik will retain the top executive role in the expanded generic drug empire, if the transaction closes.[19] As president, he will be in charge of the merged entity's sales and marketing operations.[20] He will also serve on the merged company's board.[21]

Mr. Malik's role in the alleged price fixing scheme is significant. He allegedly conceived and directed many of the schemes.[22] In one example, he is alleged to have agreed to cede market share in one market to a specific competitor in exchange for an agreement from that competitor to allow Mylan to enter a different market without competition.[23]

Despite the alarm bells raised by Mr. Malik's planned role in the merged firm, the Commission's analysis does not discuss his involvement in the ongoing price fixing and market allocation allegations in the industry or his plans for the company. In my view, the Commission owes the public a clear explanation about Mr. Malik's role. In matters like this, it is critical that the Commission rely on a wide range of data and evidence, including testimony from key executives.[24]

Conclusion

I am concerned that executives in the pharmaceutical industry routinely propose anticompetitive mergers without any fear that their transactions will ever be blocked. In my view, the status quo approach of seeking settlements through divestitures of individual products is myopic and misses some of the fundamental elements of how firms compete in this industry. I am also not aware of any instance where the Commission publicly relied on the testimony under oath of a pharmaceutical executive in approving a pharmaceutical divestiture settlement.

Unless we change our approach, anticompetitive mergers in the pharmaceutical industry will continue unabated, and we will all suffer for it. I appreciate the diligence of our staff, who work at the direction of the Commission. Unfortunately, the directives of the Commission are deeply flawed, favoring routine over rigor. For all these reasons, I respectfully dissent.

[FR Doc. 2020–25021 Filed 11–10–20; 8:45 am]

BILLING CODE 6750–01–P

[14] Beth Snyder Bulik, Mylan and Pfizer roll out tricolor branding for their giant generics combo, Viatris, FIERCEPHARMA (July 9, 2020, 10:06 a.m.), *https://www.fiercepharma.com/marketing/mylan-and-pfizer-debuts-new-viatris-generics-merged-brandunveils-tri-color-logo-for.*

[15] *See, e.g.,* Analysis Of Agreement Containing Consent Orders To Aid Public Comment, *In the Matter of Pfizer Inc./Mylan N.V.,* File No. 191 0182 (Oct. 29, 2020).

[16] *See* Statement of Commissioner Rohit Chopra *In the Matter of AbbVie, Inc./Allergan plc,* File No. 191 0169, 2, 19 (May 5, 2020), *https://www.ftc.gov/system/files/documents/public_statements/1574583/191_0169_dissenting_statement_of_commissioner_rohit_chopra_in_the_matter_of_abbvie-allergan_redacted.pdf; see also* Statement of Commissioner Rohit Chopra *In the Matter of Social Finance, Inc.,* File No. 162 3917 (Oct. 29, 2018), *https://www.ftc.gov/system/files/documents/public_statements/1418711/162_3197_statement_of_commissioner_chopra_on_sofi_10-29-18.pdf.*

[17] Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34.

[18] *See* Compl., *Connecticut* v. *Teva Pharms. USA, Inc.* ¶ 50.

[19] *See* Pfizer Press Release, *supra* note 1.

[20] Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34.

[21] *See* Pfizer Press Release, *supra* note 1.

[22] Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 10.

[23] *Id.* ¶ 188.

[24] This is particularly important in industries where the Commission cannot rely on evidence and testimony from customers who act as middlemen. We know from the allegations in the state attorneys general lawsuits that drug wholesalers and large retailers allegedly benefit when generic drug prices are higher. These firms have contractual provisions allowing for potentially greater compensation when prices are higher. *Id.* ¶¶ 71–75.

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (''PRA''), the Federal Trade Commission (''FTC'' or ''Commission'') is seeking public comment on its proposal to extend for an additional three years the Office of Management and Budget clearance for information collection requirements in its rule governing Care Labeling of Textile Wearing Apparel and Certain Piece Goods As Amended (''Care Labeling Rule''). The current clearance expires on May 31, 2021.

DATES: Comments must be filed by January 11, 2021.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Care Labeling Rule: FTC File No. P072108,'' on your comment and file your comment online at *https://www.regulations.gov,* by following the instructions on the web-based form. 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 J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Mail Code CC–9528, 600 Pennsylvania Ave. NW, Washington, DC 20580, (202) 326–2889.

SUPPLEMENTARY INFORMATION: *Title of Collection:* Care Labeling of Textile Wearing Apparel and Certain Piece Goods As Amended, 16 CFR 423.

OMB Control Number: 3084–0103.

Type of Review: Extension of currently approved collection.

Affected Public: Private Sector: Businesses and other for-profit entities.

Estimated Annual Burden Hours: 27,489,476 hours.

Estimated Annual Labor Costs: $187,184,518.

Abstract: The Care Labeling Rule requires manufacturers and importers of textile wearing apparel and certain piece goods to attach labels to their products disclosing the care needed for the ordinary use of the product. The Rule also requires manufacturers or importers to possess a reasonable basis for care instructions, and allows the use of approved care symbols in lieu of words to disclose those instructions.

Burden Statement: Staff estimates that approximately 10,744 manufacturers or importers of textile apparel, producing about 18.4 billion textile garments annually, are subject to the Rule's disclosure requirements. Staff estimates the burden of determining care instructions to be 100 hours each year per firm, for a cumulative total of 1,074,400 hours. Staff further estimates that the burden of drafting and providing labels is 80 hours each year per firm, for a total of 859,520 hours. Staff believes that the process of attaching labels is fully automated and integrated into other production steps for about 50 percent (approximately, 9.2 billion) of the approximately 18.4 billion garments that are required to have care instructions on permanent labels. For the remaining 9.2 billion items, the process is semi-automated and requires an average of approximately ten seconds per item, for a total of 25,555,556 hours per year. Thus, the total estimated annual burden for all firms is 27,489,476 hours.

The chart below summarizes the total estimated costs.

Task	Hourly rate [1]	Burden hours	Labor cost
Determine care instructions	$29.00	1,074,400	$31,157,600
Draft and order labels	18.00	859,520	15,471,360
Attach labels	[2] 5.50	25,555,556	140,555,558
Total			187,184,518

Staff believes that there are no current start-up costs or other capital costs associated with the Care Labeling Rule. Because the labeling of textile products has been an integral part of the manufacturing process for decades, manufacturers have in place the capital equipment necessary to comply with the Rule's labeling requirements. Based on knowledge of the industry, staff believes that much of the information required by the Rule would be included on the product label even absent those requirements.

Request for Comment: Pursuant to Section 3506(c)(2)(A) of the PRA, the FTC invites comments on: (1) Whether the disclosure requirements are necessary, including whether the information will be practically useful; (2) the accuracy of our burden estimates, including whether the methodology and assumptions used are valid; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of providing the required information to consumers. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before January 11, 2021.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 11, 2021. Write ''Care Labeling Rule: FTC File No. P072108'' on your comment. Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it through the *https://www.regulations.gov* website by following the instructions on the web-based form provided. Your comment, including your name and your state—will be placed on the public record of this proceeding, including the *https://www.regulations.gov* website.

If you file your comment on paper, write ''Care Labeling Rule: FTC File No. P072108'' 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 J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610, Washington, DC 20024. If possible, please submit your paper comment to the Commission by courier or overnight service.

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 include any 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 that 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 ''trade secret or any commercial or financial information which . . . is privileged or

[1] All hourly rates except for ''Attach labels'' are rounded to the nearest dollar and drawn from the U.S. Dep't of Labor, Bureau of Labor Statistics, ''Table 1. National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2019,'' at *https://www.bls.gov/news.release/ocwage.t01.htm.* The hourly labor cost estimate for determining care instructions is based on mean hourly rates for Office and Administrative Support Supervisors and the estimate for drafting and ordering labels is based on mean hourly rates for Information and Record Clerks.

[2] For imported products, the labels generally are attached in the country where the products are manufactured. According to information compiled by an industry trade association using data from the U.S. Department of Commerce, International Trade Administration and the U.S. Census Bureau, approximately 97.5% of apparel purchased in the United States is imported. With the remaining 2.5% attributable to U.S. production at an approximate domestic hourly wage of $12 to attach labels (derived from the U.S. Dep't of Labor, Bureau of Labor Statistics, ''Occupational Employment Statistics—May 2019'' which is cited in footnote 1), staff has calculated a weighted average hourly wage of $5.50 per hour attributable to U.S. and foreign labor combined. Wages in major textile exporting countries, factored into the above hourly wage estimate, were based on data from the U.S. Department of Labor, Bureau of Labor Statistics, available at: *http://www.bls.gov/fls/#compensation.*

confidential''—as provided by 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). 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 on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, 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.

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 that it receives on or before January 11, 2021. 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*.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2020–25035 Filed 11–10–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Malnutrition in Hospitalized Adults

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Malnutrition in Hospitalized Adults,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before December 14, 2020.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Malnutrition in Hospitalized Adults. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Malnutrition in Hospitalized Adults,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/malnutrition-hospitalized-adults/protocol.*

This is to notify the public that the EPC Program would find the following information on *Malnutrition in Hospitalized Adults* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQs)

Key Question 1. What is the association between malnutrition and clinical outcomes among hospitalized patients?

a. How do outcomes vary depending on measures or tools used to detect malnutrition?

b. Are patient-related risk factors, such as increased age or certain pre-existing health conditions, associated with poorer clinical outcomes?

Key Question 2. What is the effectiveness of screening or diagnostic assessment for malnutrition among hospitalized adults?

a. In studies that report on clinical outcomes, what is the diagnostic accuracy of screening or diagnostic assessment for malnutrition?

b. In studies that report on clinical outcomes, what is the effectiveness of screening or diagnostic assessment on measures of nutrition (nutritional stores)?

c. What is the impact of screening or diagnostic assessment on clinical outcomes?

Key Question 3. Among patients diagnosed with malnutrition, what is the effectiveness of hospital-initiated interventions used to treat malnutrition on clinical outcomes?

PICOTS (POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING)

Category	Definition
Population	Key Question 1 and 2: Hospitalized adults aged 18 years or older (see Methods section for exceptions). Key Question 1b subgroups include adults with no risk of malnutrition, adults with risk of malnutrition, and adults with baseline malnutrition. Risk factors of interest to this report include: • Older patients (>65 years) • Racial and ethnic minorities • Low income (*e.g.* Medicaid beneficiaries) • Patients with malignancy • Patients with gastrointestinal disease and subsequent malabsorption, including ulcerative colitis and Crohn's disease • Patients with chronic liver disease • Patients with stroke • Patients with chronic kidney disease • Patients with dementia • Patients with critical illness • Sepsis/infection Key Question 3: Adults diagnosed with protein-energy malnutrition.
Interventions/Exposures	Key Question 1: Positive screening for nutrition risk and/or diagnosis of malnutrition vs no malnutrition. Key Question 2: Malnutrition screening and diagnostic assessment tools (utilized within the U.S., Australia, New Zealand, Canada, and Europe). Examples of tools of interest include: *Screening*: • Malnutrition Screening Tool (MST) • Malnutrition Universal Screening Tool (MUST) • Nutritional Risk Index (NRI) • Nutrition Risk in Critically Ill (NUTRIC) score *Diagnostic Assessment*: • Subjective Global Assessment (SGA) • Patient Generated Subjective Global Assessment (PS–SGA) • Mini Nutritional Assessment (MNA) • AND (Academy of Nutrition and Dietetics)–ASPEN (American Society for Parenteral and Enteral Nutrition) Malnutrition Consensus Criteria (MCC) • Global Leadership Initiative on Malnutrition (GLIM) Key Question 3: Hospital-initiated malnutrition interventions. Examples of interventions include: • Parenteral nutrition • Enteral nutrition • Oral nutrition supplements • Nutrition team consultation, includes dietitian counseling • Pharmacologic interventions
Comparators	Key Question 1: Hospitalized patients without malnutrition, or direct comparisons of different definitions of malnutrition. Key Questions 2: Radiographic imaging or SGA will be used as the reference standard. Key Question 3: Usual care or another hospital-initiated malnutrition-related intervention.
Outcomes	*Clinical Outcomes (All Key Questions)*: • Mortality (inpatient and 30-day) • Length of stay • 30-day readmission • Quality of life • Functional status, includes gate speed, Karnofsky Index, handgrip strength, days on ventilator • Activities of daily • Hospital Acquired Condition (HAC) • Wound healing • Discharge disposition *Intermediate Outcomes (KQ 2)*: Diagnostic accuracy outcomes: • Sensitivity • Specificity • Predictive value • Area under the curve *Intermediate Outcomes (KQ 2 or KQ 3)*: Nutrition Stores: Direct measures of nutrition status (nutrition stores) during and post hospitalization. Examples include: • Cross-sectional areas for lumbar skeletal muscle and adipose tissue • Skeletal Muscle Index

PICOTS (POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING)—Continued

Category	Definition
	• Regional or total fat mass and muscle mass assessed using validated gold standard methods, such as body composition measures derived through Computed Tomography (CT) scans, Dual X-ray Absorptiometry (DXA), and Magnetic Resonance Imaging (MRI)
Timing	Up to 30 days post-discharge
Setting	Acute care hospitalizations

Dated: November 5, 2020.

Marquita N. Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8076–N]

RIN 0938–AU16

Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) beneficiaries enrolled in Part B of the Medicare Supplementary Medical Insurance (SMI) program beginning January 1, 2021. In addition, this notice announces the monthly premium for aged and disabled beneficiaries, the deductible for 2021, and the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. The monthly actuarial rates for 2021 are $291.00 for aged enrollees and $349.90 for disabled enrollees. The standard monthly Part B premium rate for all enrollees for 2021 is $148.50, which is equal to 50 percent of the monthly actuarial rate for aged enrollees (or approximately 25 percent of the expected average total cost of Part B coverage for aged enrollees) plus the $3.00 repayment amount required under current law. (The 2020 standard premium rate was $144.60, which included the $3.00 repayment amount.) The Part B deductible for 2021 is $203.00 for all Part B beneficiaries. If a beneficiary has to pay an income-related monthly adjustment, he or she will have to pay a total monthly premium of about 35, 50, 65, 80 or 85 percent of the total cost of Part B coverage plus a repayment amount of $4.20, $6.00, $7.80, $9.60 or $10.20, respectively.

DATES: The premium and related amounts announced in this notice are effective on January 1, 2021.

FOR FURTHER INFORMATION CONTACT: M. Kent Clemens, (410) 786–6391.

SUPPLEMENTARY INFORMATION:

I. Background

Part B is the voluntary portion of the Medicare program that pays all or part of the costs for physicians' services; outpatient hospital services; certain home health services; services furnished by rural health clinics, ambulatory surgical centers, and comprehensive outpatient rehabilitation facilities; and certain other medical and health services not covered by Medicare Part A, Hospital Insurance. Medicare Part B is available to individuals who are entitled to Medicare Part A, as well as to U.S. residents who have attained age 65 and are citizens and to aliens who were lawfully admitted for permanent residence and have resided in the United States for 5 consecutive years. Part B requires enrollment and payment of monthly premiums, as described in 42 CFR part 407, subpart B, and part 408, respectively. The premiums paid by (or on behalf of) all enrollees fund approximately one-fourth of the total incurred costs, and transfers from the general fund of the Treasury pay approximately three-fourths of these costs.

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1839 of the Social Security Act (the Act) to announce the Part B monthly actuarial rates for aged and disabled beneficiaries as well as the monthly Part B premium. The Part B annual deductible is included because its determination is directly linked to the aged actuarial rate.

The monthly actuarial rates for aged and disabled enrollees are used to determine the correct amount of general revenue financing per beneficiary each month. These amounts, according to actuarial estimates, will equal, respectively, one-half of the expected average monthly cost of Part B for each aged enrollee (age 65 or over) and one-half of the expected average monthly cost of Part B for each disabled enrollee (under age 65).

The Part B deductible to be paid by enrollees is also announced. Prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), the Part B deductible was set in statute. After setting the 2005 deductible amount at $110, section 629 of the MMA (amending section 1833(b) of the Act) required that the Part B deductible be indexed beginning in 2006. The inflation factor to be used each year is the annual percentage increase in the Part B actuarial rate for enrollees age 65 and over. Specifically, the 2021 Part B deductible is calculated by multiplying the 2020 deductible by the ratio of the 2021 aged actuarial rate to the 2020 aged actuarial rate. The amount determined under this formula is then rounded to the nearest $1.

The monthly Part B premium rate to be paid by aged and disabled enrollees is also announced. (Although the costs to the program per disabled enrollee are different than for the aged, the statute provides that the two groups pay the same premium amount.) Beginning with the passage of section 203 of the Social Security Amendments of 1972 (Pub. L. 92–603), the premium rate, which was determined on a fiscal-year basis, was limited to the lesser of the actuarial rate for aged enrollees, or the current monthly premium rate increased by the same percentage as the most recent general increase in monthly Title II Social Security benefits.

However, the passage of section 124 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) suspended this premium determination process. Section 124 of TEFRA changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). Section 606 of the Social Security Amendments of 1983 (Pub. L. 98–21), section 2302 of the Deficit Reduction Act of 1984 (DEFRA 84) (Pub. L. 98–369), section 9313 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA 85) (Pub. L. 99–272), section 4080 of the Omnibus Budget Reconciliation Act of

1987 (OBRA 87) (Pub. L. 100–203), and section 6301 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) (Pub. L. 101–239) extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). This extension expired at the end of 1990.

The premium rate for 1991 through 1995 was legislated by section 1839(e)(1)(B) of the Act, as added by section 4301 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) (Pub. L. 101–508). In January 1996, the premium determination basis would have reverted to the method established by the 1972 Social Security Act Amendments. However, section 13571 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93) (Pub. L. 103–66) changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees) for 1996 through 1998.

Section 4571 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) permanently extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees).

The BBA included a further provision affecting the calculation of the Part B actuarial rates and premiums for 1998 through 2003. Section 4611 of the BBA modified the home health benefit payable under Part A for individuals enrolled in Part B. Under this section, beginning in 1998, expenditures for home health services not considered ''post-institutional'' are payable under Part B rather than Part A. However, section 4611(e)(1) of the BBA required that there be a transition from 1998 through 2002 for the aggregate amount of the expenditures transferred from Part A to Part B. Section 4611(e)(2) of the BBA also provided a specific yearly proportion for the transferred funds. The proportions were one-sixth for 1998, one-third for 1999, one-half for 2000, two-thirds for 2001, and five-sixths for 2002. For the purpose of determining the correct amount of financing from general revenues of the Federal Government, it was necessary to include only these transitional amounts in the monthly actuarial rates for both aged and disabled enrollees, rather than the total cost of the home health services being transferred.

Section 4611(e)(3) of the BBA also specified, for the purpose of determining the premium, that the monthly actuarial rate for enrollees age 65 and over be computed as though the transition would occur for 1998 through 2003 and that one-seventh of the cost be transferred in 1998, two-sevenths in 1999, three-sevenths in 2000, four-sevenths in 2001, five-sevenths in 2002, and six-sevenths in 2003. Therefore, the transition period for incorporating this home health transfer into the premium was 7 years while the transition period for including these services in the actuarial rate was 6 years.

Section 811 of the MMA, which amended section 1839 of the Act, requires that, starting on January 1, 2007, the Part B premium a beneficiary pays each month be based on his or her annual income. Specifically, if a beneficiary's modified adjusted gross income is greater than the legislated threshold amounts (for 2021, $88,000 for a beneficiary filing an individual income tax return and $176,000 for a beneficiary filing a joint tax return), the beneficiary is responsible for a larger portion of the estimated total cost of Part B benefit coverage. In addition to the standard 25-percent premium, these beneficiaries now have to pay an income-related monthly adjustment amount. The MMA made no change to the actuarial rate calculation, and the standard premium, which will continue to be paid by beneficiaries whose modified adjusted gross income is below the applicable thresholds, still represents 25 percent of the estimated total cost to the program of Part B coverage for an aged enrollee. However, depending on income and tax filing status, a beneficiary can now be responsible for 35, 50, 65, 80, or 85 percent of the estimated total cost of Part B coverage, rather than 25 percent. Section 402 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) modified the income thresholds beginning in 2018, and section 53114 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) further modified the income thresholds beginning in 2019. For years beginning in 2019, the BBA of 2018 established a new income threshold. If a beneficiary's modified adjusted gross income is greater than or equal to $500,000 for a beneficiary filing an individual income tax return and $750,000 for a beneficiary filing a joint tax return, the beneficiary is responsible for 85 percent of the estimated total cost of Part B coverage. The BBA of 2018 specified that these new income threshold levels be inflation-adjusted beginning in 2028. The end result of the higher premium is that the Part B premium subsidy is reduced, and less general revenue financing is required, for beneficiaries with higher income because they are paying a larger share of the total cost with their premium. That is, the premium subsidy continues to be approximately 75 percent for beneficiaries with income below the applicable income thresholds, but it will be reduced for beneficiaries with income above these thresholds. The MMA specified that there be a 5-year transition period to reach full implementation of this provision. However, section 5111 of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) modified the transition to a 3-year period.

Section 4732(c) of the BBA added section 1933(c) of the Act, which required the Secretary to allocate money from the Part B trust fund to the state Medicaid programs for the purpose of providing Medicare Part B premium assistance from 1998 through 2002 for the low-income Medicaid beneficiaries who qualify under section 1933 of the Act. This allocation, while not a benefit expenditure, was an expenditure of the trust fund and was included in calculating the Part B actuarial rates through 2002. For 2003 through 2015, the expenditure was made from the trust fund because the allocation was temporarily extended. However, because the extension occurred after the financing was determined, the allocation was not included in the calculation of the financing rates for these years. Section 211 of MACRA permanently extended this expenditure, which is included in the calculation of the Part B actuarial rates for 2016 and subsequent years.

Another provision affecting the calculation of the Part B premium is section 1839(f) of the Act, as amended by section 211 of the Medicare Catastrophic Coverage Act of 1988 (MCCA 88) (Pub. L. 100–360). (The Medicare Catastrophic Coverage Repeal Act of 1989 (Pub. L. 101–234) did not repeal the revisions to section 1839(f) of the Act made by MCCA 88.) Section 1839(f) of the Act, referred to as the ''hold-harmless'' provision, provides that, if an individual is entitled to benefits under section 202 or 223 of the Act (the Old-Age and Survivors Insurance Benefit and the Disability Insurance Benefit, respectively) and has the Part B premium deducted from these benefit payments, the premium increase will be reduced, if necessary, to avoid causing a decrease in the individual's net monthly payment. This decrease in payment occurs if the increase in the individual's Social Security benefit due to the cost-of-living adjustment under section 215(i) of the Act is less than the increase in the premium. Specifically, the reduction in the premium amount applies if the individual is entitled to

benefits under section 202 or 223 of the Act for November and December of a particular year and the individual's Part B premiums for December and the following January are deducted from the respective month's section 202 or 223 benefits. The hold-harmless provision does not apply to beneficiaries who are required to pay an income-related monthly adjustment amount.

A check for benefits under section 202 or 223 of the Act is received in the month following the month for which the benefits are due. The Part B premium that is deducted from a particular check is the Part B payment for the month in which the check is received. Therefore, a benefit check for November is not received until December, but December's Part B premium has been deducted from it.

Generally, if a beneficiary qualifies for hold-harmless protection, the reduced premium for the individual for that January and for each of the succeeding 11 months is the greater of either—

- The monthly premium for January reduced as necessary to make the December monthly benefits, after the deduction of the Part B premium for January, at least equal to the preceding November's monthly benefits, after the deduction of the Part B premium for December; or
- The monthly premium for that individual for that December.

In determining the premium limitations under section 1839(f) of the Act, the monthly benefits to which an individual is entitled under section 202 or 223 of the Act do not include retroactive adjustments or payments and deductions on account of work. Also, once the monthly premium amount is established under section 1839(f) of the Act, it will not be changed during the year even if there are retroactive adjustments or payments and deductions on account of work that apply to the individual's monthly benefits.

Individuals who have enrolled in Part B late or who have re-enrolled after the termination of a coverage period are subject to an increased premium under section 1839(b) of the Act. The increase is a percentage of the premium and is based on the new premium rate before any reductions under section 1839(f) of the Act are made.

Section 1839 of the Act, as amended by section 601(a) of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), specified that the 2016 actuarial rate for enrollees age 65 and older be determined as if the hold-harmless provision did not apply. The premium revenue that was lost by using the resulting lower premium (excluding the forgone income-related premium revenue) was replaced by a transfer of general revenue from the Treasury, which will be repaid over time to the general fund.

Similarly, section 1839 of the Act, as amended by section 2401 of the Continuing Appropriations Act, 2021 and Other Extensions Act (Pub. L. 116–159), specifies that the 2021 actuarial rate for enrollees age 65 and older be determined as the sum of the 2020 actuarial rate for enrollees age 65 and older and one-fourth of the difference between the 2020 actuarial rate and the preliminary 2021 actuarial rate (as determined by the Secretary of HHS) for such enrollees. The premium revenue lost by using the resulting lower premium (excluding the forgone income-related premium revenue) will be replaced by a transfer of general revenue from the Treasury, which will be repaid over time.

Starting in 2016, in order to repay the balance due (which includes the transfer amounts and the forgone income-related premium revenue from the Bipartisan Budget Act of 2015 and the Continuing Appropriations Act, 2021 and Other Extensions Act), the Part B premium otherwise determined will be increased by $3.00. These repayment amounts will be added to the Part B premium otherwise determined each year and will be paid back to the general fund of the Treasury, and they will continue until the balance due is paid back.

High-income enrollees pay the $3 repayment amount plus an additional $1.20, $3.00, $4.80, $6.60, or $7.20 in repayment as part of the income-related monthly adjustment amount (IRMAA) premium dollars, which reduce (dollar for dollar) the amount of general revenue received by Part B from the general fund of the Treasury. Because of this general revenue offset, the repayment IRMAA premium dollars are not included in the direct repayments made to the general fund of the Treasury from Part B in order to avoid a double repayment. (Only the $3.00 monthly repayment amounts are included in the direct repayments).

These repayment amounts will continue until the balance due is zero. (In the final year of the repayment, the additional amounts may be modified to avoid an overpayment.) The repayment amounts (excluding those for high-income enrollees) are subject to the hold-harmless provision. The original balance due was $9,066,409,000, consisting of $1,625,761,000 in forgone income-related premium revenue plus a transfer amount of $7,440,648,000 from the provisions of the Bipartisan Budget Act of 2015. The increase in the balance due in 2021 will be $8,799,829,000, consisting of $946,046,000 in forgone income-related premium income plus a transfer amount of $7,853,783,000 from the provisions of the Continuing Appropriations Act, 2021 and Other Extensions Act. An estimated $6,761,022,000 will have been collected for repayment to the general fund by the end of 2020.

II. Provisions of the Notice

A. Notice of Medicare Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible

The Medicare Part B monthly actuarial rates applicable for 2021 are $291.00 for enrollees age 65 and over and $349.90 for disabled enrollees under age 65. In section II.B. of this notice, we present the actuarial assumptions and bases from which these rates are derived. The Part B standard monthly premium rate for all enrollees for 2021 is $148.50.

The following are the 2021 Part B monthly premium rates to be paid by (or on behalf of) beneficiaries who file either individual tax returns (and are single individuals, heads of households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year), or joint tax returns.

Beneficiaries who file individual tax returns with income:	Beneficiaries who file joint tax returns with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $88,000	Less than or equal to $176,000	$0.00	$148.50
Greater than $88,000 and less than or equal to $111,000	Greater than $176,000 and less than or equal to $222,000.	59.40	207.90

Beneficiaries who file individual tax returns with income:	Beneficiaries who file joint tax returns with income:	Income-related monthly adjustment amount	Total monthly premium amount
Greater than $111,000 and less than or equal to $138,000.	Greater than $222,000 and less than or equal to $276,000.	148.50	297.00
Greater than $138,000 and less than or equal to $165,000.	Greater than $276,000 and less than or equal to $330,000.	237.60	386.10
Greater than $165,000 and less than $500,000	Greater than $330,000 and less than $750,000	326.70	475.20
Greater than or equal to $500,000	Greater than or equal to $750,000	356.40	504.90

In addition, the monthly premium rates to be paid by (or on behalf of) beneficiaries who are married and lived with their spouses at any time during the taxable year, but who file separate tax returns from their spouses, are as follows:

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $88,000	$0.00	$148.50
Greater than $88,000 and less than $412,000	326.70	475.20
Greater than or equal to $412,000	356.40	504.90

The Part B annual deductible for 2021 is $203.00 for all beneficiaries.

B. Statement of Actuarial Assumptions and Bases Employed in Determining the Monthly Actuarial Rates and the Monthly Premium Rate for Part B Beginning January 2021

The actuarial assumptions and bases used to determine the monthly actuarial rates and the monthly premium rates for Part B are established by the Centers for Medicare & Medicaid Services' Office of the Actuary. The estimates underlying these determinations are prepared by actuaries meeting the qualification standards and following the actuarial standards of practice established by the Actuarial Standards Board.

1. Actuarial Status of the Part B Account in the Supplementary Medical Insurance Trust Fund

Under section 1839 of the Act, the starting point for determining the standard monthly premium is the amount that would be necessary to finance Part B on an incurred basis. This is the amount of income that would be sufficient to pay for services furnished during that year (including associated administrative costs) even though payment for some of these services will not be made until after the close of the year. The portion of income required to cover benefits not paid until after the close of the year is added to the trust fund and used when needed.

Because the premium rates are established prospectively, they are subject to projection error. Additionally, legislation enacted after the financing was established, but effective for the period in which the financing is set, may affect program costs. As a result, the income to the program may not equal incurred costs. Trust fund assets must therefore be maintained at a level that is adequate to cover an appropriate degree of variation between actual and projected costs, and the amount of incurred, but unpaid, expenses. Numerous factors determine what level of assets is appropriate to cover variation between actual and projected costs. For 2021, the four most important of these factors are (1) the impact of the COVID–19 pandemic on program spending; (2) the difference from prior years between the actual performance of the program and estimates made at the time financing was established; (3) the likelihood and potential magnitude of expenditure changes resulting from enactment of legislation affecting Part B costs in a year subsequent to the establishment of financing for that year; and (4) the expected relationship between incurred and cash expenditures. The first factor, the impact of the pandemic on program spending, brings a higher-than-usual degree of uncertainty to projected costs for the 2021 Part B financing. The other three factors are analyzed on an ongoing basis, as the trends can vary over time.

Table 1 summarizes the estimated actuarial status of the trust fund as of the end of the financing period for 2019 and 2020.

TABLE 1—ESTIMATED ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND AS OF THE END OF THE FINANCING PERIOD

Financing period ending	Assets (in millions)	Liabilities (in millions)	Assets less liabilities (in millions)
December 31, 2019	$99,602	$31,566	$68,036
December 31, 2020	123,051	32,884	90,167

2. Monthly Actuarial Rate for Enrollees Age 65 and Older

The monthly actuarial rate for enrollees age 65 and older is one-half of the sum of monthly amounts for (1) the projected cost of benefits; and (2) administrative expenses for each enrollee age 65 and older, after adjustments to this sum to allow for interest earnings on assets in the trust fund and an adequate contingency margin. The contingency margin is an amount appropriate to provide for possible variation between actual and projected costs and to amortize any surplus assets or unfunded liabilities.

Section 1839 of the Act, as amended by section 2401 of the Continuing Appropriations Act, 2021 and Other Extensions Act (Pub. L. 116–159), specifies that the 2021 monthly actuarial rate for enrollees age 65 and older be determined as the sum of the 2020 monthly actuarial rate for enrollees age 65 and older and one-fourth of the difference between the 2020 monthly actuarial rate and the preliminary 2021 monthly actuarial rate (as determined by the Secretary of HHS) for such enrollees. The premium revenue lost by using the resulting lower premium (excluding the forgone income-related premium revenue) will be replaced by a transfer of general revenue from the Treasury, which will be repaid over time.

The preliminary monthly actuarial rate for enrollees age 65 and older for 2021 is determined by first establishing per enrollee costs by type of service from program data through 2020 and then projecting these costs for subsequent years. The projection factors used for financing periods from January 1, 2018 through December 31, 2021 are shown in Table 2. The 2020 monthly actuarial rate for enrollees age 65 and older is $283.20, and the preliminary 2021 monthly actuarial rate for enrollees age 65 and older is $314.30. In accordance with the provisions of the Continuing Appropriations Act, 2021 and Other Extensions Act, the 2021 monthly actuarial rate for enrollees age 65 and older is $291.00 ($283.20 + 0.25 × (314.30 − 283.20)).

As indicated in Table 3, the projected per enrollee amount required to pay for one-half of the total of benefits and administrative costs for enrollees age 65 and over for 2021 is $307.52. Based on current estimates, the assets at the end of 2020 are not sufficient to cover the amount of incurred, but unpaid, expenses, to provide for substantial variation between actual and projected costs, and to accommodate the unusually high degree of uncertainty due to the COVID–19 pandemic. Thus, a positive contingency margin is needed to increase assets to a more appropriate level. The preliminary monthly actuarial rate of $314.30 provides an adjustment of $8.17 for a contingency margin and −$1.39 for interest earnings.

The contingency margin for 2021 is affected by several factors. First, in response to the pandemic, about $43 billion was paid out of the Part B account as part of the Accelerated and Advanced Payment (AAP) programs. Providers are to repay their AAP payments to Part B over time through reduced Part B claims payments. However, until the AAP payments have been repaid, the Part B account would not have the roughly $43 billion in assets, and the financing for 2021 would need to be increased to restore the assets used to make these payments. The Continuing Appropriations Act, 2021 and Other Extensions Act requires that a transfer be made from the Treasury to Part B to restore the roughly $43 billion in AAP payments paid out and specifies that any future AAP provider repayments be transferred to the Treasury. Because the 2021 Part B financing includes the assumption that roughly $43 billion will be transferred from the Treasury to Part B before the end of calendar year 2020, the AAP payments do not impact contingency margin.

Second, in order to take into account the uncertainty and potential impact of the COVID–19 pandemic, assumptions were developed for testing and treatment for COVID–19, utilization of non-COVID-related care, potential costs for COVID–19 vaccines, and possible paths of the pandemic. Several Part B pandemic cost scenarios were developed based on these assumptions. The difference between the best-estimate pandemic scenario and the highest-cost pandemic scenario was used to establish the additional contingency margin needed to account for the potential costs and uncertainty from the pandemic.

Third, starting in 2011, manufacturers and importers of brand-name prescription drugs pay a fee that is allocated to the Part B account of the SMI trust. For 2021, the total of these brand-name drug fees is estimated to be $2.8 billion. The contingency margin for 2021 has been reduced to account for this additional revenue.

The traditional goal for the Part B reserve has been that assets minus liabilities at the end of a year should represent between 15 and 20 percent of the following year's total incurred expenditures. To accomplish this goal, a 17-percent reserve ratio, which is a fully adequate contingency reserve level, has been the normal target used to calculate the Part B premium. The financing rates for 2021 are set above the normal target due to the higher-than-usual uncertainty for 2021. The actuarial rate of $291.00 per month for aged beneficiaries, as announced in this notice for 2021, reflects the combined effect of the factors and legislation previously described and the projected assumptions listed in Table 2.

3. Monthly Actuarial Rate for Disabled Enrollees

Disabled enrollees are those persons under age 65 who are enrolled in Part B because of entitlement to Social Security disability benefits for more than 24 months or because of entitlement to Medicare under the end-stage renal disease (ESRD) program. Projected monthly costs for disabled enrollees (other than those with ESRD) are prepared in a manner parallel to the projection for the aged using appropriate actuarial assumptions (see Table 2). Costs for the ESRD program are projected differently because of the different nature of services offered by the program.

As shown in Table 4, the projected per enrollee amount required to pay for one-half of the total of benefits and administrative costs for disabled enrollees for 2021 is $377.23. The monthly actuarial rate of $349.90 also provides an adjustment of −$1.61 for interest earnings and −$25.72 for a contingency margin, reflecting the same factors and legislation described previously for the aged actuarial rate at magnitudes appropriate to the disabled rate determination. Based on current estimates, the assets associated with the disabled Medicare beneficiaries at the end of 2020 are sufficient to cover the amount of incurred, but unpaid, expenses and to provide for a significant degree of variation between actual and projected costs. As noted for the aged actuarial rate, the 2021 contingency margin is set above the normal target level in order to accommodate the higher uncertainty due to the COVID–19 pandemic.

The actuarial rate of $349.90 per month for disabled beneficiaries, as announced in this notice for 2021, reflects the combined net effect of the factors and legislation described previously for aged beneficiaries and the projection assumptions listed in Table 2.

4. Sensitivity Testing

Several factors contribute to uncertainty about future trends in medical care costs. It is appropriate to

test the adequacy of the rates using alternative cost growth rate assumptions. The results of those assumptions are shown in Table 5. One set represents increases that are higher and, therefore, more pessimistic than the current estimate. The other set represents increases that are lower and, therefore, more optimistic than the current estimate. The values for the alternative assumptions were determined from a statistical analysis of the historical variation in the respective increase factors. The historical variation may not be representative of the current level of uncertainty due to the COVID–19 pandemic.

As indicated in Table 5, the monthly actuarial rates would result in an excess of assets over liabilities of $101,796 million by the end of December 2021 under the cost growth rate assumptions shown in Table 2 and under the assumption that the provisions of current law are fully implemented. This result amounts to 21.6 percent of the estimated total incurred expenditures for the following year.

Assumptions that are somewhat more pessimistic (and that therefore test the adequacy of the assets to accommodate projection errors) produce a surplus of $65,262 million by the end of December 2021 under current law, which amounts to 12.4 percent of the estimated total incurred expenditures for the following year. Under fairly optimistic assumptions, the monthly actuarial rates would result in a surplus of $176,475 million by the end of December 2021, or 34.2 percent of the estimated total incurred expenditures for the following year.

The sensitivity analysis indicates that, in a typical year, the premium and general revenue financing established for 2021, together with existing Part B account assets, would be adequate to cover estimated Part B costs for 2021 under current law, should actual costs prove to be somewhat greater than expected. However, the current level of uncertainty due to the pandemic may differ from the historical variation included in this analysis.

5. Premium Rates and Deductible

As determined in accordance with section 1839 of the Act, the following are the 2021 Part B monthly premium rates to be paid by beneficiaries who file either individual tax returns (and are single individuals, heads of households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year) or joint tax returns.

Beneficiaries who file individual tax returns with income:	Beneficiaries who file joint tax returns with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $88,000	Less than or equal to $176,000	$0.00	$148.50
Greater than $88,000 and less than or equal to $111,000	Greater than $176,000 and less than or equal to $222,000.	59.40	207.90
Greater than $111,000 and less than or equal to $138,000.	Greater than $222,000 and less than or equal to $276,000.	148.50	297.00
Greater than $138,000 and less than or equal to $165,000.	Greater than $276,000 and less than or equal to $330,000.	237.60	386.10
Greater than $165,000 and less than $500,000	Greater than $330,000 and less than $750,000	326.70	475.20
Greater than or equal to $500,000	Greater than or equal to $750,000	356.40	504.90

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouses at any time during the taxable year, but who file separate tax returns from their spouses, are as follows:

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $88,000	$0.00	$148.50
Greater than $88,000 and less than $412,000	326.70	475.20
Greater than or equal to $412,000	356.40	504.90

TABLE 2—PROJECTION FACTORS [1] 12-MONTH PERIODS ENDING DECEMBER 31 OF 2018–2021

[In percent]

Calendar year	Physicians' services	Durable medical equipment	Carrier lab [2]	Physician-administered drugs	Other carrier services [3]	Outpatient hospital	Home health agency	Hospital lab [4]	Other intermediary services [5]	Managed care
Aged:										
2018	1.6	18.1	11.4	12.2	2.3	8.4	1.4	−1.0	7.6	7.4
2019	3.8	7.3	4.3	11.0	2.2	5.6	3.9	−3.6	5.5	8.4
2020	−14.0	−1.5	−13.5	6.3	−5.8	−6.5	−3.7	−7.0	−3.7	8.5
2021	29.3	0.5	17.7	9.6	14.9	36.6	19.0	8.8	15.0	3.6
Disabled:										
2018	−0.6	13.5	3.7	7.9	1.9	4.8	0.5	−1.3	5.3	7.6
2019	5.5	5.4	10.4	12.0	5.8	7.3	3.7	0.6	11.1	8.3
2020	−9.3	0.3	−15.2	11.5	1.6	−3.7	−1.5	−3.8	−0.6	9.5
2021	24.7	1.5	23.0	8.9	8.8	34.9	22.4	6.8	22.2	3.0

[1] All values for services other than managed care are per fee-for-service enrollee. Managed care values are per managed care enrollee.
[2] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[3] Includes ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.

[4] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[5] Includes services furnished in dialysis facilities, rural health clinics, federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 3—DERIVATION OF MONTHLY ACTUARIAL RATE FOR ENROLLEES AGE 65 AND OVER FOR FINANCING PERIODS ENDING DECEMBER 31, 2018 THROUGH DECEMBER 31, 2021

	CY 2018	CY 2019	CY 2020	Preliminary CY 2021	CY 2021
Covered services (at level recognized):					
Physician fee schedule	$72.28	$73.02	$60.48	$76.83	$76.83
Durable medical equipment	6.05	6.32	5.99	5.93	5.93
Carrier lab [1]	4.28	4.35	3.61	4.19	4.19
Physician-administered drugs	16.07	17.37	17.74	19.92	19.92
Other carrier services [2]	9.33	9.28	8.41	9.52	9.52
Outpatient hospital	49.46	50.84	45.71	61.52	61.52
Home health	8.85	8.95	8.29	9.72	9.72
Hospital lab [3]	2.17	2.04	1.82	1.95	1.95
Other intermediary services [4]	18.61	19.13	17.70	20.06	20.06
Managed care	100.65	113.46	129.87	137.11	137.11
Total services	287.76	304.75	299.62	346.77	346.77
Cost sharing:					
Deductible	−6.40	−6.32	−6.74	−6.94	−6.94
Coinsurance	−28.62	−28.79	−26.02	−30.36	−30.36
Sequestration of benefits	−5.05	−5.39	−1.78	−6.17	−6.17
HIT payment incentives	0.16	0.00	0.00	0.00	0.00
Total benefits	247.85	264.26	265.07	303.30	303.30
Administrative expenses	3.90	4.11	4.71	4.21	4.21
Incurred expenditures	251.75	268.36	269.79	307.52	307.52
Value of interest	−1.80	−1.88	−1.09	−1.39	−1.39
Contingency margin for projection error and to amortize the surplus or deficit [5]	11.95	−1.58	14.50	8.17	−15.13
Monthly actuarial rate	$261.90	$264.90	$283.20	$314.30	$291.00

[1] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[2] Includes ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[3] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[4] Includes services furnished in dialysis facilities, rural health clinics, federally qualified health centers, rehabilitation and psychiatric hospitals, etc.
[5] The significant negative margin included in the 2021 actuarial rate is attributable to the application of the provisions of the Continuing Appropriations Act, 2021 and Other Extensions Act.

TABLE 4—DERIVATION OF MONTHLY ACTUARIAL RATE FOR DISABLED ENROLLEES FOR FINANCING PERIODS ENDING DECEMBER 31, 2018 THROUGH DECEMBER 31, 2020

	CY 2018	CY 2019	CY 2020	CY 2021
Covered services (at level recognized):				
Physician fee schedule	$73.05	$72.63	$61.25	$72.93
Durable medical equipment	12.09	12.02	11.02	10.81
Carrier lab [1]	5.71	6.00	4.73	5.51
Physician-administered drugs	14.80	15.54	15.84	17.51
Other carrier services [2]	12.32	12.38	11.70	12.20
Outpatient hospital	65.16	65.53	57.86	75.43
Home health	6.95	6.78	6.19	7.20
Hospital lab [3]	2.61	2.48	2.21	2.26
Other intermediary services [4]	50.78	52.79	51.68	53.18
Managed care	103.40	124.70	154.31	168.50
Total services	346.87	370.84	376.79	425.52
Cost sharing:				
Deductible	−6.16	−6.05	−6.45	−6.65
Coinsurance	−41.95	−41.78	−38.85	−41.50
Sequestration of benefits	−5.97	−6.45	−2.21	−7.53
HIT payment incentives	0.16	0.00	0.00	0.00
Total benefits	292.95	316.56	329.29	369.85
Administrative expenses	4.60	4.92	7.89	7.38
Incurred expenditures	297.55	321.48	337.15	377.23
Value of interest	−2.68	−2.52	−1.38	−1.61

TABLE 4—DERIVATION OF MONTHLY ACTUARIAL RATE FOR DISABLED ENROLLEES FOR FINANCING PERIODS ENDING DECEMBER 31, 2018 THROUGH DECEMBER 31, 2020—Continued

	CY 2018	CY 2019	CY 2020	CY 2021
Contingency margin for projection error and to amortize the surplus or deficit [5]	0.13	−3.56	7.83	−25.72
Monthly actuarial rate	$295.00	$315.40	$343.60	$349.90

[1] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[2] Includes ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[3] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[4] Includes services furnished in dialysis facilities, rural health clinics, federally qualified health centers, rehabilitation and psychiatric hospitals, etc.
[5] The significant negative margin included in the 2021 actuarial rate is attributable to the application of the provisions of the Continuing Appropriations Act, 2021 and Other Extensions Act.

TABLE 5—ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SMI TRUST FUND UNDER THREE SETS OF ASSUMPTIONS FOR FINANCING PERIODS THROUGH DECEMBER 31, 2021

As of December 31,	2019	2020	2021
Actuarial status (in millions):			
Assets	$99,602	$123,051	$138,974
Liabilities	$31,566	$32,884	$37,178
Assets less liabilities	$68,036	$90,167	$101,796
Ratio [1]	17.7%	20.2%	21.6%
Low-cost projection:			
Actuarial status (in millions):			
Assets	$99,602	$144,338	$176,457
Liabilities	$31,566	$30,519	$35,245
Assets less liabilities	$68,036	$113,819	$141,212
Ratio [1]	18.9%	28.2%	34.2%
High-cost projection:			
Actuarial status (in millions):			
Assets	$99,602	$101,797	$104,088
Liabilities	$31,566	$35,245	$38,826
Assets less liabilities	$68,036	$66,552	$65,262
Ratio [1]	16.7%	13.7%	12.4%

[1] Ratio of assets less liabilities at the end of the year to the total incurred expenditures during the following year, expressed as a percent.

III. Collection of Information Requirements

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.*).

IV. Regulatory Impact Analysis

A. Statement of Need

Section 1839 of the Act requires us to annually announce (that is, by September 30th of each year) the Part B monthly actuarial rates for aged and disabled beneficiaries as well as the monthly Part B premium. We also announce the Part B annual deductible because its determination is directly linked to the aged actuarial rate.

B. Overall Impact

We have examined the impacts of this notice 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)), and Executive Order 13771 on Reducing and Controlling Regulatory Costs (January 30, 2017).

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). A regulatory impact analysis (RIA) must be prepared for major notices with economically significant effects ($100 million or more in any one year). The 2021 standard Part B premium of $148.50 is $3.90 higher than the 2020 premium of $144.60. We estimate that this premium increase, for the approximately 59 million Part B enrollees in 2021, will have an annual effect on the economy of $100 million or more. As a result, this notice is economically significant under section 3(f)(1) of Executive Order 12866 and is a major action as defined under the Congressional Review Act (5 U.S.C. 804(2)).

As discussed earlier, this notice announces that the monthly actuarial rates applicable for 2021 are $291.00 for enrollees age 65 and over and $349.90 for disabled enrollees under age 65. It also announces the 2021 monthly Part B premium rates to be paid by

beneficiaries who file either individual tax returns (and are single individuals, heads of households, qualifying widows or widowers with dependent children, or married individuals filing separately who lived apart from their spouses for the entire taxable year) or joint tax returns.

Beneficiaries who file individual tax returns with income:	Beneficiaries who file joint tax returns with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $88,000	Less than or equal to $176,000	$0.00	$148.50
Greater than $88,000 and less than or equal to $111,000	Greater than $176,000 and less than or equal to $222,000.	59.40	207.90
Greater than $111,000 and less than or equal to $138,000.	Greater than $222,000 and less than or equal to $276,000.	148.50	297.00
Greater than $138,000 and less than or equal to $165,000.	Greater than $276,000 and less than or equal to $330,000.	237.60	386.10
Greater than $165,000 and less than $500,000	Greater than $330,000 and less than $750,000	326.70	475.20
Greater than or equal to $500,000	Greater than or equal to $750,000	356.40	504.90

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouses at any time during the taxable year, but who file separate tax returns from their spouses, are also announced and listed in the following chart:

Beneficiaries who are married and lived with their spouses at any time during the year, but who file separate tax returns from their spouses:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $88,000	$0.00	$148.50
Greater than $88,000 and less than $412,000	326.70	475.20
Greater than or equal to $412,000	356.40	504.90

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under 65) beneficiaries enrolled in Part B of the Medicare SMI program beginning January 1, 2021. Also, this notice announces the monthly premium for aged and disabled beneficiaries as well as the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As we discussed previously, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this notice will not have a significant effect on 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 one year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. Part B enrollees who are also enrolled in Medicaid have their monthly Part B premiums paid by Medicaid. The cost to each state Medicaid program from the 2021 premium increase is estimated to be less than the threshold. This notice does not impose mandates that will have a consequential effect of the threshold amount or more on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of states. Accordingly, the requirements of Executive Order 13132 do not apply to this notice.

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 1871 of the Act and section 553(b) of the Administrative Procedure Act (APA). Section 1871(a)(2) of the Act provides that no rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard

governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under Medicare shall take effect unless it is promulgated through notice and comment rulemaking. Unless there is a statutory exception, section 1871(b)(1) of the Act generally requires the Secretary of the Department of Health and Human Services (the Secretary) to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment before establishing or changing a substantive legal standard regarding the matters enumerated by the statute. Similarly, under 5 U.S.C. 553(b) of the APA, the agency is required to publish a notice of proposed rulemaking in the **Federal Register** before a substantive rule takes effect. Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act usually require a 30-day delay in effective date after issuance or publication of a rule, subject to exceptions. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the advance notice and comment requirement and the delay in effective date requirements. Sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and the 30-day delay in effective date. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act expressly authorize an agency to dispense with notice and comment rulemaking for good cause if the agency makes a finding that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest.

The annual updated amounts for the Part B monthly actuarial rates for aged and disabled beneficiaries, the Part B premium, and Part B deductible set forth in this notice do not establish or change a substantive legal standard regarding the matters enumerated by the statute or constitute a substantive rule that would be subject to the notice requirements in section 553(b) of the APA. However, to the extent that an opportunity for public notice and comment could be construed as required for this notice, we find good cause to waive this requirement.

Section 1839 of the Act requires the Secretary to determine the monthly actuarial rates for aged and disabled beneficiaries, as well as the monthly Part B premium (including the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts), for each calendar year in accordance with the statutory formulae, in September preceding the year to which they will apply. Further, the statute requires that the agency promulgate the Part B premium amount, in September preceding the year to which it will apply, and include a public statement setting forth the actuarial assumptions and bases employed by the Secretary in arriving at the amount of an adequate actuarial rate for enrollees age 65 and older. We include the Part B annual deductible, which is established pursuant to a specific formula described in section 1833(b) of the Act, because the determination of the amount is directly linked to the rate of increase in actuarial rate under section 1839(a)(1) of the Act. We have calculated the monthly actuarial rates for aged and disabled beneficiaries, the Part B deductible, and the monthly Part B premium as directed by the statute; since the statute establishes both when the monthly actuarial rates for aged and disabled beneficiaries and the monthly Part B premium must be published and the information that the Secretary must factor into those amounts, we do not have any discretion in that regard. We find notice and comment procedures to be unnecessary for this notice and we find good cause to waive such procedures under section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act, if such procedures may be construed to be required at all. Through this notice, we are simply notifying the public of the updates to the monthly actuarial rates for aged and disabled beneficiaries and the Part B deductible, as well as the monthly Part B premium amounts and the income-related monthly adjustment amounts to be paid by certain beneficiaries, in accordance with the statute, for CY 2021. As such, we also note that even if notice and comment procedures were required for this notice, for the previously stated reason, we would find good cause to waive the delay in effective date of the notice, as additional delay would be contrary to the public interest under section 1871(e)(1)(B)(ii) of the Act. Publication of this notice is consistent with section 1839 of the Act, and we believe that any potential delay in the effective date of the notice, if such delay were required at all, could cause unnecessary confusion both for the agency and Medicare beneficiaries.

Dated: October 30, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 2, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–25029 Filed 11–6–20; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8075–N]

RIN 0938–AU15

Medicare Program; CY 2021 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces Medicare's Hospital Insurance (Part A) premium for uninsured enrollees in calendar year 2021. This premium is paid by enrollees age 65 and over who are not otherwise eligible for benefits under Medicare Part A (hereafter known as the ''uninsured aged'') and by certain individuals with disabilities who have exhausted other entitlement. The monthly Part A premium for the 12 months beginning January 1, 2021 for these individuals will be $471. The premium for certain other individuals as described in this notice will be $259.

DATES: The premium announced in this notice is effective on January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Yaminee Thaker, (410) 786–7921.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1818 of the Social Security Act (the Act) provides for voluntary enrollment in the Medicare Hospital Insurance Program (Medicare Part A), subject to payment of a monthly premium, of certain persons aged 65 and older who are uninsured under the Old-Age, Survivors, and Disability Insurance (OASDI) program or the Railroad Retirement Act and do not otherwise meet the requirements for entitlement to Medicare Part A. These ''uninsured aged'' individuals are uninsured under the OASDI program or the Railroad Retirement Act, because they do not have 40 quarters of coverage under Title II of the Act (or are/were not

married to someone who did). (Persons insured under the OASDI program or the Railroad Retirement Act and certain others do not have to pay premiums for Medicare Part A.)

Section 1818A of the Act provides for voluntary enrollment in Medicare Part A, subject to payment of a monthly premium for certain individuals with disabilities who have exhausted other entitlement. These are individuals who were entitled to coverage due to a disabling impairment under section 226(b) of the Act, but who are no longer entitled to disability benefits and premium-free Medicare Part A coverage because they have gone back to work and their earnings exceed the statutorily defined ''substantial gainful activity'' amount (section 223(d)(4) of the Act).

Section 1818A(d)(2) of the Act specifies that the provisions relating to premiums under section 1818(d) through section 1818(f) of the Act for the aged will also apply to certain individuals with disabilities as described above.

Section 1818(d)(1) of the Act requires us to estimate, on an average per capita basis, the amount to be paid from the Federal Hospital Insurance Trust Fund for services incurred in the upcoming calendar year (CY) (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A. We must then determine the monthly actuarial rate for the following year (the per capita amount estimated above divided by 12) and publish the dollar amount for the monthly premium in the succeeding CY. If the premium is not a multiple of $1, the premium is rounded to the nearest multiple of $1 (or, if it is a multiple of 50 cents but not of $1, it is rounded to the next highest $1).

Section 13508 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) amended section 1818(d) of the Act to provide for a reduction in the premium amount for certain voluntary enrollees (sections 1818 and 1818A of the Act). The reduction applies to an individual who is eligible to buy into the Medicare Part A program and who, as of the last day of the previous month:

- Had at least 30 quarters of coverage under Title II of the Act;
- Was married, and had been married for the previous 1-year period, to a person who had at least 30 quarters of coverage;
- Had been married to a person for at least 1 year at the time of the person's death if, at the time of death, the person had at least 30 quarters of coverage; or
- Is divorced from a person and had been married to the person for at least 10 years at the time of the divorce if, at the time of the divorce, the person had at least 30 quarters of coverage.

Section 1818(d)(4)(A) of the Act specifies that the premium that these individuals will pay for CY 2021 will be equal to the premium for uninsured aged enrollees reduced by 45 percent.

Section 1818(g) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary), at the request of a state, to enter into a Part A buy-in agreement with a state to pay Medicare Part A premiums for Qualified Medicare Beneficiaries (QMBs). Under the QMB program, state Medicaid agencies must pay the Medicare Part A premium for those not eligible for premium-free Part A if those individuals meet all of the eligibility requirements for the QMB program under the state's Medicaid state plan. (Entering into a Part A buy-in agreement would permit a state to avoid any Medicare late enrollment penalties that the individual may owe and would allow states to enroll persons in Part A at any time of the year, without regard to Medicare enrollment periods). Some of these individuals may be eligible for the Qualified Disabled Working Individuals program, through which state Medicaid programs provide coverage for the Part A premiums of individuals eligible to enroll in Part A by virtue of section 1818A of the Act who meet certain financial eligibility criteria.

II. Monthly Premium Amount for CY 2021

The monthly premium for the uninsured aged and certain individuals with disabilities who have exhausted other entitlement for the 12 months beginning January 1, 2021, is $471. The monthly premium for the individuals eligible under section 1818(d)(4)(B) of the Act, and therefore, subject to the 45 percent reduction in the monthly premium, is $259.

III. Monthly Premium Rate Calculation

As discussed in section I of this notice, the monthly Medicare Part A premium is equal to the estimated monthly actuarial rate for CY 2021 rounded to the nearest multiple of $1 and equals one-twelfth of the average per capita amount, which is determined by projecting the number of Medicare Part A enrollees aged 65 years and over as well as the benefits and administrative costs that will be incurred on their behalf.

The steps involved in projecting these future costs to the Federal Hospital Insurance Trust Fund are:

- Establishing the present cost of services furnished to beneficiaries, by type of service, to serve as a projection base;
- Projecting increases in payment amounts for each of the service types; and
- Projecting increases in administrative costs.

We base our projections for CY 2021 on—(1) current historical data; and (2) projection assumptions derived from current law and the President's Fiscal Year 2021 Budget.

We estimate that in CY 2021, 54,661,560 people aged 65 years and over will be entitled to (enrolled in) benefits (without premium payment) and that they will incur about $308.997 billion in benefits and related administrative costs. Thus, the estimated monthly average per capita amount is $471.08 and the monthly premium is $471. Subsequently, the full monthly premium reduced by 45 percent is $259.

IV. Costs to Beneficiaries

The CY 2021 premium of $471 is approximately 2.8 percent higher than the CY 2020 premium of $458. We estimate that approximately 706,000 enrollees will voluntarily enroll in Medicare Part A by paying the full premium. We estimate that over 90 percent of these individuals will have their Part A premium paid for by states, since they are enrolled in the QMB program. Furthermore, the CY 2021 reduced premium of $259 is approximately 2.8 percent higher than the CY 2020 premium of $252. We estimate an additional 84,000 enrollees will pay the reduced premium. Therefore, we estimate that the total aggregate cost to enrollees paying these premiums in CY 2021, compared to the amount that they paid in CY 2020, will be about $117 million.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 1871 of the Act and section 553(b) of the Administrative Procedure Act (APA). Section 1871(a)(2) of the Act provides that no rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under Medicare shall take effect unless it is promulgated through notice and comment rulemaking. Unless there is a statutory exception, section 1871(b)(1)

of the Act generally requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment before establishing or changing a substantive legal standard regarding the matters enumerated by the statute. Similarly, under 5 U.S.C. 553(b) of the APA, the agency is required to publish a notice of proposed rulemaking in the **Federal Register** before a substantive rule takes effect. Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act usually require a 30-day delay in effective date after issuance or publication of a rule, subject to exceptions. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the advance notice and comment requirement and the delay in effective date requirements. Sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and the 30-day delay in effective date. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act expressly authorize an agency to dispense with notice and comment rulemaking for good cause if the agency makes a finding that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest.

The annual Part A premium announcement set forth in this notice does not establish or change a substantive legal standard regarding the matters enumerated by the statute or constitute a substantive rule which would be subject to the notice requirements in section 553(b) of the APA. However, to the extent that an opportunity for public notice and comment could be construed as required for this notice, we find good cause to waive this requirement.

Section 1818(d) of the Act requires the Secretary during September of each year to determine and publish the amount to be paid, on an average per capita basis, from the Federal Hospital Insurance Trust Fund for services incurred in the impending CY (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A. Further, the statute requires that the agency determine the applicable premium amount for each CY in accordance with the statutory formula, and we are simply notifying the public of the changes to the Medicare Part A premiums for CY 2021. We have calculated the Part A premiums as directed by the statute; the statute establishes both when the premium amounts must be published and the information that the Secretary must factor into the premium amounts, so we do not have any discretion in that regard. We find notice and comment procedures to be unnecessary for this notice and we find good cause to waive such procedures under section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act, if such procedures may be construed to be required at all. Through this notice, we are simply notifying the public of the updates to the Medicare Part A premiums, in accordance with the statute, for CY 2021. As such, we also note that even if notice and comment procedures were required for this notice, for the reasons stated above, we would find good cause to waive the delay in effective date of the notice, as additional delay would be contrary to the public interest under section 1871(e)(1)(B)(ii) of the Act. Publication of this notice is consistent with section 1818(d) of the Act, and we believe that any potential delay in the effective date of the notice, if such delay were required at all, could cause unnecessary confusion both for the agency and Medicare beneficiaries.

VI. Collection of Information Requirements

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.*).

VII. Regulatory Impact Analysis

Although this notice does not constitute a substantive rule, we nevertheless prepared this Regulatory Impact Analysis section in the interest of ensuring that the impacts of this notice are fully understood.

A. Statement of Need

Section 1818(d) of the Act requires the Secretary during September of each year to determine and publish the amount to be paid, on an average per capita basis, from the Federal Hospital Insurance Trust Fund for services incurred in the impending CY (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A.

B. Overall Impact

We have examined the 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)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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 economically significant effects ($100 million or more in any 1 year). Although we do not consider this notice to constitute a substantive rule, this notice is economically significant under section 3(f)(1) of Executive Order 12866. As stated in section IV of this notice, we estimate that the overall effect of the changes in the Part A premium will be a cost to voluntary enrollees (sections 1818 and 1818A of the Act) of about $117 million.

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, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and

suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. This annual notice announces the Medicare Part A premiums for CY 2021 and will have an impact on certain Medicare beneficiaries. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This annual notice announces the Medicare Part A premiums for CY 2021 and will have an impact on certain Medicare beneficiaries. As a result, we are not preparing an analysis for section 1102(b) of the Act, because the Secretary has determined that this notice 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 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 2020, that threshold is approximately $156 million. This notice does not impose mandates that will have a consequential effect of $156 million or more on state, local, or tribal governments or on the private sector.

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 requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This notice will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have Federalism implications.

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

C. Congressional Review

Consistent with the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), this notice has been transmitted to the Congress and the Comptroller General for review.

Dated: October 30, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 2, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–25028 Filed 11–6–20; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8074–N]

RIN 0938–AU14

Medicare Program; CY 2021 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year (CY) 2021 under Medicare's Hospital Insurance Program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts. For CY 2021, the inpatient hospital deductible will be $1,484. The daily coinsurance amounts for CY 2021 will be: $371 for the 61st through 90th day of hospitalization in a benefit period; $742 for lifetime reserve days; and $185.50 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

DATES: The deductible and coinsurance amounts announced in this notice are effective on January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Yaminee Thaker, (410) 786 7921 for general information.

Gregory J. Savord, (410) 786 1521 for case mix analysis.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to determine and publish each year the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year (CY).

II. Computing the Inpatient Hospital Deductible for CY 2021

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding CY, adjusted by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act) used for updating the payment rates to hospitals for discharges in the fiscal year (FY) that begins on October 1 of the same preceding CY, and adjusted to reflect changes in real case-mix. The adjustment to reflect real case-mix is determined on the basis of the most recent case-mix data available. The amount determined under this formula is rounded to the nearest multiple of $4 (or, if midway between two multiples of $4, to the next higher multiple of $4).

Under section 1886(b)(3)(B)(i)(XX) of the Act, the percentage increase used to update the payment rates for FY 2021 for hospitals paid under the inpatient prospective payment system is the market basket percentage increase, otherwise known as the market basket update, reduced by an adjustment based on changes in the economy-wide productivity (the multifactor productivity (MFP) adjustment) (see section 1886(b)(3)(B)(xi)(II) of the Act). Under section 1886(b)(3)(B)(viii) of the Act, for FY 2021, the applicable percentage increase for hospitals that do not submit quality data as specified by the Secretary is reduced by one quarter

of the market basket update. We are estimating that after accounting for those hospitals receiving the lower market basket update in the payment-weighted average update, the calculated deductible will not be affected, since the majority of hospitals submit quality data and receive the full market basket update. Section 1886(b)(3)(B)(ix) of the Act requires that any hospital that is not a meaningful electronic health record (EHR) user (as defined in section 1886(n)(3) of the Act) will have three-quarters of the market basket update reduced by 100 percent for FY 2017 and each subsequent FY. We are estimating that after accounting for these hospitals receiving the lower market basket update, the calculated deductible will not be affected, since the majority of hospitals are meaningful EHR users and are expected to receive the full market basket update.

Under section 1886 of the Act, the percentage increase used to update the payment rates (or target amounts, as applicable) for FY 2021 for hospitals excluded from the inpatient prospective payment system is as follows:

- The percentage increase for long term care hospitals is the market basket percentage increase reduced by the MFP adjustment (see section 1886(m)(3)(A) of the Act). In addition, these hospitals may also be impacted by the quality reporting adjustments and the site-neutral payment rates (see sections 1886(m)(5) and 1886(m)(6) of the Act).
- The percentage increase for inpatient rehabilitation facilities is the market basket percentage increase reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. In addition, these hospitals may also be impacted by the quality reporting adjustments (see section 1886(j)(7) of the Act).
- The percentage increase used to update the payment rate for inpatient psychiatric facilities is the market basket percentage increase reduced by the MFP adjustment (see section 1886(s)(2)(A)(i) of the Act). In addition, these hospitals may also be impacted by the quality reporting adjustments (see section 1886(s)(4) of the Act).
- The percentage increase used to update the target amounts for other types of hospitals that are excluded from the inpatient prospective payment system and that are paid on a reasonable cost basis, subject to a rate-of-increase ceiling, is the inpatient prospective payment system operating market basket percentage increase, which is described at section 1886(b)(3)(B)(ii)(VIII) of the Act and 42 CFR 413.40(c)(3). These other types of hospitals include cancer hospitals, children's hospitals, extended neoplastic disease care hospitals, and hospitals located outside the 50 states, the District of Columbia, and Puerto Rico.

The inpatient prospective payment system market basket percentage increase for FY 2021 is 2.4 percent and the MFP adjustment is 0.0 percentage point, as announced in the final rule that appeared in the **Federal Register** on September 18, 2020 entitled, ''Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Final Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals'' (85 FR 58432). Therefore, the percentage increase for hospitals paid under the inpatient prospective payment system that submit quality data and are meaningful EHR users is 2.4 percent (that is, the FY 2021 market basket update of 2.4 percent less the MFP adjustment of 0.0 percentage point). The average payment percentage increase for hospitals excluded from the inpatient prospective payment system is 2.34 percent. This average includes long term care hospitals, inpatient rehabilitation facilities, and other hospitals excluded from the inpatient prospective payment system. Weighting these percentages in accordance with payment volume, our best estimate of the payment-weighted average of the increases in the payment rates for FY 2021 is 2.39 percent.

To develop the adjustment to reflect changes in real case-mix, we first calculated an average case-mix for each hospital that reflects the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the Medicare inpatient prospective payment system in FY 2020 compared to FY 2019. (We excluded from this calculation hospitals whose payments are not based on the inpatient prospective payment system because their payments are based on alternate prospective payment systems or reasonable costs.) We used Medicare bills from prospective payment hospitals that we received as of July 2020. These bills represent a total of about 6.1 million Medicare discharges for FY 2020 and provide the most recent case-mix data available at this time. Based on these bills, the change in average case-mix in FY 2020 is 2.8 percent. Based on these bills and past experience, we expect the overall case mix change to be 3.8 percent as the year progresses and more FY 2020 data become available.

Section 1813 of the Act requires that the inpatient hospital deductible be adjusted only by that portion of the case-mix change that is determined to be real. Real case-mix is that portion of case-mix that is due to changes in the mix of cases in the hospital and not due to coding optimization. COVID–19 has complicated the determination of real case-mix increase. COVID–19 cases typically have higher-weighted MS–DRGs which would cause a real increase in case-mix while hospitals have experienced a reduction in lower-weighted cases which would also cause a real increase in case-mix. We compared the average case-mix for February 2020 through July 2020 (COVID–19 period) with average case-mix for October 2019 through January 2020 (pre-COVID–19 period). Since this increase applies for only a portion of CY 2020, we allocated this increase by the estimated discharges over the 2 periods—a 2.5 percent increase for FY 2020. The 1.3-percent residual case-mix increase is a mixture of real case-mix and coding optimization. Over the past several years, we have observed total case mix increases of about 0.5 percent per year and have assumed that they are real. Thus, since we do not have further information at this time, we expect that 0.5 percent of the residual 1.3 percent change in average case-mix for FY 2020 will be real. The combination of the 2.5-percent COVID–19 effect and the remaining residual 0.5-percent real case-mix increase is a 3.0-percent increase in real case-mix for FY 2020. Note that all case-mix calculations do not include the extra 20 percent adjustment in the MS–DRG relative weights for COVID–19 cases. The extra 20-percent adjustment is a payment artifact that should not be included in the measurement of case-mix.

Thus, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 2.39 percent, and the real case-mix adjustment factor for the deductible is 3.0 percent. Therefore, using the statutory formula as stated in section 1813(b) of the Act, we calculate the inpatient hospital deductible for services furnished in CY 2021 to be $1,484. This deductible amount is determined by multiplying $1,408 (the inpatient hospital deductible for CY 2020 (84 FR 61619)) by the payment-weighted average increase in the payment rates of 1.0239 multiplied by the increase in real case-mix of 1.03, which equals $1,484.90 and is rounded to $1,484.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for CY 2021

The coinsurance amounts provided for in section 1813 of the Act are defined as fixed percentages of the inpatient hospital deductible for services furnished in the same CY. The increase in the deductible generates increases in the coinsurance amounts. For inpatient hospital and extended care services furnished in CY 2021, in accordance with the fixed percentages defined in the law, the daily coinsurance for the 61st through 90th day of hospitalization in a benefit period will be $371 (one-fourth of the inpatient hospital deductible as stated in section 1813(a)(1)(A) of the Act); the daily coinsurance for lifetime reserve days will be $742 (one-half of the inpatient hospital deductible as stated in section 1813(a)(1)(B) of the Act); and the daily coinsurance for the 21st through 100th day of extended care services in a skilled nursing facility (SNF) in a benefit period will be $185.50 (one-eighth of the inpatient hospital deductible as stated in section 1813(a)(3) of the Act).

IV. Cost to Medicare Beneficiaries

The Table below summarizes the deductible and coinsurance amounts for CYs 2020 and 2021, as well as the number of each that is estimated to be paid.

PART A DEDUCTIBLE AND COINSURANCE AMOUNTS FOR CALENDAR YEARS 2020 AND 2021

Type of cost sharing	Value		Number paid (in millions)	
	2020	2021	2020	2021
Inpatient hospital deductible	$1,408	$1,484	5.81	6.45
Daily coinsurance for 61st–90th Day	352	371	1.31	1.46
Daily coinsurance for lifetime reserve days	704	742	0.65	0.72
SNF coinsurance	176.00	185.50	28.82	32.19

The estimated total increase in costs to beneficiaries is about $2,450 million (rounded to the nearest $10 million) due to: (1) The increase in the deductible and coinsurance amounts; and (2) the increase in the number of deductibles and daily coinsurance amounts paid. We determine the increase in cost to beneficiaries by calculating the difference between the 2020 and 2021 deductible and coinsurance amounts multiplied by the estimated increase in the number of deductible and coinsurance amounts paid.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 1871 of the Act and section 553(b) of the Administrative Procedure Act (APA). Section 1871(a)(2) of the Act provides that no rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under Medicare shall take effect unless it is promulgated through notice and comment rulemaking. Unless there is a statutory exception, section 1871(b)(1) of the Act generally requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment before establishing or changing a substantive legal standard regarding the matters enumerated by the statute. Similarly, under 5 U.S.C. 553(b) of the APA, the agency is required to publish a notice of proposed rulemaking in the **Federal Register** before a substantive rule takes effect. Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act usually require a 30-day delay in effective date after issuance or publication of a rule, subject to exceptions. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the advance notice and comment requirement and the delay in effective date requirements. Sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and the 30-day delay in effective date. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act expressly authorize an agency to dispense with notice and comment rulemaking for good cause if the agency makes a finding that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest.

The annual inpatient hospital deductible and the hospital and extended care services coinsurance amounts announcement set forth in this notice does not establish or change a substantive legal standard regarding the matters enumerated by the statute or constitute a substantive rule which would be subject to the notice requirements in section 553(b) of the APA. However, to the extent that an opportunity for public notice and comment could be construed as required for this notice, we find good cause to waive this requirement.

Section 1813(b)(2) of the Act requires publication of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts between September 1 and September 15 of the year preceding the year to which they will apply. Further, the statute requires that the agency determine and publish the inpatient hospital deductible and hospital and extended care services coinsurance amounts for each CY in accordance with the statutory formulae, and we are simply notifying the public of the changes to the deductible and coinsurance amounts for CY 2021. We have calculated the inpatient hospital deductible and hospital and extended care services coinsurance amounts as directed by the statute; the statute establishes both when the deductible and coinsurance amounts must be published and the information that the Secretary must factor into the deductible and coinsurance amounts, so we do not have any discretion in that regard. We find notice and comment procedures to be unnecessary for this notice and we find good cause to waive such procedures under section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act, if such procedures may be construed to be required at all. Through this notice, we are simply notifying the public of the updates to the inpatient hospital deductible and the hospital and extended care services coinsurance amounts, in accordance with the statute, for CY 2021. As such, we also note that even if notice and comment procedures were required for this notice, for the reasons stated above, we would find good cause to waive the delay in

effective date of the notice, as additional delay would be contrary to the public interest under section 1871(e)(1)(B)(ii) of the Act. Publication of this notice is consistent with section 1813(b)(2) of the Act, and we believe that any potential delay in the effective date of the notice, if such delay were required at all, could cause unnecessary confusion both for the agency and Medicare beneficiaries.

VI. Collection of Information Requirements

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.*).

VII. Regulatory Impact Analysis

Although this notice does not constitute a substantive rule, we nevertheless prepared this Regulatory Impact Analysis section in the interest of ensuring that the impacts of this notice are fully understood.

A. Statement of Need

Section 1813(b)(2) of the Act requires the Secretary to publish, between September 1 and September 15 of each year, the amounts of the inpatient hospital deductible and hospital and extended care services coinsurance applicable for services furnished in the following CY.

B. Overall Impact

We have examined the 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)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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 economically significant effects ($100 million or more in any 1 year). Although we do not consider this notice to constitute a substantive rule, this notice is economically significant under section 3(f)(1) of Executive Order 12866. As stated in section IV of this notice, we estimate that the total increase in costs to beneficiaries associated with this notice is about $2,450 million due to: (1) The increase in the deductible and coinsurance amounts; and (2) the increase in the number of deductibles and daily coinsurance amounts paid.

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, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2021 and will have an impact on the Medicare beneficiaries. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2021 and will have an impact on the Medicare beneficiaries. As a result, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this notice 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 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 2020, that threshold is approximately $156 million. This notice does not impose mandates that will have a consequential effect of $156 million or more on state, local, or tribal governments or on the private sector.

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 requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This notice will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have Federalism implications.

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

C. Congressional Review

Consistent with the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), this notice has been transmitted to the Congress and the Comptroller General for review.

Dated: October 30, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 2, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–25024 Filed 11–6–20; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0530]

Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Voluntary Disclosure of Sesame as an Allergen.'' The draft guidance, when finalized, will provide food manufacturers with FDA's current views on sesame as an allergen and will provide recommendations to voluntarily disclose sesame in certain circumstances where such disclosure is not currently required. The guidance is intended to help individuals who are allergic to sesame identify those foods that may contain sesame as an ingredient. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by January 11, 2021 to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by January 11, 2021.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–0530 for ''Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Carol D'lima, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Voluntary Disclosure of Sesame as an Allergen.'' We are issuing this draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person

and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of October 30, 2018 (83 FR 54594), we published a document inviting data and other information on the prevalence and severity of sesame allergies in the United States and the prevalence of sesame-containing foods sold in the United States that are not required to disclose sesame as an ingredient. The document also asked specific questions regarding the prevalence of allergies and allergic reactions due to sesame in the United States and the prevalence and amounts of undeclared sesame in foods. For example, we asked for examples of products or product categories that contain sesame as a spice, flavor, color, or incidental additive. The notice also stated that we had received a citizen petition in 2014 requesting, in part, that we issue a rule to require that sesame seeds and sesame products be regulated similarly to how major food allergens are regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (available at *https://www.regulations.gov/docket?D=FDA-2014-P-2035*). Among the various issues, the petition wanted FDA to require sesame's disclosure by the common or usual name ''sesame'' in food labeling and when present in ingredients, including a spice, flavoring, coloring, or incidental additive.

We received over 4,800 comments to the document from individual consumers and patients, as well as consumer and patient advocacy groups, medical professionals and patient caretakers, industry and trade associations, and academic institutions. Some comments submitted data and information from published studies. Data and information received in response to the document highlighted U.S. national prevalence data on sesame and other food allergens. Our communications about the notice directed the public to submit adverse events due to sesame to the CFSAN Adverse Event Reporting System (CAERS). We received over 500 individual adverse event reports.

Under our statute and regulations, if whole sesame seeds are used as an ingredient, they must be declared on the label (see section 403(i) of the FD&C Act (21 U.S.C 343(i)); 21 CFR 101.4); however, under current regulations, sesame can, in some circumstances, such as when ground in a spice blend, be declared in an ingredient statement as simply ''spice'' or ''flavor,'' so its presence may not be obvious to consumers. Some comments to the document highlighted the lack of consistent labeling of sesame on food and stated this was a major problem for those with a sesame allergy.

Based on information received in the comments to the notice, the 2014 citizen petition, and comments submitted to the corresponding docket, other correspondence, as well as adverse event reports and recent publications with prevalence data, it appears that sesame allergy may be an increasing problem in the U.S. population. We continue to evaluate the emerging evidence and are working to develop factors to inform future regulatory actions related to sesame and other emerging food allergens, including possible labeling requirements. As we engage in this important work, we recommend, in the interim, that manufacturers voluntarily take steps to help consumers who are allergic or sensitive to sesame by disclosing the presence of sesame in packaged foods, even in circumstances where such disclosure would not be required (*e.g.,* in spices and flavorings). The guidance would recommend, when finalized, that manufacturers voluntarily declare sesame in the ingredient list when it is used in foods as a ''flavor'' or ''spice'' in a parenthetical following the spice or flavor, such as, ''spice (sesame),'' ''spices (including sesame),'' ''flavor (sesame),'' or ''flavors (including sesame).'' Similarly, if a term is used for a food that is or contains sesame, such as tahini, the guidance would recommend that sesame be included in a parenthesis, *e.g.,* ''tahini (sesame)'' in the ingredient list. This will help consumers, especially those allergic to sesame, avoid foods that could cause an allergic reaction.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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.

Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry

OMB Control Number 0910–0792—Revision

The draft guidance, when finalized, will provide food manufacturers with recommendations regarding voluntarily declaring sesame in certain circumstances where such declaration is not currently required. For example, if a term is used for a food that is or contains sesame, the guidance would recommend that sesame should be included in a parenthesis in the ingredient list.

Description of respondents: The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs
Review labels to follow guidance recommendations	77,500	1	77,500	1	77,500	0
Redesign labels to follow guidance recommendations	775	1	775	16	12,400	$1,414,375
Total					89,900	1,414,375

[1] There are no operating and maintenance costs associated with this collection of information.

We base these estimates from our experience with our food allergen labeling program and our labeling cost model. We estimate that there are approximately 775,000 Universal Product Codes (UPCs) of FDA-regulated foods. Using FDA's labeling cost model, we estimate the entry rate of new UPCs to be approximately 8 percent per year. Based on the approximate entry rate of new UPCs, we estimate the rate of new or reformulated UPCs to be approximately 10 percent per year, or 77,500 products (775,000 ×10 percent). Thus, we estimate that 77,500 new or reformulated products are sold annually in the United States. Assuming an association of 1 respondent to each of the 77,500 new or reformulated products, we estimate that 77,500 respondents will each review the label of one of the 77,500 new or reformulated products, as reported in table 1, row 1. We have no data on how many label reviews would identify an opportunity to redesign the label. Therefore, we further estimate, for the purposes of this analysis, that 1 percent of the reviewed labels of new or reformulated products, or 775 labels (77,500 × 1 percent) would be redesigned as recommended by the guidance. Assuming an association of 1 respondent to each of the 775 labels, we estimate that 775 respondents will each redesign 1 label. Using our labeling cost model, we estimate that it will take an average of 16 hours to complete the administration and internal design work for the redesign of a label to follow the recommendations of the guidance, as reported in table 1, row 2. Consequently, the burden of redesigning the 775 labels of new or reformulated products is 12,400 hours, as reported in table 1, row 2.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: November 2, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–24727 Filed 11–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–N–3065; FDA–2016–N–4620; FDA–2019–N–6063; FDA–2017–N–1066; FDA–2018–N–3065; FDA–2008–N–0424; and FDA–2019–N–5711]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Required Warnings for Cigarette Packages and Advertisements	0910–0877	04/30/2023
Medical Devices; Reports of Corrections and Removals	0910–0359	10/31/2023
Customer/Partner Service Surveys	0910–0360	10/31/2023
Annual Reporting for Custom Device Exemption	0910–0767	10/31/2023
Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act	0910–0800	10/31/2023
Postmarketing Safety Reporting for Combination Products	0910–0834	10/31/2023
Importation of Prescription Drugs	0910–0888	10/31/2023

Dated: November 5, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25019 Filed 11–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0998]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collections of information in the regulations for in vivo radiopharmaceuticals used for diagnosis and monitoring.

DATES: Submit either electronic or written comments on the collection of information by January 11, 2021.

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 January 11, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 11, 2021. 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–2014–N–0998 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring.'' 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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, including each proposed extension of an existing 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.

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring—21 CFR Part 315

OMB Control Number 0910–0409—Extension

This information collection supports our regulations in part 315 (21 CFR part 315) that require manufacturers of diagnostic radiopharmaceuticals to submit information that demonstrates the safety and effectiveness of: (1) A new diagnostic radiopharmaceutical; or (2) a new indication for use of an approved diagnostic radiopharmaceutical. Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables us to properly evaluate the safety and effectiveness profiles of such radiopharmaceuticals.

The information, which is usually submitted as part of a new drug application (NDA) or biologics license application (BLA) or as a supplement to an approved application typically includes, but is not limited to, nonclinical and clinical data on the pharmacology; toxicology; adverse events; radiation safety assessments; and chemistry, manufacturing, and controls. The content and format of an application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50) and have been approved under OMB control number 0910–0001. This information collection supports part 315, which is currently approved under OMB control number 0910–0409.

In table 1, row 1, we estimate the annual reporting burden for preparing the safety and effectiveness sections of an application. This estimate does not include the time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Based on past submissions of human drug applications, new indication supplements for diagnostic radiopharmaceuticals, or both, we estimate that six submissions will be received annually and that 2,000 hours would be spent preparing the portions of the application that would be affected by this information collection. We further estimate the total time needed to prepare complete applications for diagnostic radiopharmaceuticals as approximately 12,000 hours. This information collection does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours, because safety and effectiveness information is already required in § 314.50 and has been approved under OMB control number 0910–0001. In fact, clarification of our criteria for the evaluation of diagnostic radiopharmaceuticals in this information collection is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies.

In table 1, row 2, we estimate the annual reporting burden for preparing the safety and effectiveness sections of a supplement to an approved application. This estimate does not include the time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Based on past submissions of human drug applications, new indication supplements for diagnostic radiopharmaceuticals, or both, we estimate that nine submissions will be received annually. We estimate the total time needed to prepare complete applications for supplements to new applications for diagnostic radiopharmaceuticals as approximately between 500 and 1,000 hours. We calculated the median of this estimate to arrive at approximately 750 hours. We further estimate that the total time needed to prepare the portions of the application that would be affected by this information collection as 6,750. As previously stated, this information collection does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 750 hours, because safety and effectiveness information is already required in § 314.50 and has been approved under OMB control number 0910–0001.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR NDAS AND SUPPLEMENTS TO APPROVED NDAS FOR DIAGNOSTIC RADIOPHARMACEUTICALS [1]

Manufacturers' activity (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
NDAs (§§ 315.4, 315.5, and 315.6)	6	1	6	2,000	12,000
Supplements to Approved NDAs (§§ 315.4, 315.5, and 315.6)	9	1	9	750	6,750
Total					18,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 13 responses with a corresponding increase of 14,750 burden hours, including submissions involving NDAs. We attribute this adjustment to an increase in the number of submissions for NDAs for diagnostic radiopharmaceuticals we received over the past few years and because we are now capturing supplements to approved NDAs for diagnostic radiopharmaceuticals.

Dated: November 5, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25023 Filed 11–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–N–0908; FDA–2010–N–0583; FDA–2020–N–0257; FDA–2008–N–0490; FDA–2011–N–0017; FDA–2011–N–0144; FDA–2015–D–3327; FDA–2020–N–1207]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Submission of Petitions: Food Additive, Color Additive (Including Labeling), Submission of Information to a Master File in Support of Petitions, and Electronic Submission Using FDA Form 3503	0910–0016	09/30/2023
Radioactive Drug Research Committees	0910–0053	09/30/2023
Rapid Response Surveys	0910–0500	09/30/2023
Cosmetic Labeling and Voluntary Cosmetic Registration	0910–0599	09/30/2023
Voluntary National Retail Food Regulatory Program Standards	0910–0621	09/30/2023
FDA's Voluntary Qualified Importer Program; Guidance for Industry	0910–0840	09/30/2023
GFI: E6(R2) Good Clinical Practice; International Council for Harmonisation	0910–0843	09/30/2023
List of US Manufacturers of Specific CVM-Regulated Products with Interest in Exporting Covered Products to China	0910–0884	09/30/2023

Dated: November 5, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25022 Filed 11–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval: Public Comment Request; Information Collection Request Title: Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report OMB No. 0915–0172—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR must be received no later than December 14, 2020.

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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report OMB No. 0915–0172—Revision.

Abstract: HRSA is updating the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report.* This Guidance is used annually by the 50 states and nine jurisdictions (hereafter referred to as ''state'') in applying for Block Grants under Title V of the Social Security Act and in preparing the required Annual Report. The updates being proposed by HRSA's Maternal and Child Health Bureau (MCHB) for this edition of the Guidance continue to honor the federal-state partnership that is supported by the Title V Maternal and Child Health Services Block Grant and reinforce the state's role in developing a Five-Year Action Plan that addresses its individual priority needs. These proposed updates build on and further refine the reporting structure and vision that was outlined in the previous edition. As such, they are intended to enable a state to provide an articulate and comprehensive description of its Title V program activities and its leadership efforts in advancing and assuring a public health system that serves the Maternal and Child Health population. HRSA's proposed updates

to this edition of the Guidance were informed by comments received from State Title V program leadership, national Maternal and Child Health leaders and other stakeholders. Publication of a 60-day **Federal Register** Notice on June 15, 2020 (85 FR 36217) generated comments on proposed changes to the narrative instructions, reporting forms, and appendices.

While retaining the current organizational structure, performance measure framework and focus on family partnership, specific updates to this edition of the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report* include the following:

(1) Add clarifying language/instructions for completing the reporting forms and updating the Glossary of terms, references and citations, as needed.

(2) Revise the content of the National Outcome/Performance Measure Detail Sheets to include the 2030 *Healthy People* Objectives and to provide clear links to evidence-based and-informed strategies, federally available/state-reported data and data notes.

(3) Revise the format for Form #10e, which serves as the detail sheet for the state-specific measures (*i.e.,* Evidence-based and -Informed Strategy Measures (ESM), State Performance Measures (SPM), and State Outcome Measures (SOM)). Implement a staggered approach that requires states to use the revised form for all newly established state-specific measures and allows states to transition existing measures to the new form by the end of the five-year reporting cycle.

(4) Provide continued emphasis on family partnership and engagement at the systems level and include the Family Engagement in Systems Assessment Tool and Toolkit (FESAT) as one possible tool for State Title V programs to consider.

(5) Share background information, resources, state examples/metrics and definitions to assist states in their efforts to advance population health strategies for children with special health care needs (CSHCN).

(6) Expand Form 5 to include infants in the state's reporting on the number (5a) and percent (5b) of CSHCN served by Title V, *i.e.,* update the reporting to include infants and children with special health care needs (0–21 years).

(7) Enhance the narrative and performance reporting on State Title V efforts to build or expand program capacity related to Maternal and Child Health data access and cross-program data linkages, Maternal and Child Health workforce development/training, and emergency planning/preparedness.

a. Integrate key aspects of the annual performance and progress reporting for the State Systems Development Initiative (SSDI) grant into the Title V Maternal and Child Health Services Block Grant Application/Annual Report to allow for more focused narrative reporting on SSDI program goals and activities relative to the State Title V Maternal and Child Health program and provide an annual assessment of the state's progress in building/expanding Maternal and Child Health data capacity through an added reporting form.

b. Enhance the annual narrative reporting to include a more robust description of the State Title V workforce capacity (*e.g.,* number/types of Full-Time Equivalents, trends/shifts in Maternal and Child Health workforce, and key external partners) and professional development efforts, while providing resources to assist State Title V programs in their ongoing assessment of Maternal and Child Health workforce and training needs.

c. Expand the annual narrative reporting to include a descriptive analysis of the

Title V program's role in the state's emergency planning and preparedness efforts, with the intended purpose of enabling each State Title V program to better assess capacity within the state for responding to emerging public health threats and disasters that could potentially impact the Maternal and Child Health population.

(8) Expand and enhance the Appendices to include supportive background information, examples, resources and tools.

In consideration of the increasing demands that are being placed on State Title V programs at this time due to the COVID–19 emergency and given that no major changes to the reporting requirements are being proposed, the burden estimates presented in the table below are based on the previous burden estimates for completion of the Title V Maternal and Child Health Services Block Grant Application/Annual Report. These estimates were developed based on prior estimates and consultations with a few States. When the COVID–19 emergency subsides, HRSA can solicit additional information from states to derive more accurate burden estimates.

The addition of clarifying instructions, state examples, reformatted Glossary, expanded background information and supportive resources and tools, where possible, is expected to assist State Title V programs in responding to the reporting requirements. It is anticipated that further reductions in burden will be realized through the proposed revisions to the National Outcome/Performance Measure detail sheets and to Form #10e. These reductions in burden will be partially offset by the addition of one reporting form (formerly part of the state's annual performance reporting for the SSDI grant). This reporting will be coupled with expanded narrative reporting on the state's SSDI grant activities, along with other capacity-building efforts that relate to the Maternal and Child Health workforce and emergency planning and preparedness.

A 60-day notice published in the **Federal Register** on June 15, 2020, vol. 85, No. 115; pp. 36217–18. There were 10 public comments.

Need and Proposed Use of the Information: Each year, all states are required to submit an Application/Annual Report for Federal funds for their Title V Maternal and Child Health Services Block Grant to States Program to the HRSA's MCHB (Section 505(a) of Title V of the Social Security Act). In addition, the State Maternal and Child Health Services Block Grant programs are required to conduct a state-wide, comprehensive Needs Assessment every five years. The information and instructions for the preparation and submission of this Application/Annual Report are contained in the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report.*

Likely Respondents: By legislation (Section 505(a) of Title V of the Social Security Act), the Maternal and Child Health Services Block Grant Application/Annual Report must be developed by, or in consultation with, the State Maternal and Child Health agency.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This estimate includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Burden per response (in hours)	Total burden hours
Application and Annual Report without Five-Year Needs Assessment Summary	59	1	59	120	7,080
Average Total Annual Burden	59		59		7,080

States will use the updated edition of the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report* to prepare and submit the fiscal year (FY) 2022, FY 2023 and FY 2024 Applications/FY 2020, FY 2021 and FY 2022 Annual Reports, which will not contain the Five-Year Needs Assessment Summary. States will submit the next Five-Year Needs Assessment Summary in 2025, as part of the FY 2026 Application/FY 2024 Annual Report. Instructions for preparing the FY 2025, FY 2026 and FY 2027 Applications/FY 2023, FY 2024 and FY 2025 Annual Reports will be provided in the subsequent edition of the Application/Annual Report Guidance.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–25031 Filed 11–10–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

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 material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Review Subcommittee Member Conflict Panel.

Date: December 2, 2020.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700 B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2120, MSC 6902, Bethesda, MD 20892, 301–443–4032, *anna.ghambaryan@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: November 4, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–24985 Filed 11–10–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NIMH HIV/AIDS Training Review (R25, T32, K99).

Date: December 4, 2020.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892–9608, 301–443–4525, *steinerr@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel NIMH HIV/AIDS Review (P30).

Date: December 9, 2020.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Jasenka Borzan, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Mental Health, 6001 Executive Blvd., Neuroscience Center, Room 6150, Bethesda, MD 20892, 301–435–1260, *jasenka.borzan@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 4, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–24980 Filed 11–10–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Neurodevelopmental and Neurological Disorders.

Date: November 30, 2020.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Special Topics in Aging: Falls and Frailty, Diet, Inflammation and Hydrocephalus.

Date: December 1, 2020.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Biobehavioral Regulation, Learning and Ethology.

Date: December 2, 2020.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3089B, MSC 7848, Bethesda, MD 20892, (301) 402–4411, *tianbi@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Medical Imaging Investigations.

Date: December 4, 2020.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, (301) 237–9870, *xuguofen@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Mechanisms of Bacterial Pathogenesis and Transmission.

Date: December 4, 2020.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gagan Pandya, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, RM 3200, MSC 7808, Bethesda, MD 20892, (301) 435–1167, *pandyaga@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Topics in Bacterial Pathogenesis.

Date: December 4, 2020.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Susan Daum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, Bethesda, MD 20892, (301) 827–7233, *susan.daum@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Autoimmunity, Immunology, and Transplantation.

Date: December 4, 2020.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jian Wang, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095D, MSC 7812, Bethesda, MD 20892, (301) 435–2778, *wangjia@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 5, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–24981 Filed 11–10–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute Of Allergy And Infectious Diseases; Notice of Closed Meeting

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 material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Centers for AIDS Research (P30) and Developmental Centers for AIDS Research (P30).

Date: December 7–8, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 6701 Rockledge Drive, Room 1206, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: John C. Pugh, Ph.D., Scientific Review Officer, National Institute of Allergy and Infectious Diseases, National Institutes of Health 6701 Rockledge Drive, Room 1206, Bethesda, MD 20892, (301) 435–2398, *pughjohn@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 6, 2020.

Tyeshia M. Roberson,

Program Analyst Office of Federal Advisory Committee Policy.

[FR Doc. 2020–25051 Filed 11–10–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

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). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The date of March 9, 2021 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
Gulf County, Florida and Incorporated Areas Docket No.: FEMA–B–1977	
City of Port St. Joe	Building Department, 1002 10th Street, Port St. Joe, FL 32456.
City of Wewahitchka	Administration Department, 318 South 7th Street, Wewahitchka, FL 32465.
Unincorporated Areas of Gulf County	Gulf County Emergency Management Department, 1000 Cecil G. Costin, Sr. Boulevard, Port St. Joe, FL 32456.
Okaloosa County, Florida and Incorporated Areas Docket No.: FEMA–B–1652	
City of Crestview	Community Development Services Department, 198 North Wilson Street, Crestview, FL 32536.
City of Destin	City Hall, 4200 Indian Bayou Trail, Destin, FL 32541.
City of Fort Walton Beach	Growth Management Department, 105 Miracle Strip Parkway Southwest, Fort Walton Beach, FL 32548.
City of Laurel Hill	Administration Department, 8209 Highway 85 North, Laurel Hill, FL 32567.
City of Mary Esther	Code Enforcement, Planning, and Zoning Department, 195 Christobal Road North, Mary Esther, FL 32569.
City of Niceville	Public Library, 206 Partin Drive North, Niceville, FL 32578.
City of Valparaiso	Administration Department, 465 Valparaiso Parkway, Valparaiso, FL 32580.
Town of Cinco Bayou	Administration Department, 10 Yacht Club Drive, Cinco Bayou, FL 32548.
Town of Shalimar	Administration Department, 2 Cherokee Road, Shalimar, FL 32579.
Unincorporated Areas of Okaloosa County	Okaloosa County Growth Management Administration, 1250 North Eglin Parkway, Suite 301, Shalimar, FL 32579.

Community	Community map repository address
Red Lake County, Minnesota and Incorporated Areas Docket Nos.: FEMA–B–1965	
City of Brooks	Brooks Community Federal Credit Union, 200 Main Street, Brooks, MN 56715.
City of Oklee	Oklee Municipal Center, 301 Main Street, Oklee, MN 56742.
City of Plummer	Municipal Building, 185 Minnesota Street, Plummer, MN 56748.
City of Red Lake Falls	City Hall, 108 2nd Street Southwest, Red Lake Falls, MN 56750.
Red Lake Band of Chippewa Tribe	Red Lake Nation Government Center, 15484 Migizi Drive, Red Lake, MN 56671.
Unincorporated Areas of Red Lake County	Red Lake County Courthouse, 124 Langevin Avenue, Red Lake Falls, MN 56750.
St. Charles County, Missouri and Incorporated Areas Docket No.: FEMA–B–1873	
City of St. Charles	City Hall, 200 North 2nd Street, St. Charles, MO 63301.
Unincorporated Areas of St. Charles County	County Administration Building, 201 North 2nd Street, Suite 420, St. Charles, MO 63301.
Defiance County, Ohio and Incorporated Areas Docket No.: FEMA–B–1972	
City of Defiance	City Hall, 631 Perry Street, Defiance, OH 43512.
Unincorporated Areas of Defiance County	Defiance County Building, 500 Court Street, Defiance, OH 43512.
Lorain County, Ohio and Incorporated Areas Docket No.: FEMA–B–1806 and FEMA–B–1965	
City of Avon Lake	City Hall, Engineering and Public Works Department, 150 Avon Belden Road, Avon Lake, OH 44012.
City of Lorain	City Hall, Engineering Department, 200 West Erie Avenue, 4th Floor, Lorain, OH 44052.
City of Sheffield Lake	Building/Fire Department, 4750 Richelieu Avenue, Sheffield Lake, OH 44054.
City of Vermilion	City Hall, 5511 Liberty Avenue, Vermilion, OH 44089.

[FR Doc. 2020–24973 Filed 11–10–20; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency; DHS.

ACTION: Notice; correction.

SUMMARY: On August 21, 2020, FEMA published in the **Federal Register** a changes in flood hazard determination notice that contained an erroneous table. This notice provides corrections to that table, to be used in lieu of the information published at 85 FR 41608. The table provided here represents the changes in flood hazard determinations and communities affected for the City of Sanibel, Lee County, Florida.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

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 specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 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 FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more

stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

Correction

In the changes in flood hazard determination notice published at 85 FR 41608 in the August 21, 2020 issue of the **Federal Register**, FEMA published a table with erroneous information. This table contained inaccurate Date of modification for the City of Sanibel, Lee County, Florida.

In this document, FEMA is publishing a table containing the accurate information. The information provided below should be used in lieu of that previously published.

(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.
Florida: Lee	City of Sanibel (20–04–2943P).	The Honorable Kevin Ruane, Mayor, City of Sanibel, 800 Dunlop Road, Sanibel, FL 33957.	Community Services Department, 800 Dunlop Road, Sanibel, FL 33957.	Nov. 10, 2020	120402

[FR Doc. 2020–24982 Filed 11–10–20; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0002; Internal Agency Docket No. FEMA–B–2067]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

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 specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 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 FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(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	Online location of letter of map revision	Date of modification	Community No.
Colorado:						
Denver	City and County of Denver (20–08–0372P).	The Honorable Michael B. Hancock, Mayor, City and County of Denver, 1437 North Bannock Street, Room 350, Denver, CO 80202.	Department of Public Works, 201 West Colfax Avenue, Denver, CO 80202.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 11, 2021	080046
Eagle	Town of Basalt (20–08–0275P).	Mr. Ryan Mahoney, Manager, Town of Basalt, 101 Midland Avenue, Basalt, CO 81621.	Town Hall, 101 Midland Avenue, Basalt, CO 81621.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 26, 2021	080052
Eagle	Unincorporated areas of Eagle County (20–08–0275P).	Mr. Jeff Schroll, Eagle County Manager, P.O. Box 850, Eagle, CO 81631.	Eagle County Engineering Department, 500 Broadway Street, Eagle, CO 81631.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 26, 2021	080051
El Paso	Unincorporated areas of El Paso County (20–08–0369P).	The Honorable Mark Waller, Chairman, El Paso County Board of Commissioners, 200 South Cascade Avenue, Suite 100, Colorado Springs, CO 80903.	Pikes Peak Regional Development Center, 2880 International Circle, Colorado Springs, CO 80910.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 16, 2021	080059
Connecticut:						
Fairfield	Town of Darien (20–01–0611P).	The Honorable Jayme J. Stevenson, First Selectman, Town of Darien Board of Selectmen, 2 Renshaw Road, Room 202, Darien, CT 06820.	Planning and Zoning Department, 2 Renshaw Road, Darien, CT 06820.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 22, 2021	090005
New Haven	Town of Branford (20–01–0799P).	The Honorable James B. Cosgrove, First Selectman, Town of Branford Board of Selectmen, 1019 Main Street, Branford, CT 06405.	Engineering Department, 1019 Main Street, Branford, CT 06405.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 15, 2021	090073
Florida:						
Bay	City of Panama City Beach (20–04–1474P).	The Honorable Mark Sheldon, Mayor, City of Panama City Beach, 116 South Arnold Road, Panama City Beach, FL 32413.	Building Division, 116 South Arnold Road, Panama City Beach, FL 32413.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 28, 2021	120013
Bay	Unincorporated areas of Bay County (19–04–4735P).	The Honorable Philip "Griff" Griffitts, Chairman, 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.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 16, 2021	120004
Collier	City of Marco Island (20–04–4781P).	Mr. Mike McNees, Manager, City of Marco Island, 50 Bald Eagle Drive, Marco Island, FL 34145.	Building Services Department, 50 Bald Eagle Drive, Marco Island, FL 34145.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 22, 2021	120426
Hillsborough	City of Tampa (20–04–0296P).	The Honorable Jane Castor, Mayor, City of Tampa, 306 East Jackson Street, Tampa, FL 33602.	Planning and Development Department, 1400 North Boulevard, Tampa, FL 33607.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 8, 2021	120114
Hillsborough	Unincorporated areas of Hillsborough County (20–04–0296P).	Ms. Bonnie M. Wise, Hillsborough County Administrator, 601 East Kennedy Boulevard, Tampa, FL 33602.	Hillsborough County Development Services Department, 601 East Kennedy Boulevard, Tampa, FL 33602.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 8, 2021	120112
Lake	City of Leesburg (20–04–0931P).	Mr. Al Minner, Manager, City of Leesburg, 501 West Meadow Street, Leesburg, FL 34748.	Planning and Zoning Department, 204 North 5th Street, Leesburg, FL 34748.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 13, 2021	120136
Lake	Unincorporated areas of Lake County (20–04–0931P).	The Honorable Leslie Campione, Chair, Lake County Board of Commissioners, 315 West Main Street, Tavares, FL 32778.	Lake County Public Works Department, 323 North Sinclair Avenue, Tavares, FL 32778.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 13, 2021	120421
Lee	Town of Fort Myers Beach (20–04–3679P).	The Honorable Ray Murphy, Mayor, Town of Fort Myers Beach, 2525 Estero Boulevard, Fort Myers Beach, FL 33931.	Community Development Department, 2525 Estero Boulevard, Fort Myers Beach, FL 33931.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 19, 2021	120673

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Monroe	Unincorporated areas of Monroe County (20–04–4173P).	The Honorable Heather Carruthers, Mayor, Monroe County Board of Commissioners, 500 Whitehead Street, Suite 102, Key West, FL 33040.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 19, 2021	125129
Orange	Unincorporated areas of Orange County (20–04–1076P).	The Honorable Jerry L. Demings, Mayor, Orange County, 201 South Rosalind Avenue, 5th Floor, Orlando, FL 32801.	Orange County Planning and Development Department, 4200 South John Young Parkway, Orlando, FL 32839.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 12, 2021	120179
Osceola	Unincorporated areas of Osceola County (20–04–1076P).	The Honorable Viviana Janer, Chair, Osceola County Board of Commissioners, 1 Courthouse Square, Suite 4700, Kissimmee, FL 34741.	Osceola County Building Department, 1 Courthouse Square, Suite 1400, Kissimmee, FL 34741.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 12, 2021	120189
Palm Beach	Unincorporated areas of Palm Beach County (19–04–6690P).	The Honorable Dave Kerner, Mayor, Palm Beach County, 301 North Olive Avenue, Suite 1201, West Palm Beach, FL 33401.	Palm Beach County Department of Planning, Zoning and Building Department, 2300 North Jog Road, West Palm Beach, FL 33401.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 29, 2021	120192
Montana: Lewis and Clark.	City of Helena (20–08–0095P).	The Honorable Wilmot Collins, Mayor, City of Helena, 316 North Park Avenue, Room 323, Helena, MT 59623.	City Hall, 316 North Park Avenue, Helena, MT 59623.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 28, 2021	300040
New Hampshire:						
Rockingham	Town of Salem (20–01–0650P).	Mr. Christopher A. Dillon, Manager, Town of Salem, 33 Geremonty Drive, Salem, NH 03079.	Town Hall, 33 Geremonty Drive, Salem, NH 03079.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 19, 2021	330142
Strafford	City of Dover (20–01–0517P).	The Honorable Robert Carrier, Mayor, City of Dover, 288 Central Avenue, Dover, NH 03820.	Planning Department, 288 Central Avenue, Dover, NH 03820.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 26, 2021	330145
North Carolina:						
Henderson	Unincorporated areas of Henderson County (20–04–2036P).	The Honorable Grady Hawkins, Chairman, Henderson County Board of Commissioners, 1 Historic Courthouse Square, Suite 1, Hendersonville, NC 27102.	Henderson County Administration Building, 100 North King Street, Hendersonville, NC 28792.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 17, 2020	370125
Johnston	Town of Wilson's Mills (20–04–2016P).	The Honorable Jim Uzzle, Jr., Mayor, Town of Wilson's Mills, P.O. Box 448, Wilson's Mills, NC 27593.	Town Hall, 100 Railroad Street, Wilson's Mills, NC 27593.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 4, 2021	370262
Johnston	Unincorporated areas of Johnston County (20–04–2016P).	The Honorable Ted G. Godwin, Chairman, Johnston County Board of Commissioners, P.O. Box 1049 Smithfield, NC 27577.	Johnston County Planning Department, 309 East Market Street, Smithfield, NC 27577.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 4, 2021	370138
Oklahoma:						
Payne	City of Stillwater (20–06–0276P).	The Honorable Will Joyce, Mayor, City of Stillwater, 723 South Lewis Street, Stillwater, OK 74047.	Development Services Department, 723 South Lewis Street, Stillwater, OK 74047.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 22, 2021	405380
Payne	Unincorporated areas of Payne County (20–06–0276P).	The Honorable Kent Bradley, Chairman, Payne County Board of Commissioners, 506 Expo Circle South, Stillwater, OK 74074.	Payne County Administrative Building, 315 West 6th Street, Suite 203, Stillwater, OK 74074.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 22, 2021	400493
Tennessee:						
Shelby	City of Memphis (20–04–1185P).	The Honorable Jim Strickland, Mayor, City of Memphis, 125 North Main Street, Room 700, Memphis, TN 38103.	Engineering Division, 125 North Main Street, Room 677, Memphis, TN 38103.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 27, 2021	470177

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Shelby	Unincorporated areas of Shelby County (20–04–1185P).	The Honorable Lee Harris, Mayor, Shelby County, 160 North Main Street, Memphis, TN 38103.	Shelby County Department of Engineering, 6463 Haley Road, Memphis, TN 38134.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 27, 2021	470214
Texas:						
Bell	City of Temple (20–06–2105P).	The Honorable Tim Davis, Mayor, City of Temple, 2 North Main Street, Suite 103, Temple, TX 76501.	Department of Public Works, Engineering Division, 3210 East Avenue H, Building A, Suite 107, Temple, TX 76501.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 16, 2021	480034
Denton	City of Sanger (20–06–1045P).	The Honorable Thomas Muir, Mayor, City of Sanger, P.O. Box 1729, Sanger, TX 76266.	City Hall, 201 Bolivar Street, Sanger, TX 76266.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 25, 2021	480786
Denton	Unincorporated areas of Denton County (20–06–1045P).	The Honorable Andy Eads, Denton County Judge, 110 West Hickory Street, 2nd Floor, Denton, TX 76201.	Denton County Public Works, Engineering Department, 1505 East McKinney Street, Suite 175, Denton, TX 76209.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 25, 2021	480774
Guadalupe	City of San Marcos (20–06–3176P).	The Honorable Jane Hughson, Mayor, City of San Marcos, 630 East Hopkins Street, San Marcos, TX 78666.	Engineering Department, 630 East Hopkins Street, San Marcos, TX 78666.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 31, 2020	485505

[FR Doc. 2020–24976 Filed 11–10–20; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2011–0008]

Aviation Security Advisory Committee (ASAC) Meeting

AGENCY: Transportation Security Administration, DHS.

ACTION: Committee management; notice of federal advisory committee meeting.

SUMMARY: The Transportation Security Administration (TSA) will hold a meeting of the Aviation Security Advisory Committee (ASAC) to discuss issues listed in the Meeting Agenda section below. This meeting will be open to the public as stated in the Supplemental section below. In light of the current COVID–19 public health crisis, the meeting will be virtual.

DATES: The Committee will meet on Thursday, December 10, 2020, from 10:00 a.m. to 1:00 p.m. Eastern Standard Time. This meeting may end early if all business is completed. As listed in the Public Participation section below, requests to attend the meeting must be received by November 30, 2020. Requests to address the Committee must be received by November 30, 2020.

ADDRESSES: The meeting will be held virtually by teleconference. See Public Participation below for information on how to register to attend the meeting. Attendance information will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Tamika McCree Elhilali, Aviation Security Advisory Committee Designated Federal Official, Transportation Security Administration (TSA–28), 601 South 12th Street, Arlington, VA 20598–6028, *ASAC@tsa.dhs.gov,* 571–227–2632.

SUPPLEMENTARY INFORMATION:

I. Background

Notice of this meeting is given in accordance with the Aviation Security Stakeholder Participation Act, codified at 49 U.S.C. 44946. Pursuant to 49 U.S.C. 44946(f), ASAC is exempt from the Federal Advisory Committee Act (5 U.S.C. App.). The ASAC provides advice and industry perspective to the Administrator of TSA on aviation security matters, including the development, refinement, and implementation of policies, programs, rulemaking, and security directives pertaining to aviation security.

II. Meeting Agenda

The Committee will meet to discuss items listed in the agenda below:

- Legislative Update
- Subcommittee and Work Group briefings on calendar year (CY) 2020 activities, key issues, and areas of focus for CY 2021:
  - Air Cargo
  - Airlines
  - Airports
  - General Aviation
  - Insider Threat
  - International Aviation
  - Security Technology
- Public Comments
- Discussion of the CY 2021 Committee Agenda
- Closing Comments and Adjournment

III. Public Participation

The meeting will be open to the public and attendance may be limited due to technological and telephonic meeting constraints. Members of the public, all non-ASAC members, and non-TSA staff who wish to attend must register via email by submitting their name, contact number, and affiliation to *ASAC@tsa.dhs.gov* by November 30, 2020. Attendees will be admitted on a first-to-register basis. Attendance information will be provided upon registration.

In addition, members of the public must make advance arrangements by November 30, 2020 to present oral or written statements. The statements must specifically address issues pertaining to the items listed in the Meeting Agenda section; requests must be submitted via email to: *ASAC@tsa.dhs.gov*. The public comment period will begin at approximately 12:00 p.m. and will end at 1:00 p.m. Speakers are requested to limit their comments to three minutes.

The ASAC and TSA are committed to providing equal access to this virtual meeting for all participants. If you need alternative formats or services because of a disability, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section before November 30, 2020.

Dated: November 5, 2020. .

Eddie D. Mayenschein,

Assistant Administrator, Policy, Plans, and Engagement (PPE).

[FR Doc. 2020–25000 Filed 11–10–20; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0117]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: myE-Verify Program

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until December 14, 2020.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2010–0014. All submissions received must include the OMB Control Number 1615–0117 in the body of the letter, the agency name and Docket ID USCIS–2010–0014.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on August 18, 2020, at 85 FR 50831, allowing for a 60-day public comment period. USCIS did not receive any comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2010–0014 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* myE-Verify Program.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G–1499; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals and Households. myE-Verify (previously E-Verify Self Check) allows workers in the United States to enter data into the E-Verify system to ensure that the information relating to their eligibility to work is correct and accurate. This is necessary so that workers in the United States can correct their records before a hiring decision is made. This will lead to a more reliable and accurate E-Verify system that works better for both employers and employees.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection Form G–1499 is 250,000 and the estimated hour burden per response is 0.083 hour. Of this 250,000, an estimated 75,000 respondents will need to correct information that may have been entered incorrectly to continue using myE-Verify; this estimated burden per response is 0.083 hour. Of this 250,000, an estimated 10,000 respondents may be required to pursue further action to correct their records at the appropriate agency; this estimated burden per response is 1.183 hour. Of this 250,000, an estimated 25,000 respondents will be required to provide additional information for a second Authentication Check; this estimated burden per response is 0.25 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 45,153 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $0. There are no mailing or other costs associated with this collection of information.

Dated: November 5, 2020.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2020–25039 Filed 11–10–20; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–NEW]

Agency Information Collection Activities; New Collection: Report of Request/Receipt of Benefits by Aliens

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed new collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until January 11, 2021.

ADDRESSES: All submissions received must include the OMB Control Number 1615–NEW in the body of the letter, the agency name and Docket ID USCIS–2020–0020. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2020–0020. USCIS is limiting communications for this Notice as a result of USCIS' COVID–19 response actions.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number 240–721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2020–0020 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New Collection.

(2) *Title of the Form/Collection:* Report of Request/Receipt of Benefits by Aliens.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G–1558; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Federal Government; State, local or Tribal Government. This information collection is used by any benefit granting agency to report a request of or receipt of certain benefits by an alien.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection G–1558 is 2,400 and the estimated hour burden per response is 0.833 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 2,000 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $18,600.

Dated: November 5, 2020.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2020–25038 Filed 11–10–20; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6050–N–04]

Relief From HUD Public Housing and Section 8 Requirements Available During CY 2020 and CY 2021 to Public Housing Agencies To Assist With Recovery and Relief Efforts on Behalf of Families Affected by Presidentially Declared Major Disasters

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notification.

SUMMARY: This notification advises the public that HUD, in order to more effectively and expeditiously respond to Presidentially declared Major Disaster Declarations (MDDs), is establishing for calendar year (CY) 2020 and CY 2021 an expedited process for the review of requests for relief from HUD regulatory and/or administrative requirements (''HUD requirements'') for Public Housing Agencies (PHAs) located in

counties that are included in MDDs. PHAs located in areas covered by MDDs issued for which a related disaster occurs during CY 2020 and CY 2021 may request waivers of certain HUD Public Housing and Section 8 requirements and receive expedited review of such requests utilizing the flexibilities and expedited waiver process set out by this notification.

DATES: This document announces the waivers and flexibilities set out in this document as of the date of signature.

FOR FURTHER INFORMATION CONTACT: Tesia Irinyenikan, Office of Field Operations, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Room 3180, Washington, DC 20410–5000, or email *PIH_Disaster_Relief@hud.gov.* Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background Information

On several occasions in recent years, after Presidential disaster declarations, HUD has published documents announcing waivers and flexibilities available to PHAs, Tribes, and Tribally Designated Housing Entities (TDHEs) located in areas covered by MDDs.[1] In the interest of expediting HUD's ability to provide administrative relief to PHAs in MDD declaration areas, based on HUD's past experience, HUD is publishing this notification on waivers and flexibilities that will be made available to PHAs on an expedited basis following MDDs. The notification is organized as follows:

- Section II describes the flexibilities that are currently available to MDD PHAs under statutes and/or regulations. MDD PHAs may avail themselves of these flexibilities, following the process described in Section IV of the notification.
- Section III describes certain HUD requirements that, if waived, may facilitate an MDD PHA's ability to participate in relief and recovery efforts. An MDD PHA may request a waiver of a HUD requirement not listed in Section III and receive expedited review of the request if the MDD PHA demonstrates that the waiver is needed to assist in its relief and recovery efforts. An MDD PHA may not adopt any requested waiver prior to receiving HUD approval.
- Section IV describes certain HUD requirements that, if granted an exception, may facilitate an MDD PHA's ability to participate in relief and recovery efforts. An MDD PHA may request an exception not listed in Section IV and receive expedited review of the request if the MDD PHA demonstrates that the exception is needed to assist in its relief and recovery efforts. An MDD PHA may not adopt any requested exception prior to receiving HUD approval.
- Section V provides the instructions for submitting waiver requests.
- Section VI states that a Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

Waiver requests approved by HUD pursuant to this notification will be published in the **Federal Register** and will identify the MDD PHAs receiving such approvals. The process that HUD will use in assessing applications for waivers and flexibilities is covered below.

This notification applies only to Presidentially declared MDDs that occurred during CY 2020 and CY 2021. However, upon finding of good cause, HUD may consider extending the time period of regulatory waivers or flexibilities described below, subject to statutory limitations and pursuant to 24 CFR 5.110.

Pursuant to the authority provided under the Coronavirus Aid, Relief and Economic Security (CARES) Act (Pub. L. 116–36), HUD established waivers, administrative flexibilities and alternative requirements for numerous statutory and regulatory requirements for the Public Housing program, the Housing Choice Voucher (HCV) program, Indian Housing Block Grant (IHBG) program and the Indian Community Development Block Grant (ICBG) program. The Office of Public and Indian Housing's CARES Act-related Policy Notices, and other COVID–19 resources can be found at HUD's Public and Indian Housing COVID–19 Resources web page, *https://www.hud.gov/program_offices/public_indian_housing/covid_19_resources.*

Some of the regulatory waivers and exceptions found in Notice PIH 2020–13 (HA), REV–1 (COVID–19 Statutory and Regulatory Waivers Alternative Requirements . . .), or its replacement, are also applicable to MDD PHAs. However, the authority, pursuant to the CARES Act, to waive statutory requirements is not applicable under this notice. An MDD PHA seeking a waiver of a HUD regulation listed below, or of any other HUD requirement needed to assist the MDD PHA in its relief and recovery efforts must submit a waiver request pursuant to the process that will be provided in Section V of this notification. HUD will not approve an MDD PHA's or other recipient's request to waive a fair housing, civil rights, labor standards, or HUD's environmental review requirements.

II. Flexibilities That are Available to MDD PHAs During CY 2020 and CY 2021

HUD is exercising discretionary authority from section 106 of the Department of Housing and Urban Development Reform Act of 1989 and consistent with 24 CFR 5.110 to provide relief from the requirements described in this section of this notification. Upon application to HUD and appropriate documentation of good cause, HUD may approve, as noted below, regulatory relief for disaster relief and recovery to MDD PHAs. If a PHA needs the regulatory relief for more time, please submit documentation of good cause, and HUD may consider extending the flexibilities, subject to statutory limitations and pursuant to 24 CFR 5.110, to facilitate an MDD PHA's ability to participate in relief and recovery efforts. Unless otherwise stated, the deadline for requesting waivers is four months after the initial MDD.

A. 24 CFR 990.145(b) (Public housing dwelling units with approved vacancies). Section 990.145 lists the categories of vacant public housing units that are eligible to receive operating subsidy and are therefore considered to be ''approved vacancies.'' Under Section 990.145(b)(2), a PHA shall receive operating subsidy for units

[1] See, Regulatory and Administrative Waivers Granted for Public and Indian Housing Programs to Assist with Recovery and Relief in Hurricane Katrina Disaster Areas, 70 FR 57716 (October 3, 2005); Regulatory and Administrative Waivers Granted for Public and Indian Housing Programs to Assist with Recovery and Relief in Hurricane Rita Disaster Areas; and Additional Administrative Relief for Hurricane Katrina, 70 FR 66222 (November 1, 2005); Extension of Regulatory and Administrative Waivers Granted for Public and Indian Housing Programs to Assist With Recovery and Relief in Hurricanes Katrina, Rita, and Wilma Disaster Areas, 71 FR 78022 (December 27, 2006); Regulatory and Administrative Waivers Granted for Public and Indian Housing Programs to Assist with Recovery and Relief in Hurricane Wilma Disaster Areas, 71 FR 12988 (March 13, 2006); Regulatory and Administrative Waivers Granted for Public and Indian Housing Programs to Assist with Recovery and Relief in Superstorm Sandy Disaster Areas, 77 FR 71439 (November 30, 2012); Relief From HUD Requirements Available to PHAs to Assist With Recovery and Relief Efforts on Behalf of Families Affected by Hurricanes Harvey, Irma, Maria and Future Natural Disasters Where Major Disaster Declarations Might be Issued in 2017, 82 FR 46821 (October 6, 2017) and; Relief From HUD Requirements Available During Calendar Year (CY) 2018 to Public Housing Agencies To Assist With Recovery and Relief Efforts on Behalf of Families Affected by Presidentially-Declared Major Disasters, 83 FR 46180 (September 12, 2018).

that are vacant due to a federally declared, state declared or other declared disaster, subject to prior HUD approval, on a project-by-project basis. If an MDD PHA has a unit that has been vacated due to a Presidentially-declared disaster, then the MDD PHA, with HUD approval, may treat the unit as an ''approved vacancy.'' Upon the request of an MDD PHA and HUD approval, on a case-by-case basis, such units may be considered approved vacancies for a period not to exceed 12 months from the date of HUD approval.

III. HUD Requirements That May Be Waived

For an MDD PHA, HUD will review requests for waivers of HUD requirements on an expedited basis. This section lists procedural and substantive requirements for regulatory waivers in event of an MDD. An MDD PHA may also request a waiver of a HUD requirement not listed in this section and receive expedited review of the request if the MDD PHA documents that the waiver is needed for major disaster relief and/or recovery. If a PHA needs the regulatory relief for more time, please submit documentation of good cause, and HUD may consider extending the waiver, subject to statutory limitations and pursuant to 24 CFR 5.110, to facilitate an MDD PHA's ability to participate in relief and recovery efforts. PHAs should note that waivers of essential program requirements such as property inspection or income verification will not be granted in their entirety although modifications or requirements may be considered. Also, HUD's ability to grant waivers or approval of alternative requirements imposed by statute is limited to expressed statutory authority. PHAs should go through the hierarchy of verifying income as found in PIH Notice 2018–24 if sources of income are difficult to find. Similarly, while the requirement for Housing Quality Standards (HQS) inspections cannot be waived, HUD can consider variations to the acceptability criteria to HQS in case of disaster (under the authority of § 982.401(a)(4)).

An MDD PHA seeking a waiver of a HUD requirement listed below or of any other HUD requirement needed to assist the MDD PHA in its relief and recovery efforts must submit a waiver request pursuant to the process that will be provided in Section IV of this notification. The request must be submitted to HUD not later than 4 months following the date of the relevant disaster declaration. HUD will not approve an MDD PHA's or other recipient's request to waive a fair housing, civil rights, labor standards, or environmental protection requirement.

A. 24 CFR 905.400(i)(5) (Capital Fund Formula; Replacement Housing Factor to reflect formula need for projects with demolition or disposition occurring on or after October 1, 1998, and prior to September 30, 2013). Section 905.400 describes the Capital Fund formula. Section 905.400(i)(5) limits the use of replacement housing funds to the development of new public housing. To help address housing needs because of the displacement caused by the MDD, HUD will consider waiving section 905.400(i)(5) to allow all unexpended Capital Fund Replacement Housing Factor Grants to be used for public housing modernization. Should HUD waive this requirement, the waiver will be in effect for funds obligated within 12 months from the date of HUD approval.

B. 24 CFR 982.503(c) (HUD approval of exception payment standard amount). 24 CFR 982.503(c) authorizes HUD to approve an exception payment standard amount that is higher than 110 percent of the published fair market rent (FMR). Typically, a PHA must provide data about the local market to substantiate the need for an exception payment standard. In a major disaster declaration situation, however, the typical data sources may fail to capture conditions on the ground. In these cases, HUD considers the most recently available data on the rental market, prior to the disaster, then estimates the number of households seeking housing units in the wake of the disaster to arrive at an emergency exception payment standard amount. In the event of a disaster, HUD will consider, based on this data, whether exception payment standard amounts up to 150 percent of the FMR have a good cause justification even in the absence of supporting data. If so, an MDD PHA may request this payment standard. Upon approval by HUD, an exception payment standard adopted pursuant to this notification may be adopted for any Housing Assistance Payments (HAP) contract entered as of the effective date of this notification. HUD intends for these exception payment standards to remain in effect until HUD implements changes to the FMRs in the affected areas under an MDD. MDD PHAs are reminded that increased per-family costs resulting from the use of exception payment standards may result in a reduction in the number of families assisted or may require other cost-saving measures for an MDD PHA to stay within its funding limitations.

C. 24 CFR 982.633(a) (Occupancy of home). This section establishes the requirement that PHAs may make HAP for homeownership assistance only while a family resides in their home and must stop HAP no later than the month after a family moves out. HUD will consider a request from an MDD PHA wishing to waive this requirement to allow families displaced from their homes located in areas affected by MDD(s) to comply with mortgage terms or make necessary repairs. A PHA requesting a waiver of this type must show good cause by demonstrating that the family is not already receiving assistance from another source. *Note:* An MDD PHA must separately request a waiver of the requirement at § 982.312 (that a family be terminated from the program if they have been absent from their home for 180 consecutive calendar days).

D. Waivers not identified FR–6050–N–04. An MDD PHA may request a waiver of HUD requirement not listed in Section III of this notice. Please be reminded that HUD will only consider waivers or flexibilities subject to statutory limitations and pursuant to 24 CFR 5.110. COVID–19 MDDs are not covered under this notice. Agencies seeking administrative or regulatory relief due to a COVID–19 MDD, must follow the guidance prescribed in specific COVID–19 notices issued by the Office of Public and Indian Housing, pursuant to the Coronavirus Aid, Relief and Economic Security (CARES) Act (Pub. L. 136–36). See *e.g.,* PIH Notice 2020–05, issued April 10, 2020.

IV. Exceptions

Notice PIH 2012–10, Section 8(c) (Verification of the Social Security Number (SSN)). PHAs are required to transmit form HUD–50058 not later than 30 calendar days following receipt of an applicant's or participant's SSN documentation. HUD is willing to consider a request to extend this requirement to 90 calendar days, for a period not to exceed 12 months from the date of HUD approval.

V. Notification and Expedited Waiver Process During CY 2020 and CY2021—Instructions

HUD has developed a checklist (Attachment A to this notification) that an MDD PHA must complete and submit to take advantage of the provisions identified in this notification and the expedited review of waiver requests. Each provision on the checklist indicates the documentation that must accompany the MDD PHA's submission. Each request for a waiver (Section 3 of the checklist) must include a good-cause justification stating why

the waiver is needed for the PHA's relief and recovery efforts.

To complete the checklist, take the following steps:

1. *Copy and paste* the checklist found in Attachment A into a new document on your computer, saving the document with the following filename format: FR–6050–N–04–XX123. The Federal Register docket number (FR–6050–N–04), a hyphen, then your Agency's HA Code. For example: FR–6050–N–04–AL123. HUD will consider other methods of submission as needed.

2. Complete the section titled ''Information about Requesting Agency'' in its entirety. This section must be complete. An official of the MDD PHA must sign where indicated. If the information about the requesting agency is incomplete or the checklist has not been signed, then the checklist will be returned without review.

3. Complete Sections 1, 2, and/or 3 of the checklist, as applicable, noting the documentation (if any) that accompanies each provision.

4. Address an email to both *PIH_Disaster_Relief@hud.gov* and your HUD Field Office Public Housing Director. In the subject line, type ''PHA Name—PHA Code—MDD Disaster Relief—Month and Year''. For example, Allenway Housing Authority—AL123–MDD Disaster Relief—October 2020.

5. Attach the completed checklist, letter of justification, and all supporting documentation as applicable to your email.

6. Click ''Send.''

Checklists and any supporting documentation or information must be submitted not later than 4 months following the MDD. Requests submitted AFTER that time period will not be considered except in special cases outside of the agency's control.

VI. Finding of No Significant Impact

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

The FONSI is available for public inspection between 8 a.m. and 5 p.m. weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, an advance appointment to review the docket file must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

R. Hunter Kurtz,

Assistant Secretary for Public and Indian Housing.

Attachment A—Checklist

Relief From HUD Public Housing and Section 8 Requirements Available During CY 2020 and CY 2021 to Public Housing Agencies To Assist With Recovery and Relief Efforts on Behalf of Families Affected by Presidentially Declared Major Disasters

Information About Requesting Agency

NAME OF PHA: _____
PHA CODE: _____
Address: _____
City or Locality: (must be covered under PDD) _____
Parish: _____
Date of Submission: _____
Signature of PHA Official: _____
Name/Title of PHA Official: _____
Phone number of PHA Official: _____

Section 1. List the Presidentially-Declared Major Disaster your agency is under: _____

Section 2. Insert an ''X'' next to the applicable flexibilities.

An MDD PHA may adopt the flexibilities listed below.

____A. 24 CFR 990.145(b) (Public housing dwelling units with approved vacancies). (Public Housing Financial Management Division)

My agency requests HUD approval to treat certain vacant public housing units in our inventory as approved vacancies for the continued receipt of Operating Subsidy. I have attached a project-by-project listing of the units for which this approval is requested. I understand that any units that remain vacant shall be considered approved vacancies only for a period not to exceed 12 months from the date of HUD approval.

Section 3. Insert an ''X'' next to the applicable waiver requests.

An MDD PHA may request a waiver of a HUD requirement listed below or of any other HUD requirement and receive expedited review of the request, if the MDD PHA demonstrates that the waiver is needed for relief and recovery purposes. Each request must include a good-cause justification for the waiver, documenting why the waiver is needed for such purposes. No requested waiver may be implemented unless and until written approval from HUD has been obtained.

____A. 24 CFR 905.400(i)(5) (Capital Fund Formula; Replacement Housing Factor to reflect formula needs for projects with demolition or disposition occurring on or after October 1, 1998, and prior to September 2013). (Office of Capital Improvements)

My agency requests a waiver of 24 CFR 905.400(i)(5) to allow for the use of Capital Fund Replacement Housing Factor grants with undisbursed balances for public housing modernization. I understand that this waiver will be in effect only for funds obligated within 12 months from the date of HUD approval.

____B. 24 CFR 982.503(c) (HUD approval of exception payment standard amount). (Housing Voucher Management and Operations)

My agency requests to establish an exception payment standard amount that is higher than 110 percent of the published fair market rent (FMR). I have attached our proposed emergency exception payment standard schedule, which shows both the dollar amounts requested and those amounts as a percentage of the FMRs in effect at the time of the request. I understand that any approved exception payment standard will remain in effect until HUD revises the FMRs for the area. I also understand that increased per-family costs resulting from the use of such exception payment standard may result in a reduction in the number of families assisted or may require my agency to adopt other cost-saving measures.

____C. 24 CFR 982.633(a) (Occupancy of home). (Housing Voucher Management and Operations)

My agency requests a waiver of 24 CFR 982.633(a) so that we may continue HAP for homeownership for families displaced from their homes if needed to comply with mortgage terms or make necessary repairs. We have determined that the family is not receiving assistance from another source. I understand that such payments must cease if the family remains absent from their home for more than 180 consecutive calendar days.

____D. Waivers not identified in the PIH Notice, *Relief from HUD Public Housing and Section 8 Requirements Available During CY2020 and 2021 to PHAs to Assist with Recovery and Relief Efforts on Behalf of Families Affected by Presidentially Declared Major Disasters* [FR–6050–N–04].

My agency seeks waivers of the HUD requirements listed below. None of the requests are to waive a fair housing, civil rights, labor standards, or environmental review requirements. I have included documentation justifying the need for the waivers.

Section 4. Insert an ''X'' next to the applicable exception request.

An MDD PHA may request an exception of the HUD requirement listed below and receive expedited review of the request, if the MDD PHA demonstrates that the exception is needed for relief and recovery purposes. Each request must include a good-cause justification for the exception, documenting why the exception is needed for such purposes. No requested exception may be implemented unless and until written approval from HUD has been obtained.

____Notice PIH 2012–10, Section 8(c) (Verification of the Social Security Number (SSN)). (Real Estate Assessment Center)

My agency requests a waiver of section 8(c) of Notice PIH 2012–10 to allow for the submission of Form HUD–50058 90 calendars days from receipt of an applicant's or participant's SSN documentation. I understand that this waiver will be in effect for a period not to exceed 12 months from the date of HUD approval.

Regulation	Description
Example: 24 CFR 982.54.	*Example: A waiver of this regulation will facilitate our agency's capacity to participate in relief and recovery efforts by*

[FR Doc. 2020–24955 Filed 11–10–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2020–N144; FXES11130100000–212–FF01E00000]

Endangered Species; Receipt of Recovery Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit application; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application for a permit to conduct activities intended to enhance the propagation and survival of endangered species under the Endangered Species Act of 1973, as amended. We invite the public and local, State, Tribal, and Federal agencies to comment on this application. Before issuing the requested permit, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before December 14, 2020.

ADDRESSES:

Document availability and comment submission: Submit a request for a copy of the application and related documents and submit any comments by one of the following methods. All requests and comments should specify the applicant name and application number (*e.g.,* Dana Ross TE–08964A–2):

- *Email: permitsR1ES@fws.gov.*
- *U.S. Mail:* Marilet Zablan, Program Manager, Restoration and Endangered Species Classification, Ecological Services, U.S. Fish and Wildlife Service, Portland Regional Office, 911 NE 11th Avenue, Portland, OR 97232–4181.

FOR FURTHER INFORMATION CONTACT: Colleen Henson, Regional Recovery Permit Coordinator, Ecological Services, (503) 231–6131 (phone); *permitsR1ES@fws.gov* (email). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on an application for a permit under section 10(a)(1)(A) of the Endangered Species Act, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permit would allow the applicant to conduct activities intended to promote recovery of species that are listed as endangered under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes such activities as pursuing, harassing, trapping, capturing, or collecting, in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found in the Code of Federal Regulations (CFR) at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Application Available for Review and Comment

Proposed activities in the following permit request are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing this permit. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to this application. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
TE–48278D	Archipelago Research and Conservation, Kalaheo, HI.	Band-rumped storm-petrel (*Oceanodroma castro*) Hawaiian petrel (*Pterodroma sandwichensis*).	Hawaii	Harass by survey; monitor nests; capture; handle; band; biosample; conduct scent research; telemetry/tagging; release; install train and burrow cameras, artificial burrows, and social attraction arrays; and salvage.	Amend.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time.

While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue a permit to the applicant listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Marjorie Nelson,

Acting Assistant Regional Director—Ecological Services, Pacific Region.

[FR Doc. 2020–25020 Filed 11–10–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–31124; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before October 24, 2000, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by November 27, 2020.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State≤.'' If you have no access to email you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before October 24, 2000. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers:

COLORADO

Chaffee County

Maxwell Park School, (Rural School Buildings in Colorado MPS), Northwest corner, Jct. of Cty. Rds. 321 and 326, Buena Vista vicinity, MP100005853

Denver County

James, Harry C., House, 685 North Emerson St., Denver, SG100005854

Pueblo County

Central Junior High School-Keating Junior High School, 215 East Orman Ave., Pueblo, SG100005855

INDIANA

Bartholomew County

Daugherty, James and Annetta, House and Barn, 6443 South Jonesville Rd., Columbus vicinity, SG100005878

Brown County

Brown County State Park, (New Deal Resources on Indiana State Lands MPS), 1405 IN 46 West, Nashville vicinity, MP100005867

Floyd County

East Spring Street Historic District (Boundary Increase) Roughly bounded by alley north/northwest of Elm St., the west curb line of Vincennes St., alley south/southwest of Market St., and the east curb line of 5th St., New Albany, BC100005877

Marion County

St. Timothy's Episcopal Church, 2601 East Thompson Rd., Indianapolis, SG100005873

Tate-Tatum Farm, 1780 East Rayletown Rd., Sanders vicinity, SG100005874

Vanderburgh County

Hebron Meadows Historic District (Residential Planning and Development in Indiana, 1940–1973 MPS) Roughly bounded by 4000–4311 Bellemeade Ave., 700–961 South Colony Rd., 700–901 South Meadow Rd., 698–961 Blue Ridge Rd., and the north side of Washington Ave., including 4020–4328, Evansville, MP100005870

Vigo County

Rocky Edge, 46 Allendale, Terre Haute, SG100005872

Terre Haute City Hall (Downtown Terre Haute MRA), 17 Harding Ave., Terre Haute, MP100005875

Wabash County

F. & A.M. Tuscan Lodge No. 143, 828 Washington St., Lagro, SG100005869

I.O.R.M. Hall, Tonkawa No. 126, 828 Washington St., Lagro, SG100005871

Washington County

Blue River Friends Hicksite Meeting House and Cemetery, 1232 North Quaker Rd., Salem vicinity, SG100005866

NEW JERSEY

Camden County

Cole Landing Tavern, 500 Cole Landing Rd., Gloucester Township, SG100005879

Hunterdon County

Thatcher House (Traditional Patterned Brickwork Buildings in New Jersey MPS), 255 Ridge Rd., Kingwood Township, MP100005851

Monmouth County

Asbury Park Public Library, 500 1st Ave., Asbury Park City, SG100005840

NEW YORK

Oswego County

West Broadway Commercial Historic District, 109–126 West Broadway, Fulton, SG100005848

Amboy District No. 2 Schoolhouse, 398 NY 69, East Amboy vicinity, SG100005849

Richmond County

Olmstead, Frederick Law, Sr., Farmhouse, 4515 Hylan Blvd., Staten Island, SG100005846

Seneca County

Jones, Hannah and George W. House, 7246 Main St., Ovid vicinity, SG100005847

NORTH CAROLINA

Guilford County

Blue Bell Company Plant (Greensboro MPS) 620 South Elm St., Greensboro, MP100005841

NORTH DAKOTA

Grand Forks County

Administration Building for the City of Grand Forks at the Grand Forks Airport (Federal Relief Construction in North Dakota, 1931–1943, MPS) 802 North 43rd St., Grand Forks, MP100005844

OHIO

Franklin County

Ohio Baptist General Association Headquarters (Twentieth-Century African American Civil Rights Movement in Ohio MPS) 48 Parkwood Ave., Columbus, MP100005845

Lucas County

The Broer-Freeman Building, 622 Jefferson Ave., Toledo, SG100005856

OKLAHOMA

Caddo County

Bridgeport Bridge (Route 66 and Associated Resources in Oklahoma AD MPS) North US 281 over the South Canadian R., Bridgeport vicinity, MP100005858

Bridgeport Bridge (US Highway 66, from Chicago to Santa Monica) North US 281 over the South Canadian R., Bridgeport vicinity, MP100005858

Carter County

Young Cemetery, 1/8th of a mi. north of Seven Sisters Hills Rd., Ardmore vicinity, SG100005859

Le Flore County

Hotel Lowrey, 301 Dewey Ave., Poteau, SG100005860

Noble County

Schultz-Neal Stone Barn, 250 yds. east of US 177/OK 15, 7 mi. southeast of of Red Rock, Red Rock vicinity, SG100005861

Oklahoma County

Brockway Community Center, 1440 North Everest Ave., Oklahoma City, SG100005862

McClean House, 141 NE 26th St., Oklahoma City, SG100005863

Tulsa County

Tulsa Boys' Home Historic District, Bounded by East 8th St., South Quincy Ave., East 7th St., and South Rockford Ave., Tulsa, SG100005864

Washington County

First United Methodist Church, 500 South Johnstone Ave., Bartlesville, SG100005865

VIRGINIA

Danville Independent City

Schoolfield Historic District, Park Ave., Park Cir., Memorial Dr., Dan R., Laurel Ave., Rutledy Cr., Fairfield and Selma Aves., Danville, SG100005881

Fairfax County

Bois Doré, 8008 Georgetown Pike, McLean, SG100005880

Roanoke Independent City

Southwest Historic District (Boundary Increase) Roughly bounded by Westview, Westport, Salem, Jackson, Norfolk, Rorer, Campbell, Marshall, Day, Jefferson, and Clark Aves., Roanoke R., 13th and 21st Sts. St., Roanoke, BC100005882

WEST VIRGINIA

Jefferson County

Rocks, The, 1003 Westside Ln., Charles Town, SG100005843

A request for removal has been made for the following resource:

GEORGIA

Fulton County

Wilson, Judge William, House, 501 Fairburn Rd. SW, Atlanta, OT80001078

A request to move has been received for the following resource:

NORTH CAROLINA

Wake County

Jones, Nancy, House, NC 54, Cary vicinity, MV84002540

Additional documentation has been received for the following resource:

INDIANA

Floyd County

East Spring Street Historic District (Additional Documentation) Roughly bounded by East 5th, East Spring, East 8th, and East Market Sts., New Albany, AD02001566

Nominations submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nominations and responded to the Federal Preservation Officer within 45 days of receipt of the nominations and supports listing the properties in the National Register of Historic Places.

FLORIDA

Volusia County

Leeper, Doris, House, ½ mi. south of Eldora Rd., Canaveral NS, New Smyrna Beach vicinity, SG100005857

GEORGIA

Richmond County

Neuropsychiatric Tuberculosis Ward-Building 7 (United States Second Generation Veterans Hospitals MPS) 1900 Maryland Ave., Charlie Norwood VA Medical Center, Augusta, MP100005883

Neuropsychiatric Infirmary—Building 76 (United States Second Generation Veterans Hospitals MPS) 1798 Maryland Ave., Charlie Norwood VA Medical Center, Augusta, MP100005884

Authority: Section 60.13 of 36 CFR part 60.

Dated: October 27, 2020.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2020–25033 Filed 11–10–20; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1183]

Certain Foldable Reusable Drinking Straws and Components and Accessories Thereof; Commission Determination Not To Review an Initial Determination Granting a Motion for Partial Summary Determination and Finding a Violation of Section 337; Request for Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 18) of the presiding administrative law judge (''ALJ'') granting complainant's motion for partial summary determination and finding a violation of section 337. The Commission requests written submissions from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

FOR FURTHER INFORMATION CONTACT: Cathy Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–2392. 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 on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 13, 2019, based on a complaint filed on behalf of The Final Co. LLC (''Final'' or ''Complainant'') of Santa Fe, New Mexico. 84 FR 61639 (Nov. 13, 2019). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain foldable reusable drinking straws and components and accessories thereof by reason of infringement of claims 1–12, 14–17, and 20 of U.S. Patent No. 10,123,641 (''the '641 patent''). *Id.* The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation names seventeen respondents, specifically, Huizhou Sinri Technology Company Limited of Guangdong, China; Hebei Serun Import and Export Trade Co., Ltd. of Hebei, China; Dongguan Stirling Metal Products Co., Ltd. of Guangdong, China; Ningbo Wwpartner Plastic Manufacture Co., Ltd. of Zhejiang, China; Shenzhen Yuanzhen Technology Co., Ltd. of Shenzhen, China; Jiangmen Boyan Houseware Co., Ltd. of Guangdong, China; Shanghai Rbin Industry And Trade Co., Ltd. of Shanghai, China; Jiangmen Shengke Hardware Products Co., Ltd. of Guangdong, China; Funan Anze Trading Co., Ltd. of Anhui, China; Hangzhou Keteng Trade Co., Ltd. of Zhejiang, China; Hunan Jiudi Shiye Import And Export Trading Co., Ltd. of Hunan, China (''Hunan Jiudi''); Shenzhen Yaya Gifts Co., Ltd. of Guangdong, China; Ningbo Weixu International Trade Co., Ltd. of Zhejiang, China (''Ningbo Weixu''); Ningbo Beland Commodity Co., Ltd. of Zhejiang, China; Xiamen One X Piece Imp. & Exp. Co., Ltd. of Fujian, China; Hunan Champion Top Technology Co., Ltd. of Hunan, China; and Yiwu Lizhi Trading Firm of Zhejiang, China. *Id.* at 61639–40. The Office of Unfair Import Investigations (''OUII'') is also named as a party in this investigation. *Id.* at 61640.

The Commission previously terminated respondents Ningbo Weixu and Hunan Jiudi from the investigation based on Complainant's partial withdrawal of the complaint. *See* Order No. 7 (Feb. 13, 2019), *unreviewed by* Comm'n Notice (Mar. 9, 2020).

On March 16, 2020, the Commission found the remaining fifteen respondents (collectively, the ''Defaulted Respondents'') in default. Order No. 8 (March 3, 2020), *unreviewed by* Notice (March 16, 2020).

On April 7, 2020, Complainant filed a motion for summary determination of a violation of section 337 by the Defaulted Respondents. On May 5, 2020, Complainant filed a motion for leave to supplement the MSD, and the ALJ granted leave on May 8, 2020. On May 27, 2020, OUII filed its response in support of Complainant's motion.

On July 17, 2020, the ALJ issued Order No. 13, an ID granting in part the motion for summary determination. *See* Order No. 13 (July 17, 2020). The ALJ found that Complainant established importation of the accused products and infringement of claims 1–12 and 14–17 of the '641 patent by Defaulted Respondents and that Complainant satisfied the technical prong of the domestic industry requirement. The ALJ also found, however, that Complainant did not satisfy the economic prong of the domestic industry requirement, and so the ALJ did not find a violation of section 337 by the Defaulted Respondents. The Commission determined not to review Order No. 13. *See* Notice (Aug. 18, 2020).

Also, on July 17, 2020, the ALJ issued Order No. 14, which required the parties to choose from several options on how to proceed. *See* Order No. 14, at 1–2 (July 17, 2020). On July 31, 2020, Complainant and OUII filed a joint response to Order No. 14. The joint response stated that Complainant would file an additional motion for summary determination on the remaining issues raised in the subject ID as well as a motion to amend the complaint to drop its assertion of claim 20 of the '641 patent.

On August 7, 2020, Complainant filed a motion for partial summary determination of the economic prong of the domestic industry requirement, a remedy in the form of a general exclusion order, and a bond of 100% during the Presidential review period. On August 14, 2020, Complainant moved to replace Exhibit 11C within its motion for summary determination, which was granted by the ALJ. *See* Order No. 16 (Aug. 20, 2020). On August 24, 2020, OUII filed its response in support of Complainant's motion.

On August 17, 2020, Complainant moved to terminate the investigation with respect to asserted claim 20 by reason of withdrawal of the complaint allegations. On August 26, 2020, the ALJ granted the motion to withdraw claim 20. *See* Order No. 17 (Aug. 26, 2020), *unreviewed by* Notice (Sep. 15, 2020).

On September 22, 2020, the ALJ issued the subject ID granting Complainant's motion for partial summary determination that a domestic industry exists with respect to Complainant's research and development investments under section 337(a)(3)(C) and finding a violation of section 337 with respect to claims 1–12 and 14–17 of the '641 patent by the Defaulted Respondents. Order No. 18 also denied Complainant's motion for summary determination under section 337(a)(3)(B). The ALJ's denial of summary determination in Order No. 18 as to section 337(a)(3)(B) is not an initial determination subject to Commission review and hence is not adopted by the Commission and is not a part of the Commission's determination. No petitions for review of the subject ID were filed.

The ALJ concurrently issued a Recommended Determination (''RD'') on the issues of remedy and bonding. The RD recommends the issuance of a general exclusion order and setting the bond during the period of Presidential review in the amount of one hundred percent (100%) of the entered value.

Having reviewed the record of the investigation, including the subject ID and the parties' submissions to the ALJ, the Commission has determined not to review the subject ID. Accordingly, the Commission adopts the ID's finding that a violation of section 337 has occurred in connection with claims 1–12 and 14–17 of the '641 patent.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone*

Lines, Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order would have on: (1) The public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

In their initial submissions, Complainant is also requested to identify the remedy sought and Complainant and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to state the date that the Asserted Patent expires, to provide the HTSUS subheadings under which the accused products are imported and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on Monday, November 23, 2020. Reply submissions must be filed no later than the close of business on Monday, November 30, 2020. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337–TA–1183) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on November 5, 2020.

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: November 5, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–24984 Filed 11–10–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–130 (Fifth Review)]

Chloropicrin From China; Termination of Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission instituted the subject five-year review on August 3, 2020 (85 FR 46722) to determine whether revocation of the antidumping duty order on chloropicrin from China would be likely to lead to continuation or recurrence of material injury. The Department of Commerce issued notice that it was revoking the order effective September 22, 2020, because the domestic interested parties did not file a timely response in this review (see *Chloropicrin from the People's Republic of China: Final Results of Sunset Review and Revocation of Order, issued November 2, 2020*).

DATES: Applicable September 22, 2020 (effective date of revocation of order).

FOR FURTHER INFORMATION CONTACT: Jason Duncan (202–205–3432), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained 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*).

Authority: This review is being terminated under authority of title VII of the Tariff Act of 1930 and pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). This notice is published pursuant to § 207.69 of the Commission's rules (19 CFR 207.69).

By order of the Commission.

Issued: November 5, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–24983 Filed 11–10–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting and Hearing Notice No. 08–20]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR part 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

TIME AND DATE: Thursday, November 19, 2020, at 10:00 a.m.

PLACE: This meeting will be held by teleconference. There will be no physical meeting place.

STATUS: Open. Members of the public who wish to observe the meeting via teleconference should contact Patricia M. Hall, Foreign Claims Settlement Commission, Tele: (202) 616–6975, two business days in advance of the meeting. Individuals will be given call-in information upon notice of attendance to the Commission.

MATTERS TO BE CONSIDERED: 10:00 a.m.—Issuance of Proposed Decisions under the Guam World War II Loyalty Recognition Act, Title XVII, Public Law 114–328.

CONTACT PERSON FOR MORE INFORMATION: Requests for information, advance notices of intention to observe an open meeting, and requests for teleconference dial-in information may be directed to: Patricia M. Hall, Foreign Claims Settlement Commission, 441 G St NW, Room 6234, Washington, DC 20579. Telephone: (202) 616–6975.

Brian M. Simkin,

Chief Counsel.

[FR Doc. 2020–25107 Filed 11–9–20; 11:15 am]

BILLING CODE 4410–BA–P

DEPARTMENT OF LABOR

Employment and Training Administration

Final Finding of No Significant Impact, New Orleans Job Corps Center Proposed Disposal and Reuse of Excess Property, Located at 8825 Airline Highway, New Orleans, Louisiana

AGENCY: Employment and Training Administration.

ACTION: Final finding of no significant impact.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration, pursuant to the Council on Environmental Quality Regulations implementing procedural provisions of the National Environmental Policy Act (NEPA), and the Department's own implementing regulations, provides the Department's final determination that the proposed disposal of 10 parcels totaling 0.79 acre of excess property in the residential neighborhood on two city blocks to the west of the New Orleans Job Corps Center campus will not have a significant adverse impact on the environment.

DATES: These findings are effective as of November 12, 2020.

ADDRESSES: Department of Labor, 200 Constitution Avenue NW, Room N–4460, Attn: Jose Velazquez, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Jose Velazquez; Telephone (202) 693–3099 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: A public notice of availability of the draft environmental assessment (EA), which determined that the disposal of .79 acres of excess property near the New Orleans Job Corps Center would not have a significant impact on the environment, was published in the New Orleans Advocate in New Orleans, Louisiana, on November 25, 2019. The review period extended for 15 days, ending on December 10, 2019. No public comments were received. No changes to the findings of the EA have been made.

Implementation of the proposed action alternative will not have significant impacts on the human environment. The determination is sustained by the analysis in the EA, agency, and Native American tribal consultation, the inclusion and consideration of public review, and the capability of mitigations to reduce or avoid impacts. Any adverse environmental effects that could occur are no more than minor in intensity, duration and context and less-than-significant. As described in the EA, there are no highly uncertain or controversial impacts, unique or unknown risks, significant cumulative effects, or elements of precedence. There are no previous, planned, or implemented actions, which, in combination with the proposed action alternative, would have significant effects on the human environment. Requirements of NEPA have been satisfied, and preparation of an Environmental Impact Statement is not required.

John Pallasch,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2020–24975 Filed 11–10–20; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Final Finding of No Significant Impact, Atterbury Job Corps Center Proposed Disposal and Reuse of Excess Property, Located at 3129 E Edinburgh Street, Edinburgh, Indiana

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Final finding of no significant impact.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration, pursuant to the Council on Environmental Quality Regulations implementing procedural provisions of the National Environmental Policy Act (NEPA), and the Department's own implementing regulations, provides the Department's final determination that the proposed disposal of a 91-acre area of excess property at the Atterbury Job Corps Center, and that this project will not have a significant adverse impact on the environment.

DATES: These findings are applicable as of November 12, 2020.

ADDRESSES: Department of Labor, 200 Constitution Avenue NW, Room N–4460, Attn: Jose Velazquez, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Jose Velazquez; Telephone (202) 693–3099 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: A public notice of availability of the draft environmental assessment (EA), which determined that the dispoal of 91 acres of excess property at the Atterbury Job Corps Center would not have a significant impact on the environment, was published in the Daily Journal in Johnson County, Indiana, on February 3, 2020. The review period extended for 15 days, ending on February 18, 2019. No public comments were received. No changes to the findings of the EA have been made.

Implementation of the proposed action alternative will not have significant impacts on the human environment. The determination is sustained by the analysis in the EA, agency, and Native American tribal

consultation, the inclusion and consideration of public review, and the capability of mitigations to reduce or avoid impacts. Any adverse environmental effects that could occur are no more than minor in intensity, duration and context and less-than-significant. As described in the EA, there are no highly uncertain or controversial impacts, unique or unknown risks, significant cumulative effects, or elements of precedence. There are no previous, planned, or implemented actions, which, in combination with the proposed action alternative, would have significant effects on the human environment. Requirements of NEPA have been satisfied, and preparation of an Environmental Impact Statement is not required.

John Pallasch,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2020–24974 Filed 11–10–20; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Comment Request; Nondiscrimination Compliance Information Reporting

AGENCY: United States Department of Labor—Office of the Assistant Secretary for Administration and Management (DOL–OASAM).

ACTION: Notice of information collections and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the DOL is soliciting public comments regarding this OASAM-sponsored information collection to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments pertaining to this information collection are due on or before January 11, 2021.

ADDRESSES:

Electronic submission: You may submit comments and attachments electronically at *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Mail submission: 200 Constitution Ave. NW, Room S–5315, Washington, DC 2020.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the DOL, 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 DOL'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: Anthony May by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Department of Labor collects the Nondiscrimination Compliance Information Reporting data to help ensure a recipient of certain DOL Federal financial assistance programs does not discriminate in the administration, management, or operation of programs and activities. Activities covered by this information collection include:

- A grant applicant providing assurance that the applicant is aware of and, as a condition of receipt of Federal financial assistance, agrees to comply with the assurance requirements;
- a DOL funds recipient maintaining a record of E.O. characteristics data and a log of any E.O. complaints for activities under an applicable DOL funded program;
- a person who believes a relevant E.O. requirement may have been violated filing a complaint with either the funds recipient or with the DOL Civil Rights Center;
- a State periodically filing a plan outlining administrative methods the State will use to ensure funds are not used in a discriminatory manner; and
- a DOL funds recipient posting required notices.

The DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an Information Collection Review cannot be for more than three (3) years without renewal. The DOL notes that currently approved information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review.

Agency: DOL–OASAM.

Title of Collection: Nondiscrimination Compliance Information Reporting.

OMB Control Number: 1225–0077.

Total Estimated Number of Respondents: 69,603.

Total Estimated Number of Responses: 56,425,453.

Total Estimated Annual Time Burden: 350,450 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

Dated: November 5, 2020.

Anthony May,

Management and Program Analyst.

[FR Doc. 2020–25009 Filed 11–10–20; 8:45 am]

BILLING CODE 4510–04–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Susan Harwood Training Grant Program Grantee Quarterly Progress Report

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety and 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 agency receives on or before December 14, 2020.

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: Crystal Rennie by telephone at 202–693–0456, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Section 21 of the OSH Act (29 U.S.C. 670) authorizes OSHA to conduct directly, or through grants and contracts, education and training courses. These courses must ensure an adequate number of qualified personnel to fulfill the purposes of the OSH Act, provide them with short-term training, inform them of the importance and proper use of safety and health equipment, and train employers and workers to recognize, avoid, and prevent unsafe and unhealthful working conditions. Under Section 21, OSHA awards training grants to nonprofit organizations to provide part of the required training. The agency requires organizations that receive these grants to submit quarterly progress reports that provide information on their grant-funded training activities; these reports allow OSHA to monitor the grantee's performance and to determine if an organization is using grant funds as specified in the grant application. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on April 28, 2020 (85 FR 23534).

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: Susan Harwood Grant Program Grantee Quarterly Progress Report.

OMB Control Number: 1218–0100.

Affected Public: Private Sector—Not-for-profit organizations.

Total Estimated Number of Respondents: 110.

Total Estimated Number of Responses: 440.

Total Estimated Annual Time Burden: 6,160 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Crystal Rennie,

Acting Departmental Clearance Officer.

[FR Doc. 2020–25008 Filed 11–10–20; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Vacancy Posting; Member of the Administrative Review Board; Correction

AGENCY: Department of Labor.

ACTION: Notice; correction.

SUMMARY: The Department of Labor published a vacancy posting in the **Federal Register** of October 15, 2020 for a Member, Administrative Review Board job opportunity. The vacancy posting contains incorrect dates.

FOR FURTHER INFORMATION CONTACT: Robert White, (202) 693–2547.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of October 15, 2020, in FR Doc. 2020–22791, on page 1, in the second column, correct the **DATES** caption to read:

DATES: Resumes must be submitted (postmarked, if sending by mail; submitted electronically; or received, if hand-delivered) by 11:59 p.m. EDT on November 09, 2020. Resumes must be submitted to: *white.robert.t@dol.gov* or mailed to: U.S. Department of Labor, 200 Constitution Avenue NW, ATTN: Division of Executive Resources, Room N2495, Washington, DC 20210, phone: 202–693–2457. This is not a toll-free number.

Dated: November 5, 2020.

Bryan Slater,

Assistant Secretary for Administration & Management.

[FR Doc. 2020–24979 Filed 11–10–20; 8:45 am]

BILLING CODE 4510–HW–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0052]

Material Hoists, Personnel Hoists, and Elevators; Posting Requirements; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Material Hoists, and Elevators; Posting Requirements.

DATES: Comments must be submitted (postmarked, sent, or received) by January 11, 2021.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, OSHA Docket No. OSHA–2010–0052, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. *Please note:* While OSHA's Docket Office is continuing to accept and process submissions by regular mail, due to the COVID–19 pandemic, the Docket Office is closed to the public and not able to receive submissions to the docket by hand, express mail, messenger, and courier service.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA–2010–0039) for the Information Collection Request (ICR). All comments, including any personal information you provide, such as social security number and date of birth, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the website. All submissions, including copyrighted material, are available for inspection

and copying at the OSHA Docket Office. You also may contact Theda Kenney at the below phone number to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Seleda Perryman, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

Paragraph (a)(2) of the Material Hoists, Personnel Hoists, and Elevators Standard requires that the rated load capacities, recommended operating speeds, and special hazard warnings or instructions be posted on cars and platforms. Paragraph (b)(1)(i) requires that operating rules for material hoists be established and posted at the operator's station of the hoist. These rules shall include signal system and allowable line speed for various loads. Paragraph (c)(10) requires that cars be provided with a capacity and data plate secured in a conspicuous place on the car or crosshead.

These posting requirements are used by the operator and crew of the material and personnel hoists to determine how to use the specific machine and how much it will be able to lift as assembled in one or a number of particular configurations. If not properly used, the machine would be subject to failures, endangering the workers in the immediate vicinity.

Paragraph (c)(15) requires that a test and inspection of all functions and safety devices be made following the assembly and erection of hoists. The test and inspection are to be conducted under the supervision of a competent person. A similar inspection and test is required following major alteration of an existing installation. All hoists shall be inspected and tested at three-month intervals. A certification record (the most recent) of the test and inspection must be kept on file, including the date the test and inspection was completed, the identification of the equipment and the signature of the person who performed the test and inspection. This certification ensures that the equipment has been tested and is in safe operating condition. The most recent certification record will be disclosed to a Compliance Safety and Health Officer during an OSHA inspection.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the collection of information (paperwork) requirements contained in the Material Hoists, Personnel Hoists, and Elevators; Posting Requirements. The agency requests an adjustment increase of 1,943 burden hours (from 8,104 hours to 10,047 burden hours).

Type of Review: Extension of a currently approved collection.

Title: Material Hoists, Personnel Hoists, and Elevators; Posting Requirements. (29 CFR 1926.552).

OMB Number: 1218–0231.

Affected Public: Business or other for-profit.

Number of Respondents: 10,047.

Frequency of Response: On occasion.

Total Responses: 37,451.

Average Time per Response: OSHA estimates that it an inspector will take approximately 30 minutes (30/60) to perform and record the required maintenance inspection on each Material Hoist.

Estimated Total Burden Hours: 10,047.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal; (2) by facsimile; or (3) by hard copy. All comments, attachments, and other material must identify the agency name and the OSHA docket number for this ICR (Docket No. OSHA–2010–0052). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as your social security number and date of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from the website, and for

assistance in using the internet to locate docket submissions.

V. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on November 5, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020–24978 Filed 11–10–20; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0010]

Fire Protection in Shipyard Employment Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Fire Protection in Shipyard Employment Standard.

DATES: Comments must be submitted (postmarked, sent or received) by January 11, 2021.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2011–0010, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. Please note: While OSHA's Docket Office is continuing to accept and process submissions by regular mail, due to the COVID–19 pandemic, the Docket Office is closed to the public and not able to receive submissions to the docket by hand, express mail, messenger, and courier service.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA–2011–0010) for the Information Collection Request (ICR). All comments, including any personal information you provide, such as social security number and date of birth, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other materials in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at (202) 693–2222 to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Seleda Perryman or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA to obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The Fire Protection in Shipyard Employment Standard specifies a number of collection of information (paperwork) requirements. In general, the Standard requires employers to develop a written fire safety plan and written statements or policies that contain information about fire watches and fire response duties and responsibilities. The Standard also requires the employer to obtain medical exams for certain workers and to develop training programs and to train employees exposed to fire hazards. Additionally, the Standard requires employers to create and maintain records to certify that employees have been made aware of the details of the fire safety plan and that employees have been trained as required by the Standard.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply-for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend its approval of the information collection requirements specified in the Fire Protection in Shipyard Employment Standard. The agency is requesting an adjustment increase in burden hours from 6,603 to 16,251 burden hours, a total difference of 9,648 burden hours. This adjustment increase is a result of an increase in the number

of affected workers in small businesses even though the number of affect establishments decreased according to the 2017 NAICS codes. The agency will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements.

Type of Review: Extension of a currently approved collection.

Title: Fire Protection in Shipyard Employment Standard (29 CFR part 1915, subpart P).

OMB Control Number: 1218–0248.

Affected Public: Business or other for-profits.

Number of Respondents: 588.

Number of Responses: 184,921.

Frequency of Responses: Quarterly; annually.

Average Time per Response: Various.

Estimated Total Burden Hours: 16,251.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other materials must identify the agency name and the OSHA docket number (Docket No. OSHA–2011–0010) for the ICR. You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the agency can attach them to your comments.

Due to security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website.

All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from the website, and for assistance in using the internet to find docket submissions.

V. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 et seq.) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on November 5, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020–24977 Filed 11–10–20; 8:45 am]

BILLING CODE 4510–26–P

LEGAL SERVICES CORPORATION

Sunshine Act Meetings; Notice

DATE AND TIME: The Legal Services Corporation's Board of Directors will meet remotely on Monday, November 16, 2020. The meeting will commence at 2:30 p.m., EDT, and will continue until the conclusion of the Board's agenda.

LOCATION: Public Notice of Virtual Remote Meeting

Legal Services Corporation (LSC) will be conducting the November 16, 2020 meeting remotely via ZOOM.

PUBLIC OBSERVATION: Unless otherwise noted herein, the Board meeting will be open to public observation. Members of the public who wish to participate remotely may do so by following the directions provided below.

DIRECTIONS FOR OPEN SESSION:

- To join the Zoom meeting by computer, please click this link.
- *Meeting ID:* 928 0183 3531.
- *Passcode:* 909322.
- To join the Zoom meeting with one tap from your mobile phone, please click below:

+16468769923,92801833531# US (New York)
+13017158592,92801833531# US (Germantown)

- To join the Zoom meeting by phone, please use the information below:
- Dial by your location:

+1 646 876 9923 US (New York)
+1 301 715 8592 US (Germantown)
+1 312 626 6799 US (Chicago)
+1 346 248 7799 US (Houston)
+1 408 638 0968 US (San Jose)
+1 669 900 6833 US (San Jose)
+1 253 215 8782 US (Tacoma)

Meeting ID: 928 0183 3531. Find your local number: *https://lsc-gov.zoom.us/u/acEGSfYILW.*

- When connected to the call, please immediately ''MUTE'' your telephone. Members of the public are asked to keep their telephones muted to eliminate background noises. To avoid disrupting the meeting, please refrain from placing the call on hold if doing so will trigger recorded music or other sound. From time to time, the Chair may solicit comments from the public.

STATUS OF MEETINGS: Open.

MATTERS TO BE CONSIDERED:

Board of Directors

1. Approval of agenda
2. Approval of minutes of the Board's Open Session meeting of October 20, 2020
3. Consider and act on the Board of Directors' transmittal to accompany the Inspector General's Semiannual Report to Congress for the period of April 1, 2020 through September 30, 2020
4. Public comment
5. Consider and act on other business
6. Consider and act on adjournment of meeting

CONTACT PERSON FOR INFORMATION: Karly Satkowiak, Special Counsel and Katherine Ward, Executive Assistant to the Vice President & General Counsel, at (202) 295–1633. Questions may be sent by electronic mail to *FR_NOTICE_QUESTIONS@lsc.gov.*

ACCESSIBILITY: LSC complies with the Americans with Disabilities Act and Section 504 of the 1973 Rehabilitation Act. Upon request, meeting notices and materials will be made available in alternative formats to accommodate individuals with disabilities. Individuals needing other accommodations due to disability in order to attend the meeting in person or telephonically should contact Katherine Ward, at (202) 295–1500 or *FR_NOTICE_QUESTIONS@lsc.gov,* at least 2 business days in advance of the meeting. If a request is made without advance notice, LSC will make every effort to accommodate the request but cannot guarantee that all requests can be fulfilled.

Dated: November 9, 2020.

Katherine Ward,

Executive Assistant to the Vice President for Legal Affairs and General Counsel.

[FR Doc. 2020–25161 Filed 11–9–20; 4:15 pm]

BILLING CODE 7050–01–P

NATIONAL CAPITAL PLANNING COMMISSION

Notice of Final Adoption and Effective Date

AGENCY: National Capital Planning Commission.

ACTION: Notice of final adoption and effective date.

SUMMARY: The National Capital Planning Commission (NCPC) has adopted revised Submission Guidelines related to tree preservation and replacement on federal development sites. Federal and non-federal agency applicants whose development proposals and plans are subject to statutory mandated Commission plan and project review must submit their proposals to the Commission following a process laid out in the Submission Guidelines. The adopted Submission Guidelines support the adopted revised Federal Environment Element of the Comprehensive Plan for the National Capital, Section G: Federal Elements which NCPC also adopted on November 5, 2020.

DATES AND TIME: The revised Submission Guidelines will become effective January 11, 2021.

ADDRESSES: The revised adopted Submission Guidelines are available online at: *https://www.ncpc.gov/initiatives/treereplacement/*.

FOR FURTHER INFORMATION CONTACT: Stephanie Free at (202) 482–7209 or *info@ncpc.gov*.

Authority: 40 U.S.C. 8721(e)(2).

Dated: November 5, 2020.

Anne R. Schuyler,

General Counsel.

[FR Doc. 2020–24972 Filed 11–10–20; 8:45 am]

BILLING CODE P

NATIONAL CAPITAL PLANNING COMMISSION

Notice of Final Adoption and Effective Date

AGENCY: National Capital Planning Commission.

ACTION: Notice of final adoption and effective date.

SUMMARY: The National Capital Planning Commission (NCPC) has adopted revised Submission Guidelines related to tree preservation and replacement on federal development sites. Federal and non-federal agency applicants whose development proposals and plans are subject to statutory mandated Commission plan and project review must submit their proposals to the Commission following a process laid out in the Submission Guidelines. The adopted Submission Guidelines support the adopted revised Federal Environment Element of the Comprehensive Plan for the National Capital, Section G: Federal Elements which NCPC also adopted on November 5, 2020.

DATES AND TIME: The revised Submission Guidelines will become effective January 11, 2021.

ADDRESSES: The revised adopted Submission Guidelines are available online at: *https://www.ncpc.gov/initiatives/treereplacement/*.

FOR FURTHER INFORMATION CONTACT: Stephanie Free at (202) 482–7209 or *info@ncpc.gov*.

Authority: 40 U.S.C. 8721(e)(2).

Dated: November 5, 2020.

Anne R. Schuyler,

General Counsel.

[FR Doc. 2020–24971 Filed 11–10–20; 8:45 am]

BILLING CODE 7502–02–P

NATIONAL FOUNDATION OF THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

42nd Meeting of the National Museum and Library Services Board

AGENCY: Institute of Museum and Library Services (IMLS), National Foundation of the Arts and the Humanities (NFAH).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the National Museum and Library Services Board will meet to advise the Director of the Institute of Museum and Library Services (IMLS) with respect to duties, powers, and authority of IMLS relating to museum, library, and information services, as well as coordination of activities for the improvement of these services.

DATES: The meeting will be held on December 10, 2020, from 11:00 a.m. Eastern Time until adjourned.

ADDRESSES: The meeting will convene virtually. In order to enhance openness and public participation, virtual meeting and audio conference technology will be used during the meeting. Instructions will be sent to all public registrants.

FOR FURTHER INFORMATION CONTACT: Katherine Maas, Project Specialist and Alternate Designated Federal Officer, Institute of Museum and Library Services, Suite 4000, 955 L'Enfant Plaza North SW, Washington, DC 20024; (202) 653–4798; *kmaas@imls.gov* (*mailto:kmaas@imls.gov*).

SUPPLEMENTARY INFORMATION: The National Museum and Library Services Board is meeting pursuant to the National Museum and Library Service Act, 20 U.S.C. 9105a, and the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App.

The 42nd Meeting of the National Museum and Library Services Board, which is open to the public, will convene online at 11:00 a.m. Eastern Time on December 10, 2020.

The agenda for the 42nd Meeting of the National Museum and Library Services Board will be as follows:

I. Call to Order
II. Approval of Minutes of the 41st Meeting
III. Director's Welcome and Update
IV. Governmental Engagement and Legislative Update
V. Financial Update
VI. Pandemic Response Overview, Including an Update on the REopening Archives, Libraries, and Museums (REALM) Project
VII. Pandemic Response and Issues Facing the Museum Sector
VIII. Pandemic Response and Issues Facing the Library Sector
IX. Applying Lessons To Strengthen Community Engagement

If you wish to attend the virtual public session of the meeting, please inform IMLS as soon as possible, but no later than close of business on December 8, 2020, by contacting Katherine Maas at *kmaas@imls.gov* (*mailto:kmaas@imls.gov*). Virtual meeting and audio instructions will be sent to all public registrants. Please provide notice of any special needs or accommodations by November 24, 2020.

Dated: November 6, 2020.

Kim Miller,

Senior Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2020–25025 Filed 11–10–20; 8:45 am]

BILLING CODE 7036–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0001]

Sunshine Act Meetings

TIME AND DATE: Week of November 9, 2020.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

Week of November 9, 2020

Thursday, November 12, 2020

10:00 a.m. Affirmation Session (Public Meeting) (Tentative)

a. Exelon Generating Company, LLC (Peach Bottom Atomic Power Station, Units 2 and 3)—Beyond Nuclear's Appeal Of LBP–19–5 (Tentative)

b. Entergy Nuclear Operations, Inc., Entergy Nuclear Generation Co., Holtec International, and Holtec Decommissioning International, LLC (Pilgrim Nuclear Power Station) — Pilgrim Watch Petition for Intervention (Tentative)

(Contact: Denise McGovern: 301–415–0681)

Additional Information: By a vote of 5–0 on November 7 and 9, 2020, the Commission determined pursuant to U.S.C. 552b(e) and '9.107(a) of the Commission's rules that the above referenced Affirmation Session be held with less than one week notice to the public. The meeting will be held on November 12, 2020. Due to COVID–19, there will be no physical public attendance. The public is invited to listen to the Commission's meeting live by telephone. The details may be found at the Web address—*https://www.nrc.gov/.*

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* 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.*

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.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or by email at *Tyesha.Bush@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: November 9, 2020.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2020–25154 Filed 11–9–20; 4:15 pm]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90352; File No. SR–CboeBZX–2020–078]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Equity Transaction Fee Rebate Tiers

November 5, 2020.

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 November 2, 2020, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') 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 BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the fee schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), 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 fee schedule applicable to its equities trading platform (''BZX Equities'') to: (1) Update the Supplemental Incentive Program Tiers; (2) update the Lead Market Maker (''LMM'') Add Volume Tiers and (3) eliminate the Non-Displayed Tape A Tier 1, effective November 2, 2020.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[3] no single registered equities exchange has more than 18% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays credits to members that provide liquidity and assesses fees to those that remove liquidity. The Exchange's fee schedule sets forth the standard rebates and rates applied per share for orders

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (October 28, 2020), available at *https://markets.cboe.com/us/equities/market_statistics/.*

that provide and remove liquidity, respectively. Currently, for orders priced at or above $1.00, the Exchange provides a standard rebate of $0.0020 per share for orders that add liquidity and assesses a fee of $0.0030 per share for orders that remove liquidity. For orders priced below $1.00, the Exchange provides a standard rebate of $0.0009 per share for orders that add liquidity and assesses a fee of 0.30% of total dollar value for orders that remove liquidity. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Proposed Updates to the Supplemental Incentive Program Tiers

The Exchange currently offers three different Supplemental Incentive Program Tiers under footnote 1 of the Fee Schedule, wherein a Member may receive an additional rebate for qualifying orders where a Member adds a certain Tape ADAV [4] as a percentage of that Tape's TCV. Specifically, the Supplemental Incentive Program Tiers offered are as follows:

- Supplemental Incentive Program—Tape A Tier offers an additional rebate of $0.0001 for orders yielding fee code V [5] where a Member has a Tape A ADAV greater than or equal to 0.30% of the Tape A TCV;
- Supplemental Incentive Program—Tape B Tier offers an additional rebate of $0.0001 for orders yielding fee code B [6] where a Member has a Tape B ADAV greater than or equal to 0.30% of the Tape B TCV; and
- Supplemental Incentive Program—Tape C Tier offers an additional rebate of $0.0001 for orders yielding fee code Y [7] where a Member has a Tape C ADAV greater than or equal to 0.30% of the Tape C TCV;

The proposed rule change amends the tiers' criteria by increasing the percentage of Tape ADAV over Tape TCV from 0.30% to 0.40% for Supplemental Incentive Program—Tape A and Tape C Tiers, and from 0.30% to 0.50% for Supplemental Incentive Program—Tape B Tier. The proposed rule change to the Supplemental Incentive Program Tiers does not alter any of the additional rebate amounts currently offered. Although the proposed changes to the thresholds result in more stringent criteria, Members still have an opportunity to receive the additional rebate if they meet the applicable tier threshold. Moreover, the proposed changes are designed to encourage Members to increase their Displayed liquidity in Tape A, B and C securities on the Exchange, thereby contributing to a deeper and more liquid market, which benefits all market participants and provides greater execution opportunities on the Exchange.

Proposed Updates to the LMM Add Volume Tiers

Under the Exchange's LMM Program, the Exchange offers daily incentives for LMMs in securities listed on the Exchange for which the LMM meets certain Minimum Performance Standards.[8] Such daily incentives are determined based on the number of Cboe-listed securities for which the LMM meets such Minimum Performance Standards and the average auction volume across such securities. Generally, the more LMM Securities [9] for which the LMM meets the Minimum Performance Standards and the higher the auction volume across those securities, the greater the total daily payment to the LMM. Currently, the Exchange offers 3 LMM Add Volume Tiera [*sic*] under footnote 14 of the Fee Schedule, which provides an additional rebate for applicable LMM orders. Specifically, the Supplemental Incentive Program Tiers currently offered are as follows:

- LMM Add Volume Tier 1 provides an additional rebate of $0.0001 for orders yielding fee codes B, V and Y where an LMM (1) has an ADAV greater than or equal to 0.20% of the TCV, (2) has an Average Aggregate Daily Auction Volume in LMM Securities greater than or equal to 500,000 and (3) is enrolled in at least 75 LMM Securities.
- LMM Add Volume Tier 2 provides an additional rebate of $0.0006 for orders yielding fee codes V and ''HV'' [10] where an LMM (1) is enrolled in at least 50 LMM Securities, and (2) has a Tape A ADAV greater than or equal to 0.10% of the Tape A TCV;
- LMM Add Volume Tier 3 provides an additional rebate of $0.0003 for orders yielding fee codes B and ''HB'' [11] where an LMM (1) is enrolled is enrolled in at least 50 LMM Securities, and (2) has a Tape B ADAV greater than or equal to 0.20% of the Tape B TCV;
- LMM Add Volume Tier 4 provides an additional rebate of $0.0006 for orders yielding fee codes Y and ''HY'' [12] where an LMM (1) is enrolled in at least 50 LMM Securities, and (2) has a Tape C ADAV greater than or equal to 0.10% of the Tape C TCV.

The Exchange proposes to update the TCV thresholds in LMM Add Volume Tiers 2, 3 and 4 as follows below. The Exchange notes that the additional rebates currently provided in each tier remain the same, as do the remaining criteria for each tier.

- To meet the proposed criteria in Tier 2, a Member must add a Tape A ADV greater than or equal to 0.20% (instead of 0.10%) of the Tape A TCV.
- To meet the proposed criteria in Tier 3, a Member must add a Tape B ADV greater than or equal to 0.35% (instead of 0.20%) of the Tape B TCV.
- To meet the proposed criteria in Tier 4, a Member must add a Tape C ADV greater than or equal to 0.20% (instead of 0.10%) of the Tape C TCV.

Although the proposed changes to these thresholds result in more stringent criteria, Members will still have an opportunity to receive the additional rebates for meeting the applicable tier thresholds. Moreover, the proposed changes are designed to encourage LMMs to increase both their Displayed and Non-Displayed liquidity in Tape A, B and C securities on the Exchange, thereby contributing to a deeper and more liquid market, which benefits all market participants and provides greater execution opportunities on the Exchange.

[4] ''ADAV'' means average daily added volume calculated as the number of shares added per day.

[5] Appended to orders that add liquidity to BZX (Tape A) and offered a rebate of $0.002000 per share.

[6] Appended to orders that add liquidity to BZX (Tape B) and offered a rebate of $0.00200 per share.

[7] Appended to orders that add liquidity to BZX (Tape C) and offered a rebate of $0.00200 per share.

[8] As defined in Rule 11.8(e)(1)(E), the term ''Minimum Performance Standards'' means a set of standards applicable to an LMM that may be determined from time to time by the Exchange. Such standards will vary between LMM Securities depending on the price, liquidity, and volatility of the LMM Security in which the LMM is registered. The performance measurements will include: (A) Percent of time at the NBBO; (B) percent of executions better than the NBBO; (C) average displayed size; and (D) average quoted spread. For additional detail, see Original LMM Filing.

[9] As defined in Rule 11.8(e)(1)(D), the term ''LMM Security'' means a Listed Security that has an LMM. As defined in Rule 11.8(e)(1)(B), the term ''Listed Security'' means any ETP or any Primary Equity Security or Closed-End Fund listed on the Exchange pursuant to Rule 14.8 or 14.9.

[10] Appended to non-displayed orders that add liquidity (Tape A) and are assessed a standard rebate of $0.00150.

[11] Appended to non-displayed orders that add liquidity (Tape B) and are assessed a standard rebate of $0.00150.

[12] Appended to non-displayed orders that add liquidity (Tape C) and are assessed a standard rebate of $0.00150.

Non-Displayed Add Volume Tape A Tier 1

The Exchange also proposes to eliminate Non-Displayed Add Volume Tape A Tier 1, which is currently described under footnote 1 of the fees schedule. Particularly, this tier applies to orders yielding fee code HV and provides a $0.00275 per share rebate to Members that add an ADV greater than or equal to 0.20% of the TCV as Non-Displayed orders that yield fee codes HI or HV. Particularly, no Member has reached this tier in several months and the Exchange therefore no longer wishes to, nor is it required to, maintain such tiers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[13] in general, and furthers the objectives of Section 6(b)(4),[14] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members, issuers and other persons using its facilities. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The proposed rule changes reflect a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members. The Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges, including the Exchange, and are reasonable, equitable and non-discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Additionally, as noted above, the Exchange operates in highly competitive market. The Exchange is only one of several equity venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. It is also only one of several maker-taker exchanges. Competing equity exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange. These competing pricing schedules, moreover, are presently comparable to those that the Exchange provides, including the pricing of comparable criteria and/or fees and rebates.

Regarding the proposed updates to the Supplemental Incentive and LMM Add Volume Tiers, the Exchange believes that the proposed tiers are reasonable because each of the tiers, as modified, continue to be available to all Members and provide Members an opportunity to receive an additional rebate, albeit using more stringent criteria. Additionally, the Exchange also believes that the tiers, even as amended, are reasonable, equitable and not unfairly discriminatory because competing equity exchanges offer similar tiered pricing structures with comparable criteria to that of the Supplemental Incentive [15] and LMM Add Volume Tiers.[16] The Exchange also believes that the current additional rebates continue to be commensurate with the proposed criteria. That is, the additional rebates reasonably reflect the difficulty in achieving the corresponding criteria as amended.

The Exchange further believes that the proposed criteria and corresponding additional rebates per tier are reasonable and equitable. Generally, Tape B experiences less variability in terms of broader market share, whereas Tape A and C tend to experience more volatility. As a result, the Exchange has observed that Members generally submit less Tape volume in connection with Tape A and Tape C. For example, the average Tape ADAV as a percentage of Tape TCV in Tape A and Tape C from LMM Members in the last month was lower than their average Tape ADAV over Tape TCV in Tape B. As a result, the Exchange believes Members are more easily able to meet a volume requirement for Tape B, and therefore, it is equitable to provide for a slightly higher ADAV Tape B threshold of Tape B TCV than that for Tape A and C.

The Exchange believes the proposed changes are also a reasonable means to incentivize Members to continue to provide liquidity adding, displayed volume (Supplemental Incentive Tiers) and displayed and non-displayed volume (for LMM Add Volume Tiers), which will benefit all market participants by incentivizing continuous liquidity and thus, deeper more liquid markets as well as increased execution opportunities. Particularly, the proposed changes are designed to incentivize continuous displayed liquidity, which signals other market participants to take the additional execution opportunities provided by such liquidity, while the proposed incentives to provide non-displayed liquidity will further contribute to a deeper, more liquid market and provide even more execution opportunities for active market participants at improved prices. This overall increase in activity deepens the Exchange's liquidity pool, offers additional cost savings, supports the quality of price discovery, promotes market transparency and improves market quality, for all investors.

In addition to this, the Exchange believes that the proposal represents an equitable allocation of rebates and is not unfairly discriminatory because all Members will continue to be eligible for the Supplemental Incentive Tiers, as amended, and for the LMM Add Volume Tiers, as amended. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying for the proposed tiers. The Exchange notes that most recently, seven Members satisfied Supplemental Incentive Tier Tape A, seven members satisfied Supplemental Incentive Tier Tape B, and five Members satisfied Supplemental Incentive Tier Tape C. While the Exchange has no way of predicting with certainty how the proposed tier will impact Member activity, the Exchange anticipates that approximately four Members will be able to satisfy Supplemental Incentive Tier Tape A (as amended), five Members will be able to satisfy Supplemental Incentive Tier Tape B (as amended) and three Members will be able to satisfy Supplemental Incentive Tier Tape C (as amended). With respect to the LMM Add Volume Tiers, the Exchange notes that most recently, one Member satisfied LMM Add Volume Tier 2, two Members satisfied LMM Add Volume Tier 3 and two Members satisfied LMM Add Volume Tier 4. While the Exchange has no way of predicting with certainty how the proposed tier will impact Member activity, the Exchange anticipates that approximately one Member will be able to satisfy LMM Add Volume Tier 2 (as amended), one Member will be able to

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(4).

[15] *See* NYSE Price List, ''Credit Applicable to Supplemental Liquidity Providers (''SLPs'')'' *and* Nasdaq Equity 7, Section 118(a)(1).

[16] *See e.g.,* Nasdaq Phlx Equity 7 Pricing Schedule, Section 3(c), which provides up to an additional credit of $0.0003 for various order and quoting volume thresholds for the exchange's qualified market makers (''QMMs'').

satisfy LMM Add Volume Tier 3 (as amended) and one Member will be able to satisfy LMM Add Volume Tier 4 (as amended). The Exchange also notes that the proposed tiers will not adversely impact any Member's ability to qualify for other rebate tiers. Rather, should a Member not meet the proposed criteria for a tier, the Member will merely not receive the corresponding additional rebate.

Finally, the Exchange believes the proposed amendment to remove Non-Displayed Add Volume Tape A Tier 1 is reasonable because no Member has achieved this tier in several months. Moreover, the Exchange is not required to maintain this tier and Members still have a number of other opportunities and a variety of ways to receive enhanced rebates for Non-Displayed liquidity, including the enhanced rebates under the Non-Displayed Add Volume Tiers under footnote 1 of the fees schedule. The Exchange believes the proposal to eliminate these tiers is also equitable and not unfairly discriminatory because it applies to all Members.

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. Rather, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [17]

The Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed changes apply to all Members equally in that all Members continue to be eligible for the Supplemental Incentive Tiers and LMM Add Volume Tiers (and have the same opportunity to become an LMM Member), have a reasonable opportunity to meet the tiers' criteria and will all receive the corresponding additional rebates if such criteria are met. Additionally, the proposed tier changes are designed to attract additional order flow to the Exchange. The Exchange believes that the updated tier criteria would incentivize market participants to direct liquidity adding order flow to the Exchange, bringing with it additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefits all market participants on the Exchange by enhancing market quality and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem.

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including 15 other equities exchanges and off-exchange venues and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 18% of the market share. Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [18] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[19] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

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 foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [20] and paragraph (f) of Rule 19b–4 thereunder.[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 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–CboeBZX–2020–078 on the subject line.

[17] Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

[18] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[19] NetCoalition v. SEC, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f).

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–CboeBZX–2020–078. 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–CboeBZX–2020–078 and should be submitted on or before December 3, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24962 Filed 11–10–20; 8:45 am]

BILLING CODE 8011–01–P

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90365; File No. SR–CboeEDGX–2020–052]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Rule 14.10, Requirements for Securities Issued by the Exchange or Its Affiliates

November 6, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 28, 2020, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') 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 amend Rule 14.10 (Requirements for Securities Issued by the Exchange or its Affiliates) regarding the requirements for the listing of securities that are issued by the Exchange or any of its affiliates. The Exchange notes that the changes proposed herein are substantively identical to changes adopted on Cboe BZX Exchange, Inc. (''BZX'').[3]

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), 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 14.10 (Requirements for Securities Issued by the Exchange or its Affiliates) regarding the requirements for the listing of securities that are issued by the Exchange or any of its affiliates. The Exchange notes that the changes proposed herein are substantively identical to changes adopted on Cboe BZX Exchange, Inc. (''BZX'').[4]

Rule 14.10 sets forth certain monitoring requirements that must be met throughout the continued listing and trading of securities issued by the Exchange or its affiliates. More specifically, Rule 14.10(b) and (c) provide that:

• Throughout the continued listing and trading of an Affiliate Security[5] on the Exchange, the Exchange shall prepare a quarterly report on the Affiliate Security for the Regulatory Oversight Committee (''ROC'') of the Exchange's Board of Directors that describes the Exchange's monitoring of the Affiliate Security's compliance with the Exchange's listing standards (the ''Quarterly Listing Report'');

• once a year, an independent accounting firm shall review the listing standards for the Affiliate Security to ensure that the issuer is in compliance with the listing requirements (''Annual Report''), and a copy of the Annual Report shall be forwarded promptly to the ROC; and

• throughout the trading of an Affiliate Security on the Exchange, the Exchange shall prepare a quarterly report on the Affiliate Security for the Regulatory Oversight Committee of the Exchange's Board of Directors that describes the Exchange's monitoring of the trading of the Affiliate Security, including summaries of all related surveillance alerts, complaints, regulatory referrals, trades cancelled or adjusted pursuant to Exchange Rules, investigations, examinations, formal and informal disciplinary actions, exception reports and trading data used to ensure the Affiliate Security's compliance with

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 86623 (August 9, 2019) 84 FR 41771 (August 15, 2019) (SR–CboeBZX–2019–073) (the ''BZX Filing'').

[4] *See* Securities Exchange Act Release No. 86623 (August 9, 2019) 84 FR 41771 (August 15, 2019) (SR–CboeBZX–2019–073) (the ''BZX Filing'').

[5] As defined in Rule 14.10(a)(2), the term ''Affiliate Security'' means any security issued by a EDGX Affiliate or any Exchange-listed option on any such security, with the exception of Portfolio Depository Receipts as defined in Rule 14.8(d) and Investment Company Units as defined in Rule 14.2.

the Exchange's listing and trading rules (the ''Quarterly Trading Report'' and, collectively with the Quarterly Listing Report, the ''Quarterly Reports'').

Rule 14.10(d) requires that a copy of all Quarterly Reports and Annual Reports will be forwarded promptly to the Commission.

The Exchange proposes to amend Rule 14.10(d) to remove the requirement that copies of the Quarterly Reports and Annual Reports be forwarded to the Commission and instead providing that the Exchange will forward a copy of the Quarterly Reports and/or Annual Reports to the Commission upon request.

Finally, the Exchange is proposing to make clear that the requirements under Rule 14.10(b)(1),[6] (2),[7] (3),[8] and (4)[9] do not apply to Affiliate Securities that are Exchange-listed options. The Exchange is proposing this change because there is no issuer for options as the term is used in Rule 14.10(b) and each of the requirements under Rule 14.10(b) is implicitly related to equity securities and not to options on such equity securities. The Exchange is not proposing to make any changes to the requirement for all Affiliate Securities (including options) under Rule 14.10(c) that ''[t]hroughout the trading of an Affiliate Security on the Exchange, the Exchange shall prepare a quarterly report on the Affiliate Security for the Regulatory Oversight Committee of the Exchange's Board of Directors that describes the Exchange's monitoring of the trading of the Affiliate Security, including summaries of all related surveillance alerts, complaints, regulatory referrals, trades cancelled or adjusted pursuant to Exchange Rules, investigations, examinations, formal and informal disciplinary actions, exception reports and trading data used to ensure the Affiliate Security's compliance with the Exchange's listing and trading rules.'' As such, the Exchange will continue to prepare reports on all Affiliate Securities (including those that are Exchange-listed options) as required under Rule 14.10(c).

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act[10] in general and Section 6(b)(5) of the Act[11] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in 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.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices, to 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 mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, because the proposed changes would reduce the paperwork received by the Commission and ease the burden of submitting the Quarterly Reports and Annual Reports, without changing the information available to the Commission. In discussions with the Commission Staff regarding Rule 14.10, it was determined that the Exchange no longer needed to provide copies of the Quarterly Reports and Annual Reports to the Commission. The Quarterly Reports and Annual Reports would continue to be available to the Commission, as they are subject to Section 17 of the Act[12] and Rule 17a-1 thereunder,[13] pursuant to which the Exchange is required to keep and preserve copies of the Quarterly Reports and Annual Reports, and to promptly furnish to the Commission copies of such Reports upon request of any representative of the Commission.

Finally, the Exchange believes that the clarifying change to exclude options on Affiliate Securities from the requirements of Rule 14.10(b) would promote just and equitable principles of trade and remove impediments to a free and open market by making clear that certain obligations that implicitly did not apply to options on Affiliate Securities do not, in fact, apply. As noted above, the Exchange will continue to prepare reports on all Affiliate Securities that include summaries of all related surveillance alerts, complaints, regulatory referrals, trades cancelled or adjusted pursuant to Exchange Rules, investigations, examinations, formal and informal disciplinary actions, exception reports and trading data used to ensure the Affiliate Security's compliance with the Exchange's listing and trading rules (including those that are Exchange-listed options) as required under Rule 14.10(c).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed changes to eliminate the requirement that the Exchange submit copies of the Quarterly Reports and Annual Reports to the Commission and excluding options on Affiliate Securities from the requirements of Rule 14.10(b) will have no impact on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

[6] Rule 14.10(b)(1) requires that prior to the initial listing of an Affiliate Security on the Exchange, Exchange personnel shall determine that such security satisfies the Exchange's rules for listing, and such finding must be approved by the Regulatory Oversight Committee of the Exchange's Board of Directors.

[7] Rule 14.10(b)(2) requires that throughout the continued listing of an Affiliate Security on the Exchange, the Exchange shall prepare a quarterly report on the Affiliate Security for the Regulatory Oversight Committee of the Exchange's Board of Directors that describes the Exchange's monitoring of the Affiliate Security's compliance with the Exchange's listing standards, including: the Affiliate Security's compliance with the Exchange's minimum share price requirement; and the Affiliate Security's compliance with each of the quantitative continued listing requirements.

[8] Rule 14.10(b)(3) requires that once a year, an independent accounting firm shall review the listing standards for the Affiliate Security to ensure that the issuer is in compliance with the listing requirements and a copy of the report shall be forwarded promptly to the Regulatory Oversight Committee of the Exchange's Board of Directors.

[9] Rule 14.10(b)(4) requires that in the event that the Exchange determines that the EDGX Affiliate is not in compliance with any of the Exchange's listing standards, the Exchange shall notify the issuer of such non-compliance promptly and request a plan of compliance. The Exchange shall file a report with the Commission within five business days of providing such notice to the issuer of its non-compliance. The report shall identify the date of the non-compliance, type of non-compliance, and any other material information conveyed to the issuer in the notice of non-compliance. Within five business days of receipt of a plan of compliance from the issuer, the Exchange shall notify the Commission of such receipt, whether the plan of compliance was accepted by the Exchange or what other action was taken with respect to the plan and the time period provided to regain compliance with the Exchange's listing standards, if any.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78q.

[13] 17 CFR 240.17a-1.

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 [14] and Rule 19b–4(f)(6) thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6) [16] normally does not become operative for 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[17] 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 to allow the Exchange to make the proposed changes to its rules without unnecessary delay in order to be consistent with those already in place on BZX, its affiliate. The Commission notes that the proposed rule change is based on and substantively identical to the rules of BZX.[18] For this reason, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposal operative upon filing.[19]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the 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–CboeEDGX–2020–052 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–CboeEDGX–2020–052. 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–CboeEDGX–2020–052 and should be submitted on or before December 3, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–25057 Filed 11–10–20; 8:45 am]

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[14] 15 U.S.C. 78s(b)(3)(A).

[15] 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.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] *See supra* note 3.

[19] 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).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90354; File No. SR–MIAX–2020–34]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule To Increase the Number of Additional Limited Service MIAX Express Interface Ports Available to Market Makers

November 5, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 23, 2020, Miami International Securities Exchange, LLC (''MIAX Options'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to increase the number of additional Limited Service MIAX Express Interface (''MEI'') Ports available to Market Makers.[3] The Exchange does not propose to amend the fees for additional Limited Service MEI Ports.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Market Makers'' refers to Lead Market Makers (''LMMs''), Primary Lead Market Makers (''PLMMs''), and Registered Market Makers (''RMMs'') collectively. *See* Exchange Rule 100.

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 the Fee Schedule to offer two (2) additional Limited Service MEI Ports to Market Makers. The Exchange does not propose to amend the fees charged for the additional Limited Service MEI Ports.

The Exchange initially filed the proposal to increase the number of Limited Service MEI Ports available to Market Makers on June 30, 2020, with no change to the actual fee amounts being charged.[4] The First Proposed Rule Change was published for comment in the **Federal Register** on July 20, 2020.[5] The Exchange notes that the First Proposed Rule Change did not receive any comment letters. Nonetheless, the Exchange withdrew the First Proposed Rule Change on August 24, 2020.[6] On August 25, 2020, the Exchange refiled its proposal to increase the number of Limited Service MEI Ports available to Market Makers (without increasing the actual fee amounts) to provide further clarification regarding the Exchange's annual cost for providing additional Limited Service MEI Ports.[7] The Second Proposed Rule Change was published for comment in the **Federal Register** on September 11, 2020.[8] Like the First Proposed Rule Change, the Second Proposed Rule Change did not receive any comment letters. Nonetheless, the Exchange withdrew the Second Proposed Rule Change on October 23, 2020.[9]

The Exchange now submits this proposed rule change to increase the number of additional Limited Service MEI Ports available to Market Makers (without increasing the actual fee amounts) to provide additional information regarding the Exchange's revenues, costs, and profitability for the two additional Limited Service MEI Ports. This additional analysis includes information regarding the Exchange's methodology for determining the costs and revenues for the two additional Limited Service MEI Ports.

Currently, MIAX assesses monthly MEI Port Fees on Market Makers based upon the number of MIAX matching engines[10] used by the Market Maker. Market Makers are allocated two (2) Full Service MEI Ports[11] and two (2) Limited Service MEI Ports[12] per matching engine to which they connect. The Full Service MEI Ports, Limited Service MEI Ports, and the additional Limited Service MEI Ports all include access to MIAX's primary and secondary data centers and its disaster recovery center. Market Makers may request additional Limited Service MEI Ports for which they will be assessed the existing $100 monthly fee for each additional port they request. This fee has been unchanged since 2016.[13]

The Exchange originally added the Limited Service MEI Ports to enhance the MEI Port connectivity made available to Market Makers, and has subsequently made additional Limited Service MEI Ports available to Market Makers.[14] Limited Service MEI Ports have been well received by Market Makers since their addition. The Exchange now proposes to offer to Market Makers the ability to purchase an additional two (2) Limited Service MEI Ports per matching engine over and above the current six (6) additional Limited Service MEI Ports per matching engine that are available for purchase by Market Makers. The Exchange proposes making a corresponding change to footnote 30 of the Exchange's Fee Schedule to specify that Market Makers will now be limited to purchasing eight (8) additional Limited Service MEI Ports per matching engine, for a total of ten (10) per matching engine. All fees related to MEI Ports shall remain unchanged and Market Makers that voluntarily purchase the additional Limited Service MEI Ports will remain subject to the existing $100 monthly fee per port.

The Exchange is increasing the number of additional Limited Service MEI Ports because the Exchange is expanding its network. This network expansion is necessary due to increased customer demand and increased volatility in the marketplace, both of which have translated into increased message traffic rates across the network. Consequently, this network expansion, which increases the number of switches supporting customer facing systems, is necessary in order to provide sufficient access to new and existing Members,[15] to maintain a sufficient amount of network capacity head-room, and to continue to provide the same level of service across the Exchange's low-latency, high-throughput technology environment.

Currently, the Exchange has 8 network switches that support the entire customer base of MIAX. The Exchange plans to increase this to 10 switches, which will increase the number of available customer ports by 25%. This increase in the number of available customer ports will enable the Exchange to continue to provide sufficient and

[4] *See* Securities Exchange Act Release No. 89317 (July 14, 2020), 85 FR 43918 (July 20, 2020) (SR–MIAX–2020–23) (the ''First Proposed Rule Change'').

[5] *Id.*

[6] *See* Comment Letter from Christopher Solgan, VP, Senior Counsel, the Exchange, dated August 24, 2020, notifying the Commission that the Exchange would withdraw the First Proposed Rule Change.

[7] *See* Securities Exchange Act Release No. 89769 (September 4, 2020), 85 FR 55905 (September 10, 2020) (SR–MIAX–2020–29) (the ''Second Proposed Rule Change'').

[8] *Id.*

[9] *See* Comment Letter from Christopher Solgan, VP, Senior Counsel, the Exchange, dated October 19, 2020, notifying the Commission that the Exchange would withdraw the Second Proposed Rule Change.

[10] A ''matching engine'' is a part of the MIAX electronic system that processes options quotes and trades on a symbol-by-symbol basis. Some matching engines will process option classes with multiple root symbols, and other matching engines will be dedicated to one single option root symbol (for example, options on SPY will be processed by one single matching engine that is dedicated only to SPY). A particular root symbol may only be assigned to a single designated matching engine. A particular root symbol may not be assigned to multiple matching engines. *See* Fee Schedule, Section 5)d)ii), note 29.

[11] Full Service MEI Ports provide Market Makers with the ability to send Market Maker quotes, eQuotes, and quote purge messages to the MIAX System. Full Service MEI Ports are also capable of receiving administrative information. Market Makers are limited to two Full Service MEI Ports per matching engine. *See* Fee Schedule, Section 5)d)ii), note 27.

[12] Limited Service MEI Ports provide Market Makers with the ability to send eQuotes and quote purge messages only, but not Market Maker Quotes, to the MIAX System. Limited Service MEI Ports are also capable of receiving administrative information. Market Makers initially receive two Limited Service MEI Ports per matching engine. *See* Fee Schedule, Section 5)d)ii), note 28.

[13] *See* Securities Exchange Act Release No. 79666 (December 22, 2016), 81 FR 96133 (December 29, 2016) (SR–MIAX–2016–47).

[14] *See* Securities Exchange Act Release Nos. 70137 (August 8, 2013), 78 FR 49586 (August 14, 2013) (SR–MIAX–2013–39); 70903 (November 20, 2013), 78 FR 70615 (November 26, 2013) (SR–MIAX–2013–52); 78950 (September 27, 2016), 81 FR 68084 (October 3, 2016) (SR–MIAX–2016–33); and 79198 (October 31, 2016), 81 FR 76988 (November 4, 2016) (SR–MIAX–2016–37).

[15] 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.

equal access to MIAX Systems to all Members. Absent the proposed increase in available MEI Ports, the Exchange projects that its current inventory will be depleted and it will lack sufficient capacity to continue to meet Members' access needs.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [16] in general, and furthers the objectives of Section 6(b)(5) of the Act [17] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that its proposal is consistent with the objectives of Section 6(b)(5) of the Act [18] because the proposed additional Limited Service MEI Ports will be available to all Market Makers and the current fees for the additional Limited Service MEI Ports apply equally to all Market Makers regardless of type, and access to the Exchange is offered on terms that are not unfairly discriminatory. The Exchange is proposing to increase the number of available Limited Service MEI Ports because the Exchange is expanding its network. This network expansion is necessary due to increased customer demand and increased volatility in the marketplace, both of which have translated into increased message traffic rates across the network. Consequently, this network expansion, which increases the number of switches supporting customer facing systems, is necessary in order to provide sufficient and equal access to new and existing Members, to maintain a sufficient amount of network capacity head-room, and to continue to provide the same level of service across the Exchange's low-latency, high-throughput technology environment.

Currently, the Exchange has 8 network switches that support the entire customer base of MIAX. The Exchange plans to increase this to 10 switches, which will increase the number of available customer ports by 25%. This increase in the number of available customer ports will enable the Exchange to continue to provide sufficient and equal access to MIAX Systems for all Members. Absent the proposed increase in available MEI Ports, the Exchange projects that its current inventory will be depleted and it will lack sufficient capacity to continue to meet Members' access needs. Further, the Exchange notes the decision of whether to purchase two additional Limited Service MEI Ports is completely optional and it is a business decision for each Market Maker to determine whether the additional Limited Service MEI Ports are necessary to meet their business requirements.

The Exchange further believes that the availability of the additional Limited Service MEI Ports is equitable and not unfairly discriminatory because it will enable Market Makers to maintain uninterrupted access to the MIAX System and consequently enhance the marketplace by helping Market Makers to better manage risk, thus preserving the integrity of the MIAX markets, all to the benefit of and protection of investors and the public as a whole.

The Exchange also believes that its proposal is consistent with Section 6(b)(4) of the Act because only Market Makers that voluntarily purchase the two additional Limited Service MEI Ports will be charged the existing $100 monthly fee per port, which has been unchanged since 2016.[19] The Exchange does not propose to amend the fees applicable to additional Limited Service MEI Ports which have been previously filed with the Commission and become effective after notice and public comment.[20] As stated above, the Exchange proposes to expand its network by making available two additional Limit Service MEI Ports due to increased customer demand and increased volatility in the marketplace, both of which have translated into increased message traffic rates across the network. The cost to expand the network in this manner is greater than the revenue the Exchange anticipates the additional Limited Service MEI Ports will generate. Specifically, the Exchange estimates it will incur a one-time cost of approximately $175,000 in capital expenditures on hardware, software, and other items to expand the network to make available the two additional Limited Service MEI Ports. This estimated cost also includes expense associated with providing the necessary engineering and support personnel to transition those Market Makers who wish to acquire the two additional Limited Service MEI Ports.

The Exchange projects that approximately six to seven Market Makers will purchase the additional Limited Service MEI Ports, which will be subject to the existing monthly fee of $100 per port. Accordingly, the Exchange projects that the annualized revenue from the two additional Limited Service MEI Ports will be approximately $16,800 (assuming seven Market Makers purchase the two additional Limited Service MEI Ports). Therefore, the Exchange's upfront cost in expanding its network to provide its Members with the two additional Limited Service MEI Ports—approximately $175,000—is significant relative to the anticipated annualized revenue the Exchange expects to bring in from the two additional Limited Service MEI Ports—approximately $16,800. Further, the Exchange anticipates it will incur approximately $100,371 in annualized ongoing operating expense in order to support the expanded network and the two additional Limited Service MEI Ports. Thus, even excluding the upfront capital expense (''CapEx'') of $175,000, the Exchange is not generating a supra-competitive profit from the provision of these two additional Limited Service MEI Ports. In fact, even excluding the one-time CapEx cost of $175,000, the Exchange anticipates generating an annual loss from the provision of these two additional Limited Service MEI Ports of ($83,571)—that is, $16,800 in revenue minus $100,371 in expense equates to a loss of ($83,571) to support the additional ports annually.

The Exchange conducted an extensive cost review in which the Exchange analyzed every expense item in the Exchange's general expense ledger (this includes over 150 separate and distinct expense items) to determine whether each such expense relates to the additional Limited Service MEI Ports, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the additional Limited Service MEI Ports, and thus bears a relationship that is, ''in nature and closeness,'' directly related to those services. The sum of all such portions of expenses represents the total cost of the Exchange to provide services associated with the two additional Limited Service MEI Ports.

Specifically, utilizing 2019 expense figures, total third-party expense, relating to fees paid by the Exchange to third-parties for certain products and services for the Exchange to be able to provide the two additional Limited Service MEI Ports, was approximately $12,393. This includes, but is not limited to, a portion of the fees paid to: (1) Equinix, for data center services, for the primary, secondary, and disaster

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] 15 U.S.C. 78f(b)(5).

[19] *See supra* note 13.

[20] *See supra* notes 13 and 14.

recovery locations of the Exchange's trading system infrastructure; (2) Zayo Group Holdings, Inc. (''Zayo'') for network services (fiber and bandwidth products and services) linking the Exchange's office locations in Princeton, NJ and Miami, FL to all data center locations; (3) Secure Financial Transaction Infrastructure (''SFTI'') [21], which supports network feeds for the entire U.S. options industry; (4) various other services providers (including Thompson Reuters, NYSE, Nasdaq, and Internap), which provide content, network services, and infrastructure services for critical components of options network services; and (5) various other hardware and software providers (including Dell and Cisco, which support the production environment in which Members and non-Members connect to the network to trade, receive market data, etc.).

For clarity, only a portion of all fees paid to such third-parties is included in the third-party expense herein, and no expense amount is allocated twice. Accordingly, the Exchange does not allocate its entire information technology and communication costs to the services associated with providing the two additional Limited Service MEI Ports.

The Exchange believes it is reasonable to allocate such third-party expense described above towards the total cost to the Exchange to provide the services associated with the two additional Limited Service MEI Ports. In particular, the Exchange believes it is reasonable to allocate the identified portion of the Equinix expense because Equinix operates the data centers (primary, secondary, and disaster recovery) that host the Exchange's network infrastructure. This includes, among other things, the necessary storage space, which continues to expand and increase in cost, power to operate the network infrastructure, and cooling apparatuses to ensure the Exchange's network infrastructure maintains stability. Without these services from Equinix, the Exchange would not be able to operate and support the network and provide the services associated with the two additional Limited Service MEI Ports to its Members and non-Members and their customers. The Exchange did not allocate all of the Equinix expense toward the cost of providing the services associated with the two additional Limited Service MEI Ports, only that portion which the Exchange identified as being specifically mapped to providing the services associated with the two additional Limited Service MEI Ports, approximately 0.5% of the total Equinix expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the services associated with the two additional Limited Service MEI Ports, and not any other service, as supported by its cost review.

The Exchange believes it is reasonable to allocate the identified portion of the Zayo expense because Zayo provides the internet, fiber and bandwidth connections with respect to the network, linking the Exchange with its affiliates, MIAX PEARL and MIAX Emerald, as well as the data center and disaster recovery locations. As such, all of the trade data, including the billions of messages each day per exchange, flow through Zayo's infrastructure over the Exchange's network. Without these services from Zayo, the Exchange would not be able to operate and support the network and provide the services associated with the two additional Limited Service MEI Ports. The Exchange did not allocate all of the Zayo expense toward the cost of providing the services associated with the two additional Limited Service MEI Ports, only the portion which the Exchange identified as being specifically mapped to providing the two additional Limited Service MEI Ports, approximately 0.4% of the total Zayo expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the services associated with the two additional Limited Service MEI Ports, and not any other service, as supported by its cost review.

The Exchange believes it is reasonable to allocate the identified portions of the SFTI expense and various other service providers' (including Thompson Reuters, NYSE, Nasdaq, and Internap) expense because those entities provide connectivity and feeds for the entire U.S. options industry, as well as the content, network services, and infrastructure services for critical components of the network. Without these services from SFTI and various other service providers, the Exchange would not be able to operate and support the network and provide access to its Members and non-Members and their customers. The Exchange did not allocate all of the SFTI and other service providers' expense toward the cost of providing the services associated with the two additional Limited Service MEI Ports, only the portions which the Exchange identified as being specifically mapped to providing the services associated with the two additional Limited Service MEI Ports, approximately 0.5% of the total SFTI and other service providers' expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the services associated with the two additional Limited Service MEI Ports.

The Exchange believes it is reasonable to allocate the identified portion of the other hardware and software provider expense because this includes costs for dedicated hardware licenses for switches and servers, as well as dedicated software licenses for security monitoring and reporting across the network. Without this hardware and software, the Exchange would not be able to operate and support the network and provide access to its Members and non-Members and their customers. The Exchange did not allocate all of the hardware and software provider expense toward the cost of providing the services associated with the two additional Limited Service MEI Ports, only the portions which the Exchange identified as being specifically mapped to providing the services associated with the two additional Limited Service MEI Ports, approximately 0.3% of the total hardware and software provider expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the services associated with the two additional Limited Service MEI Ports.

For 2019, total internal expense, relating to the internal costs of the Exchange to provide the services associated with the two additional Limited Service MEI Ports was $87,978. This includes, but is not limited to, costs associated with: (1) Employee compensation and benefits for full-time employees that support the services associated with providing the two additional Limited Service MEI Ports, including staff in network operations, trading operations, development, system operations, business, as well as staff in general corporate departments (such as legal, regulatory, and finance) that support those employees and functions (including an increase as a result of the higher determinism project); (2) depreciation and amortization of hardware and software used to provide the services associated with the two additional Limited Service MEI Ports,

[21] In fact, on October 22, 2019, the Exchange was notified by SFTI that it is again raising its fees charged to the Exchange by approximately 11%, without having to show that such fee change complies with the Act by being reasonable, equitably allocated, and not unfairly discriminatory. It is unfathomable to the Exchange that, given the critical nature of the infrastructure services provided by SFTI, that its fees are not required to be rule-filed with the Commission pursuant to Section 19(b)(1) of the Act and Rule 19b-4 thereunder. *See* 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b-4, respectively.

including equipment, servers, cabling, purchased software and internally developed software used in the production environment to support the network for trading; and (3) occupancy costs for leased office space for staff that provide the services associated with the two additional Limited Service MEI Ports. The breakdown of these costs is more fully-described below. For clarity, only a portion of all such internal expenses are included in the internal expense herein, and no expense amount is allocated twice. Accordingly, the Exchange does not allocate its entire costs contained in those items to the services associated with providing the two additional Limited Service MEI Ports.

The Exchange believes it is reasonable to allocate such internal expense described above towards the total cost to the Exchange to provide the services associated with the two additional Limited Service MEI Ports. In particular, the Exchange's employee compensation and benefits expense relating to providing the services associated with the two additional Limited Service MEI Ports was approximately $58,870, which is only a portion of the $9,811,685 total expense for employee compensation and benefits. The Exchange believes it is reasonable to allocate the identified portion of such expense because this includes the time spent by employees of several departments, including Technology, Back Office, Systems Operations, Networking, Business Strategy Development (who create the business requirement documents that the Technology staff use to develop network features and enhancements), Trade Operations, Finance (who provide billing and accounting services relating to the network), and Legal (who provide legal services relating to the network, such as rule filings and various license agreements and other contracts). As part of the extensive cost review conducted by the Exchange, the Exchange reviewed the amount of time spent by each employee on matters relating to the provision of services associated with the two additional Limited Service MEI Ports. Without these employees, the Exchange would not be able to provide the services associated with the two additional Limited Service MEI Ports to its Members and non-Members and their customers. The Exchange did not allocate all of the employee compensation and benefits expense toward the cost of the services associated with providing the two additional Limited Service MEI Ports, only the portions which the Exchange identified as being specifically mapped to providing the services associated with the two additional Limited Service MEI Ports, approximately 0.6% of the total employee compensation and benefits expense. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the services associated with the two additional Limited Service MEI Ports, and not any other service, as supported by its cost review.

The Exchange's depreciation and amortization expense relating to providing the services associated with the two additional Limited Service MEI Ports was $26,362, which is only a portion of the $5,272,469 total expense for depreciation and amortization. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network and provide the services associated with the two additional Limited Service MEI Ports. Without this equipment, the Exchange would not be able to operate the network and provide the services associated with the two additional Limited Service MEI Ports to its Members and non-Members and their customers. The Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing the services associated with the two additional Limited Service MEI Ports, only the portion which the Exchange identified as being specifically mapped to providing the services associated with the two additional Limited Service MEI Ports, approximately 0.5% of the total depreciation and amortization expense, as these services would not be possible without relying on such equipment. The Exchange believes this allocation is reasonable because it represents the Exchange's actual cost to provide the services associated with the two additional Limited Service MEI Ports, and not any other service, as supported by its cost review.

The Exchange's occupancy expense relating to providing the services associated with providing the two additional Limited Service MEI Ports was approximately $2,746, which is only a portion of the $686,437 total expense for occupancy. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense represents the portion of the Exchange's cost to rent and maintain a physical location for the Exchange's staff who operate and support the network, including providing the services associated with the two additional Limited Service MEI Ports. This amount consists primarily of rent for the Exchange's Princeton, NJ office, as well as various related costs, such as physical security, property management fees, property taxes, and utilities. The Exchange operates its Network Operations Center (''NOC'') and Security Operations Center (''SOC'') from its Princeton, New Jersey office location. A centralized office space is required to house the staff that operates and supports the network. The Exchange currently has approximately 160 employees. Approximately two-thirds of the Exchange's staff are in the Technology department, and the majority of those staff have some role in the operation and performance of the services associated with providing the two additional Limited Service MEI Ports. Without this office space, the Exchange would not be able to operate and support the network and provide the services associated with the two additional Limited Service MEI Ports to its Members and non-Members and their customers. Accordingly, the Exchange believes it is reasonable to allocate the identified portion of its occupancy expense because such amount represents the Exchange's actual cost to house the equipment and personnel who operate and support the Exchange's network infrastructure and the services associated with the two additional Limited Service MEI Ports. The Exchange did not allocate all of the occupancy expense toward the cost of providing the services associated with the two additional Limited Service MEI Ports, only the portion which the Exchange identified as being specifically mapped to operating and supporting the network, approximately 0.4% of the total occupancy expense. The Exchange believes this allocation is reasonable because it represents the Exchange's cost to provide the services associated with the two additional Limited Service MEI Ports, and not any other service, as supported by its cost review.

Accordingly, based on the facts and circumstances presented, the Exchange believes that its provision of the services associated with the two additional Limited Service MEI Ports will not result in excessive pricing or supra-competitive profit.

For the avoidance of doubt, none of the expenses included herein relating to the services associated with providing the two additional Limited Service MEI Ports relate to the provision of any other

services offered by the Exchange. Stated differently, no expense amount of the Exchange is allocated twice.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory to allocate the respective percentages of each expense category described above towards the total cost to the Exchange of operating and supporting the network, including providing the services associated with the two additional Limited Service MEI Ports because the Exchange performed a line-by-line item analysis of all the expenses of the Exchange, and has determined the expenses that directly relate to operation and support of the network. Further, the Exchange notes that, without the specific third-party and internal items listed above, the Exchange would not be able to operate and support the network, including providing the services associated with the two additional Limited Service MEI Ports to its Members and non-Members and their customers. Each of these expense items, including physical hardware, software, employee compensation and benefits, occupancy costs, and the depreciation and amortization of equipment, have been identified through a line-by-line item analysis to be integral to the operation and support of the network. Providing the two additional Limited Service MEI Ports at the existing rates is intended to recover the Exchange's costs of operating and supporting the network.

Accordingly, the Exchange believes that providing the two additional Limited Service MEI Ports at the existing rate is fair and reasonable because it does not result in excessive pricing or supra-competitive profit, when comparing the actual network operation and support costs to the Exchange versus the projected annual revenue from providing the two additional Limited Service MEI Ports.

Further, subjecting the two additional Limited Service MEI Ports to the existing $100 monthly fee per port is also designed to encourage Market Makers to be efficient with their port usage, thereby resulting in a corresponding increase in the efficiency that the Exchange would be able to realize in managing its aggregate costs for providing the two additional ports. There is no requirement that any Market Maker maintain a specific number of Limited Service MEI Ports and a Market Maker may choose to maintain as many or as few of such ports as each Market Maker deems appropriate.

Finally, subjecting the two additional Limited Service MEI Ports to the existing $100 monthly fee will help to encourage Limited Service MEI Port usage in a way that aligns with the Exchange's regulatory obligations. As a national securities exchange, the Exchange is subject to Regulation Systems Compliance and Integrity (''Reg. SCI'').[22] Reg. SCI Rule 1001(a) requires that the Exchange establish, maintain, and enforce written policies and procedures reasonably designed to ensure (among other things) that its Reg. SCI systems have levels of capacity adequate to maintain the Exchange's operational capability and promote the maintenance of fair and orderly markets.[23] By encouraging Members to be efficient with their usage of Limited MEI Ports, the current fee that will continue to apply to the proposed two (2) additional Limited Service MEI Ports will support the Exchange's Reg. SCI obligations in this regard by ensuring that unused ports are available to be allocated based on individual Members needs and as the Exchange's overall order and trade volumes increase.

B. Self-Regulatory Organization's Statement on Burden on Competition

MIAX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed rule change will not impose a burden on competition but will benefit competition by enhancing the Exchange's ability to compete by providing additional services to market participants. It is not intended to address a competitive issue. Rather, the proposed increase in the number of additional Limited Service MEI Ports available per Market Maker is intended to allow the Exchange to increase its inventory of MEI Ports to meet increased Member demand. The Exchange is increasing the number of available additional Limited Service MEI Ports in response to Market Maker demand for increased connectivity to the MIAX System. The Exchange's current inventory may soon be insufficient to meet those needs. Again, the Exchange is not proposing to amend the fees for MEI Ports, just to increase the number of MEI Ports available per Market Maker. The Exchange also does not believe that the proposed rule change will impose a burden on intramarket competition because the two additional Limited Service MEI Ports will be available to all Market Makers on an equal basis. It is a business decision of each Market Maker whether to pay for the additional Limited Service MEI Ports.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[24] and Rule 19b–4(f)(2)[25] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission 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–MIAX–2020–34 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–MIAX–2020–34. 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

[22] 17 CFR 242.1000–1007.

[23] 17 CFR 242.1001(a).

[24] 15 U.S.C. 78s(b)(3)(A)(ii).

[25] 17 CFR 240.19b–4(f)(2).

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–MIAX–2020–34, and should be submitted on or before December 3, 2020.[26]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

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BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90357; File No. SR–NASDAQ–2020–060]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1, To Treat as an Eligible Switch, for Purposes of IM–5900–7, an Acquisition Company That Switches From NYSE to Nasdaq After Announcing a Business Combination

November 5, 2020.

On September 1, 2020, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to treat as an Eligible Switch, for purposes of IM–5900–7, an Acquisition Company that switches from the New York Stock Exchange to Nasdaq after announcing a business combination. The proposed rule change was published for comment in the **Federal Register** on September 21, 2020.[3] No comments have been received on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is November 5, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates December 20, 2020 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NASDAQ–2020–060).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24966 Filed 11–10–20; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89875 (September 15, 2020), 85 FR 59346 (September 21, 2020).

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90363; File No. SR–NYSE–2020–89]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change To Amend Rule 7.35C

November 5, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 23, 2020, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.35C (Exchange-Facilitated Auctions) to (1) provide the Exchange authority to facilitate a Trading Halt Auction if a security has not reopened following a MWCB Halt by 3:30 p.m.; (2) widen the Auction Collar for an Exchange-facilitated Trading Halt Auction following an MWCB Halt; (3) provide that certain DMM Interest would not be cancelled following an Exchange-facilitated Auction; and (4) change the Auction Reference Price for Exchange-facilitated Core Open Auctions. 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.35C (Exchange-Facilitated Auctions) to (1) provide the Exchange authority to facilitate a Trading Halt Auction [3] if a security has not reopened following a Level 1 or Level 2 trading

[3] As defined in Rule 7.35(a)(1), an ''Auction'' refers to the process for opening, reopening, or closing of trading of Auction-Eligible Securities on the Exchange, which can result in either a trade or a quote.

halt due to extraordinary market volatility under Rule 7.12 (''MWCB Halt'') by 3:30 p.m.; (2) widen the Auction Collar for an Exchange-facilitated Trading Halt Auction following a MWCB Halt; (3) provide that certain DMM Interest [4] would not be cancelled following an Exchange-facilitated Auction; and (4) change the Auction Reference Price for Exchange-facilitated Core Open Auctions.

The first three of these proposed changes are currently in place on a temporary basis, as described in Commentaries .01–.03 to Rule 7.35C. The fourth of these proposed changes would be new and would replace the temporary rule set forth in Commentary .04 to Rule 7.35C.

Background

To slow the spread of COVID–19 through social-distancing measures, on March 18, 2020, the CEO of the Exchange made a determination under Rule 7.1(c)(3) that, beginning March 23, 2020, the Trading Floor facilities located at 11 Wall Street in New York City would close and the Exchange would move, on a temporary basis, to fully electronic trading.[5] On May 14, 2020, the CEO of the Exchange made a determination under Rule 7.1(c)(3) to reopen the Trading Floor on a limited basis on May 26, 2020 to a subset of Floor brokers, subject to safety measures designed to prevent the spread of COVID–19.[6] On June 15, 2020, the CEO of the Exchange made a determination under Rule 7.1(c)(3) to begin the second phase of the Trading Floor reopening by allowing DMMs to return on June 17, 2020, subject to safety measures designed to prevent the spread of COVID–19.[7]

Rule 7.35C sets forth the procedures for Exchange-facilitated Auctions. The first time the Exchange facilitated any Auctions pursuant to Rule 7.35C was on March 19, 2020, when two DMM firms temporarily left the Trading Floor in connection with implementing their business continuity plans related to the COVID–19 pandemic. Beginning on March 23, 2020, when the Exchange temporarily closed the Trading Floor, the Exchange began facilitating Auctions on behalf of all DMM firms. Since June 17, 2020, when DMM firms were permitted to return staff to the Trading Floor, the Exchange has not facilitated any Auctions for DMM firms that have had staff return to the Trading Floor. During the period of March 23, 2020 through June 16, 2020, among the DMM firms, the percentage of Auctions that were facilitated by the Exchange ranged from 1% to 3.2% of the securities assigned to each DMM. During this period, the vast majority of Auctions were facilitated electronically by DMMs pursuant to Rules 7.35A and 7.35B.

In connection with both the market-wide volatility associated with the COVID–19 pandemic in March 2020 and the full and partial closing of the Trading Floor facilities, the Exchange added Commentaries .01, .02, .03, and .04 to Rule 7.35C [8] that are in effect until the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on December 31, 2020.[9] These Commentaries set forth how the Exchange has been functioning during this temporary period when the Trading Floor facilities have been closed either in full or in part in connection with COVID–19.

The Exchange believes that the rules that it has added on a temporary basis to Rule 7.35C have supported the fair and orderly operation of the Exchange during both the market volatility associated with COVID–19 and the temporary period that the Trading Floor facilities have been closed either in full or in part due to COVID–19. The Exchange further believes the functionality that has been operating on a temporary basis would continue to support the fair and orderly operation of the Exchange under any circumstances where there may be either market-wide volatility or the need for the Exchange to facilitate one or more Auctions. Accordingly, the Exchange proposes that the following changes be made permanent in Exchange rules:

- Provide the Exchange with authority to facilitate a Trading Halt Auction if a security has not reopened following a MWCB Halt by 3:30 p.m. Eastern Time.
- Widen the Auction Collars for an Exchange-facilitated Trading Halt Auction following a MWCB Halt to the greater of $0.15 or 10%.
- Allow DMM Interest to remain on the Exchange Book after an Exchange-facilitated Auction.

In addition, the Exchange proposes to change the Auction Reference Price for Exchange-facilitated Core Open Auctions, which would be new.

Proposed Rule Changes

Exchange Authority To Facilitate a Trading Halt Auction Following a MWCB Halt

In the midst of the market-wide volatility relating to COVID–19 and before the Exchange temporarily closed the Trading Floor, the Exchange added Commentary .01 to Rule 7.35C, which provided, at the time of filing, that: [10]

Until May 15, 2020, to facilitate the fair and orderly reopening of securities following either a Level 1 or Level 2 trading halt due to extraordinary market volatility under Rule 7.12 (''MWCB Halt''), the CEO of the Exchange or his or her designee may determine that the Exchange will facilitate a Trading Halt Auction in one or more securities under this Rule if a security has not reopened by 3:30 p.m. If the Exchange facilitates a Trading Halt Auction following a MWCB Halt pursuant to this Commentary, the Auction Collars will be the greater of $0.15 or 10% away from the Auction Reference Price.

Following the temporary closure of the Trading Floor, the substance of this Commentary was revised and moved to

[4] For purposes of Auctions, the term ''DMM Interest'' is defined in Rule 7.35(a)(8) to mean all buy and sell interest entered by a DMM unit in its assigned securities and includes: ''DMM Auction Liquidity,'' which is non-displayed buy and sell interest that is designated for an Auction only (see Rule 7.35(a)(8)(A)); ''DMM Orders'' which are orders, as defined under Rule 7.31, entered by a DMM unit (see Rule 7.35(a)(8)(B)); and ''DMM After-Auction Orders,'' which are orders entered by a DMM unit before either the Core Open Auction or Trading Halt Auction that do not participate in an Auction and are intended instead to maintain price continuity with reasonable depth following an Auction (see Rule 7.35(a)(8)(C)).

[5] Pursuant to Rule 7.1(e), the CEO notified the Board of Directors of the Exchange of this determination. The Exchange's current rules establish how the Exchange will function fully-electronically. The CEO also closed the NYSE American Options Trading Floor, which is located at the same 11 Wall Street facilities, and the NYSE Arca Options Trading Floor, which is located in San Francisco, CA. *See* Press Release, dated March 18, 2020, available here: *https://ir.theice.com/press/press-releases/all-categories/2020/03-18-2020-204202110.*

[6] *See* Securities Exchange Act Release No. 88933 (May 22, 2020), 85 FR 32059 (May 28, 2020) (SR–NYSE–2020–47) (Notice of filing and immediate effectiveness of proposed rule change).

[7] *See* Securities Exchange Act Release No. 89086 (June 17, 2020) (SR–NYSE–2020–52) (Notice of filing and immediate effectiveness of proposed rule change).

[8] *See* Securities Exchange Act Release Nos. 88413 (March 18, 2020), 85 FR 16713 (March 24, 2020) (SR–NYSE–2020–19) (amending Rule 7.35C to add Commentary .01) (''First Rule 7.35C Filing''); 88444 (March 20, 2020), 85 FR 17141 (March 26, 2020) (SR–NYSE–2020–22) (amending Rules 7.35A to add Commentary .01, 7.35B to add Commentary .01, and 7.35C to add Commentary .02) (''Second Rule 7.35C Filing''); 88562 (April 3, 2020), 85 FR 20002 (April 9, 2020) (SR–NYSE–2020–29) (amending Rule 7.35C to add Commentary .03) (''DMM Interest Filing''); and 89059 (June 12, 2020), 85 FR 36911 (June 18, 2020) (SR–NYSE–2020–50) (amending Rule 7.35C to add Commentary .04) (''Fourth Rule 7.35C Filing'').

[9] *See* Securities Exchange Act Release No. 90005 (September 25, 2020), 85 FR 61999 (October 1, 2020) (SR–NYSE–2020–78) (Notice of filing and immediate effectiveness of proposed rule change to extend the temporary period for Commentaries to Rules 7.35, 7.35A, 7.35B, and 7.35C; and temporary rule relief in Rule 36.30 to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on December 31, 2020).

[10] *See* First Rule 7.35C Filing, *supra* note 9.

Commentary .02 to Rule 7.35C, as follows: [11]

If the Trading Floor facilities reopen, through trading on December 31, 2020, to facilitate the fair and orderly reopening of securities following a MWCB Halt, the CEO of the Exchange or his or her designee may determine that the Exchange will facilitate a Trading Halt Auction in one or more securities under this Rule if a security has not reopened by 3:30 p.m. Eastern Time. If the Exchange facilitates a Trading Halt Auction following a MWCB Halt pursuant to this Commentary, the Auction Collars will be the greater of $0.15 or 10% away from the Auction Reference Price.

As described in more detail in the First Rule 7.35C Filing, under Rule 7.35C, the Exchange will facilitate an Auction only if a DMM cannot facilitate an Auction for one or more securities. In support of the proposed rule change, the Exchange explained:

The Exchange continues to believe that DMM-facilitated Trading Halt Auctions following a MWCB Halt provide the greatest opportunity for fair and orderly reopenings of securities, and would therefore continue to provide DMMs an opportunity to reopen securities before effectuating an Exchange-facilitated Trading Halt Auction. The proposal would provide the Exchange with another tool during volatile markets to reopen securities before 3:50 p.m., for continuous trading to resume leading into the close . . . . . The Exchange believes that specifying a time in the Rule at which the Exchange could exercise such discretion would put DMMs on notice of the time that the Exchange could begin facilitating such auctions. The Exchange further believes that it is not appropriate to provide that the Exchange would automatically facilitate reopening auctions at 3:30 p.m. There may be facts and circumstances where DMMs would be able to reopen all securities before 3:50 p.m., but that the DMM-facilitated process may not have completed by 3:30 p.m. The Exchange would take those facts and circumstances into account before invoking the proposed relief. Exchange staff would communicate with the impacted DMMs verbally on the Floor during such times, and therefore the DMMs would be on notice of whether the Exchange would invoke this relief, and for which securities.

The Exchange continues to believe that the ability for the Exchange to facilitate a Trading Halt Auction following a MWCB Halt if a security has not reopened by 3:30 p.m. would promote the fair and orderly reopening of one or more securities so that continuous trading may resume leading into the close. Accordingly, the Exchange proposes that the relief described above should be made a permanent part of Rule 7.35C. To effect this change, the Exchange proposes to amend 7.35C to add new subparagraph (a)(4) as follows, which is based on current Commentary .02 to Rule 7.35C without any substantive differences:

The CEO of the Exchange, or his or her designee, may determine that the Exchange will facilitate a Trading Halt Auction in one or more securities under this Rule if a security is subject to either a Level 1 or Level 2 trading halt due to extraordinary market volatility under Rule 7.12 (''MWCB Halt'') and has not reopened by 3:30 p.m. Eastern Time.

The Exchange further proposes to delete Commentary .02 to Rule 7.35C, which would be replaced by proposed Rule 7.35C(a)(4).

There are no technology changes associated with this proposed rule change and the Exchange would be able to implement it immediately upon approval of this proposed rule change.

Wider Auction Collars for a Trading Halt Auction Following a MWCB Halt

As noted above, as set forth in Commentary .01(a) to Rule 7.35C,[12] the Exchange also widened the Auction Collars for an Exchange-facilitated Trading Halt Auction following a MWCB Halt to the greater of $0.15 or 10% away from the Auction Reference Price. Absent this temporary relief, the Auction Collars for all Exchange-facilitated Trading Halt Auctions is the greater of $0.15 or 5% away from the Auction Reference Price.

As described in the First Rule 7.35C Filing, the widening of the Auction Collars was designed to provide the Exchange with more flexibility to respond to the then unprecedented market-wide declines that resulted from the ongoing spread of COVID–19 at that time if the Exchange were to facilitate a Trading Halt Auction following a MWCB Halt. The Exchange cannot predict if and when the U.S. equities market will experience market-wide declines that would trigger a MWCB Halt again. However, if such market-wide volatility were to occur, the Exchange believes that the widened Auction Collars would promote fair and orderly reopenings following a MWCB Halt by providing a wider price range at which the Exchange could facilitate such a reopening.

To effect this change, the Exchange proposes to amend Rule 7.35C(b)(3)(A)(ii) to provide as follows (proposed new text italicized), which is based on current Commentary .01 to Rule 7.35C without any substantive differences:

The Auction Collar for the Trading Halt Auction will be based on a price that is the greater of $0.15 or 5% away from the Auction Reference Price for the Trading Halt Auction, *provided that, the Auction Collar for a Trading Halt Auction following a MWCB Halt will be the greater of $0.15 or 10% away from the Auction Reference Price.*

The Exchange further proposes to delete Commentary .01 to Rule 7.35C, which would be replaced by the proposed amendment to Rule 7.35C(b)(3)(A)(ii).

There are no technology changes associated with this proposed rule change and the Exchange would be able to implement it immediately upon approval of this proposed rule change.

DMM Interest and Exchange-Facilitated Auctions

As set forth in Rule 7.35C(a)(1), if the Exchange facilitates an Auction, DMM Interest would not be eligible to participate in such Auction and previously-entered DMM Interest would be cancelled. When a DMM cannot facilitate an Auction because the DMM unit is experiencing a system issue that prevents it from communicating with Exchange systems, cancelling DMM Interest following an Exchange-facilitated Auction would help ensure that DMM Interest that may be at stale prices does not participate in trading on the Exchange. On the other hand, by cancelling DMM Interest when the DMM units' systems are operating normally, DMMs may be limited in their ability to maintain price continuity with reasonable depth, *i.e.,* provide passive liquidity at the Exchange best bid and offer and at depth, immediately following an Exchange-facilitated Auction.

After a period of operating Exchange-facilitated Auctions, the Exchange identified a way to provide DMMs with a greater opportunity to provide passive liquidity immediately following an Auction, thereby dampening volatility, while still limiting DMM risk. To effect this change, the Exchange added Commentary .03 to Rule 7.35C, which provides that for the temporary period that begins on April 6, 2020 and ends on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on December 31, 2020, if the Exchange facilitates an Auction, DMM Interest (i) will not be eligible to participate if such Auction

[11] *See* Second Rule 7.35C Filing, *supra* note 9.

[12] Commentary .01(a) to Rule 7.35C currently provides that: ''For a temporary period that begins March 23, 2020, when the Trading Floor facilities have been closed pursuant to Rule 7.1(c)(3), and ends on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on December 31, 2020: (a) The Auction Collar for a Trading Halt Auction following a either a Level 1 or Level 2 trading halt due to extraordinary market volatility under Rule 7.12 (''MWCB Halt'') will be the greater of $0.15 or 10% away from the Auction Reference Price.''

results in a trade, and will be eligible to participate if such Auction results in a quote, and (ii) will not be cancelled unless the limit price of such DMM Interest would be priced through the Auction Price or Auction Collars, as applicable, or such DMM Interest would be marketable against other unexecuted orders.[13]

The Exchange proposes to make permanent the changes to how Exchange-facilitated Auctions function, as described in Commentary .03 to Rule 7.35C. By making this functionality permanent, such rules would continue to apply both during the continuation of the current Trading Floor closure and if the Exchange were to facilitate Auctions any time after the Trading Floor fully reopens.

To effect this change, the Exchange proposes to amend 7.35C(a)(1) as follows (new text italicized, deleted text bracketed):

If the Exchange facilitates an Auction, DMM Interest will not be eligible to participate [in] *if* such Auction *results in a trade, and will be eligible to participate if such Auction results in a quote* [and previously-entered DMM Interest will be cancelled].

This proposed rule change would make permanent the temporary functionality set forth in paragraph (a)(1) to Commentary .03.

With this change, DMM Interest would not participate in any Exchange-facilitated Auctions that would result in a trade. This is how DMM Interest currently functions when the Exchange facilitates an Auction pursuant to either Rule 7.35C(a)(1) or Commentary .03 to Rule 7.35C. Based on experience operating pursuant to Commentary .03 to Rule 7.35C, the Exchange believes that this functionality should continue permanently when the Exchange facilitates an Auction, including, for example, when the Trading Floor is open but the DMM is unable to facilitate an Auction because of a systems or technical issue.

More specifically, when a DMM facilitates an Auction that results in a trade, the DMM determines whether to participate on the buy or sell side and, based on that direction from the DMM, DMM Orders that do not participate in the Auction and that would lock or cross other orders, which would include other DMM Orders, will be cancelled.[14] If the DMM has entered both buy and sell interest in advance of the Auction and the Exchange facilitates the Auction, the DMM would not be able to control whether the DMM's buy or sell interest would participate in a trade and the Exchange would not have that instruction from the DMM of which side of the market that the DMM would participate. As a result, there may be crossing DMM Interest that could result in a wash-sale trade that would not have occurred if the DMM had facilitated the Auction. Excluding DMM Interest from participating in an Exchange-facilitated Auction that results in a trade eliminates the potential for a wash-sale trade. In addition, the Exchange believes it promotes fair and orderly Exchange-facilitated Auctions that result in a trade to exclude DMM Interest from participating in such Auctions, because if a DMM's buy or sell interest does not reflect up-to-date prices, it could impact pricing of the Auction.

By contrast, the Exchange believes that the proposed change for DMM Interest to participate in an Exchange-facilitated Auction that results in a quote would promote fair and orderly markets. This proposed change is consistent with Commentary .03(a)(1) to Rule 7.35C, but differs from current Rule 7.35C(a)(1). A security opens on a quote if there is no buy interest willing to trade with sell interest at the same price. The Exchange believes that under such circumstances, including DMM Interest in the Exchange's quote would assist the DMMs in meeting their obligation to maintain a two-sided quote as well as to maintain continuity and depth in their assigned securities.[15] Accordingly, the Exchange believes that making this change permanent would promote fair and orderly markets in connection with Exchange-facilitated Auctions that result in a quote.

The final element of the proposed change to Rule 7.35C(a)(1) is that DMM Interest would no longer be automatically cancelled after an Exchange-facilitated Auction. The Exchange believes that this proposed change would assist DMMs in meeting their obligation, as required by Rule 104(f)(2), to provide passive liquidity in order to maintain continuity with reasonable depth in their assigned securities immediately following a Core Open Auction or Trading Halt Auction that was facilitated by the Exchange. In advance of an Auction, DMMs can enter DMM Orders, which if not traded in an Auction, would be part of the DMM Interest on the Exchange Book after the Auction. In addition, DMMs can enter DMM After-Auction Orders, which do not participate in Auctions and are specifically designed to assist the DMMs to maintain passive liquidity on the Exchange immediately following an Auction, which supports their ability to maintain continuity with reasonable depth immediately following an Auction. If DMM Interest is not automatically cancelled following an Exchange-facilitated Auction, the DMM would be better able to timely meet these obligations by ensuring that passive liquidity remains on the Exchange Book immediately following an Auction.

The Exchange believes that there remain circumstances when DMM Interest should be cancelled following an Exchange-facilitated Auction. As proposed, the Exchange would cancel unexecuted DMM Interest under the same circumstances that unexecuted orders of other member organizations would be cancelled following such Auctions.

To effect this change, the Exchange proposes to amend Rule 7.35C(g)(1), which currently describes which unexecuted orders would be cancelled if a security opens or reopens on a trade via an Exchange-facilitated Auction, and Rule 7.35C(g)(2), which currently describes which unexecuted orders would be cancelled if a security opens or reopens on a quote that is above (below) the upper (lower) Auction Collar via an Exchange-facilitated Auction. The Exchange proposes that these two subparagraphs would be replaced with the following text to incorporate that under the same circumstances, DMM Interest would similarly be cancelled (proposed new text italicized):

(1) If a security opens or reopens on a trade, Market Orders (including sell short Market Orders during a Short Sale Period) and Limit Orders, *including DMM Interest,* with a limit price that is better-priced than the Auction Price and were not executed in the applicable Auction will be cancelled.

(2) If a security opens or reopens on a quote that is above (below) the upper (lower) Auction Collar, Market Orders (including sell short Market Orders during a Short Sale Period) and Limit Orders, *including DMM Interest,* with a limit price that is better-priced than the upper (lower) Auction Collar will be cancelled before such quote is published.

These proposed rule changes would make permanent the temporary functionality set forth in paragraphs (b)(1) and (2) to Commentary .03.

The Exchange further believes that if previously-entered DMM Interest would be marketable against either other DMM Interest or contra-side unexecuted

[13] *See* DMM Interest Filing, *supra* note 9.

[14] *See* Rule 7.35A(h)(3)(C) (providing that after a Core Open or Trading Halt Auction, better at-priced DMM Orders that do not receive an allocation and that lock or cross other unexecuted orders and buy and sell better-priced DMM Orders will be cancelled after the Auction Processing Period concludes).

[15] *See* Rule 104(f)(2).

orders, such DMM Interest should be cancelled. For example, if for a security, the Auction Reference Price is $10.00, the lower Auction Collar is $9.00 and the upper Auction Collar is $11.00, and the orders on the Exchange Book in advance of the Auction are as follows:

- Order 1—Buy DMM Order 1000 shares at $10.05
- Order 2—Sell DMM Order 1000 shares at $10.00
- Order 3—Buy DMM Order 1000 shares at $10.02
- Order 4—Sell Limit Order at $10.03,

the orders in this example would be processed as follows in an Exchange-facilitated Auction:

- Order 1 would be cancelled (because DMM Interest would not be eligible to participate in an Auction trade, and here, Order 1 is marketable with Orders 2 and 4).
- Order 2 would be cancelled (because DMM Interest would not be eligible to participate in an Auction trade, and here Order 2 is marketable with Order 3), and
- Order 3 would not be cancelled because it is no longer marketable with any other interest, *i.e.,* it no longer locks or crosses the price of any other contra-side interest in the Exchange Book. Order 3 would therefore be included in the opening quote.

This Exchange-facilitated Auction would result in the following quote: $10.02 (Order 3—DMM Order) × $10.03 (Order 4—Limit Order).

To effect this change, the Exchange proposes new subparagraph (g)(3) to Rule 7.35C to specify the additional circumstances when DMM Interest would be cancelled, as follows:

> The Exchange will cancel DMM Interest that is marketable against contra-side unexecuted orders. If the contra-side unexecuted order against which such DMM Interest is marketable is DMM Interest, the DMM Interest with the earlier working time will be canceled.

This proposed rule change would make permanent the temporary functionality set forth in paragraph (b)(3) to Commentary .03.

The Exchange believes that these proposed rule changes would promote fair and orderly markets whenever the Exchange facilitates an Auction under Rule 7.35C—under any circumstance—by supporting DMMs in maintaining continuity with reasonable depth in their assigned securities immediately following an Exchange-facilitated Core Open Auction or Trading Halt Auction that was facilitated by the Exchange.

The Exchange proposes that, with these proposed changes to Rules 7.35C(a)(1) and (g), Commentary .03 to Rule 7.35C would be deleted in its entirety.

In further support of making the functionality set forth in Commentary .03 to Rule 7.35C permanent, the Exchange notes that after the Exchange implemented that Commentary, the Exchange observed improved performance relating to Exchange-facilitated Auctions.

- For the period March 23, 2020 to April 3, 2020, 4.9% of all Core Open Auctions were facilitated by the Exchange. For the period April 6, 2020 through June 16, 2020, the Exchange facilitated only 2% of all Core Open Auctions. In addition, the percentage of Exchange-facilitated Core Open Auctions that were bound by an Auction Collar decreased from 1.3% from the pre-April 6, 2020 period, to 0.58% in the April 6, 2020–June 16, 2020 period.
- In addition, the Exchange observed that after April 6, 2020, Exchange-listed securities experienced reduced volatility in the first half hour of trading. The Exchange uses a quote-based metric to measure volatility in securities,[16] and based on that metric, volatility in Exchange-listed securities between the period of April 6, 2020 and June 16, 2020 was 28.4% lower than the same measure between March 23, 2020 and April 3, 2020. In addition, the Exchange further observed that between these two periods, the difference between the Core Open Auction Price and the subsequent five-minute VWAP dropped by 31.3%.

For DMM firms that have already returned staff to the Trading Floor, this proposed change has limited application because the Exchange has not facilitated any Auctions on behalf of those firms since June 16, 2020. In addition, the Exchange anticipates that once the Trading Floor facilities open in full to DMMs, and all DMM firms have staffing on the Trading Floor, the need for Exchange-facilitated Auctions would be obviated, and the Exchange will revert to pre-pandemic rates of Exchange-facilitated Auctions, which were none. Accordingly, the proposed changes to Rule 7.35C will likely have limited application and would be available as a business continuity functionality should DMMs be unable to facilitate an Auction in one or more securities, for any reason.

There are no technology changes associated with this proposed rule change and the Exchange would be able to implement it immediately upon approval of this proposed rule change.

Updated Auction Reference Price for Exchange-Facilitated Core Open Auctions

For Exchange-facilitated Auctions, the Exchange determines an Auction Price based on the Indicative Match Price for a security, which is bound by Auction Collars.[17] Rule 7.35C(b)(1) specifies the Auction Reference Price that is used for determining Auction Collars for Exchange-facilitated Core Open Auctions, which is the Imbalance Reference Price, as determined under Rule 7.35A(e)(3).[18] Currently, the Auction Collars for the Core Open Auction are at a price that is the greater of $0.15 or 10% away from the Auction Reference Price.

On June 4, 2020, the Exchange added Commentary .04 to Rule 7.35C to provide that the Auction Collars for Exchange-facilitated Core Open Auctions would be the greater of $1.00 or 10% away from the Auction Reference Price.[19] The Exchange added this Commentary to reduce the number of securities subject to a collared Exchange-facilitated Core Open Auction.[20] The Exchange observed that

[16] As described in an Exchange blog post, this metric is calculated using second-to-second ''quote returns,'' which is calculated by averaging the midpoints of all NBBO updates for a security within each second of the day from 9:35 a.m. to 4:00 p.m., and then calculating the percentage rate of return of these average quote midpoints from one second to the next. The variance of returns are then calculated in aggregated time periods (*e.g.,* 5-minute buckets) and annualized from seconds to 6.5 hour trading days to 252 trading days in the years. Finally, the Exchange takes the square root of the annualized variance in the aggregated periods, which creates the Exchange's quote volatility metric. *See* NYSE Data Insights, Introducing Quote Volatility (QV)—a new metric to measure price volatility, available here: *https://www.nyse.com/data-insights/introducing-quote-volatility-qv-a-new-metric-to-measure-price-volatility.*

[17] *See* Rule 7.35C(b)(2).

[18] *See* Rule 7.35C(b)(3)(A)(i). Pursuant to Rule 7.35A(e)(3), the Imbalance Reference Price for a Core Open Auction is the Consolidated Last Sale Price, unless a pre-opening indication has been published. Pursuant to Rule 7.35(a)(11)(A), the term ''Consolidated Last Sale Price'' means the most recent consolidated last-sale eligible trade in a security during Core Trading Hours on that trading day, and if none, the Official Closing Price from the prior trading day for that security.

[19] *See* Fourth Rule 7.35C Filing, *supra* note 9. Commentary .04 is in effect for a temporary period that began on June 4, 2020 and ends on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on December 31, 2020.

[20] In the Fourth Rule 7.35C Filing, *id.,* the Exchange explained that for the period while the Trading Floor had been temporarily closed preceding that filing, the Exchange had facilitated 2.35% of the Core Open Auctions and that approximately 30% of the Exchange-facilitated Core Open Auctions had an Indicative Match Price that was subject to an Auction Collar, and approximately 50% of these collared Exchange-facilitated Core Open Auctions were in securities trading at prices under $10.00. The Exchange further noted that if Auction Collars had not been

from June 4, 2020 up to June 17, 2020, when DMMs returned staff to the Trading Floor,[21] even with the widened Auction Collars, if there were significant overnight market-wide volatility, Exchange-facilitated Core Open Auctions had a greater likelihood of being subject to an Auction Collar. For example, for that same June 4–June 16 period, when the price of the SPDR S&P 500 ETF Trust (''SPY'')[22] moved over 1% from the prior day's close, 1.4% of the Exchange-facilitated Core Open Auctions were subject to an Auction Collar, as compared to only .5% of the Exchange-facilitated Core Open Auctions being subject to an Auction Collar when SPY moved less than 1% from the prior day's close.

The Exchange believes that adjusting the Auction Reference Price to align more closely with the anticipated price of the Core Open Auction, rather than widening the Auction Collars, would reduce the potential for an Exchange-facilitated Core Open Auction to be subject to an Auction Collar on all trading days, including when there is significant overnight market-wide volatility. Accordingly, rather than providing for a wider Auction Collar, as set forth in Commentary .04 to Rule 7.35C, the Exchange proposes to amend Rule 7.35C to update how the Auction Reference Price for Exchange-facilitated Core Open Auctions would be determined. Specifically, the Exchange proposes to determine Auction Reference Prices for Exchange-facilitated Core Open Auctions in the same manner that the Exchange's affiliates, NYSE Arca, Inc. (''NYSE Arca'') and NYSE American LLC (''NYSE American''), determine the Auction Reference Price for their electronic Core Open Auctions.

NYSE Arca Rule 7.35–E(a)(8)(A) and NYSE American Rule 7.35E(a)(8)(A) both provide that the Auction Reference Price for Core Open Auctions on those exchanges is, ''[t]he midpoint of the Auction NBBO or, if the Auction NBBO is locked, the locked price. If there is no Auction NBBO, the prior day's Official Closing Price.'' The NYSE Arca and NYSE American rules define the term ''Auction NBBO'' to mean:

> An NBBO that is used for purposes of pricing an auction. An NBBO is an Auction NBBO when (i) there is an NBB above zero and NBO for the security and (ii) the NBBO is not crossed. In addition, for the Core Open Auction, an NBBO is an Auction NBBO when the midpoint of the NBBO when multiplied by a designated percentage, is greater than or equal to the spread of that NBBO. The designated percentage will be determined by the Exchange from time to time upon prior notice to ETP Holders.[23]

The Exchange proposes to amend Rule 7.35C(b)(1) to provide that the Auction Reference Price for an Exchange-facilitated Core Open Auction would be: ''The midpoint of the Auction NBBO or, if the Auction NBBO is locked, the locked price. If there is no Auction NBBO, the Official Closing Price from the prior trading day.'' This rule text is based on NYSE Arca Rule 7.35–E(a)(8)(A) and NYSE American Rule 7.35E(a)(8)(A) without any differences.

The Exchange further proposes to amend Rule 7.35(a) to add a definition for the term ''Auction NBBO,'' which would similarly be based on the definition of that term in the NYSE Arca and NYSE American rules without any substantive differences, as follows:

> ''Auction NBBO'' means an NBBO that is used for purposes of pricing an auction. An NBBO is an Auction NBBO when (i) there is an NBB above zero and NBO for the security and (ii) the NBBO is not crossed. In addition, for the Core Open Auction, an NBBO is an Auction NBBO when the midpoint of the NBBO when multiplied by a designated percentage, is greater than or equal to the spread of that NBBO. The designated percentage will be determined by the Exchange from time to time upon prior notice to member organizations.

The Exchange proposes to add the term ''Auction NBBO'' as Rule 7.35(a)(5) and make non-substantive changes to renumber the definitions currently set forth in Rules 7.35(a)(5)–(12) as Rules 7.35(a)(6)–(13).

Because there are technology changes associated with this proposed rule change, the Exchange proposes to announce the implementation date of this change by Trader Update. The Exchange anticipates that the Exchange will implement this technology change in the first quarter of 2021.

To provide continuity, the Exchange further proposes to amend Commentary .04 to Rule 7.35C to provide that such Commentary would end on the earlier of when the Exchange implements its technology change to use the midpoint of the Auction NBBO as the Auction Reference Price for the Core Open Auction or after the Exchange closes on December 31, 2020. With this proposed rule change, the widened Auction Collars specified in that Commentary would continue to be operative until such time that the proposed changes to the Auction Reference Price for Exchange-facilitated Core Open Auctions have been approved and implemented.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[24] in general, and furthers the objectives of Section 6(b)(5) of the Act,[25] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the rules that it added on a temporary basis to Rule 7.35C have supported the fair and orderly operation of the Exchange during both the market volatility associated with COVID–19 and the temporary period that the Trading Floor facilities have been closed either in full or in part due to COVID–19. The Exchange further believes the functionality that has been operating on a temporary basis would continue to support the fair and orderly operation of the Exchange under any circumstances where there may be either market-wide volatility or the need for the Exchange to facilitate one or more Auctions.

Exchange Authority To Facilitate a Trading Halt Auction Following a MWCB Halt

The Exchange believes that it would remove impediments to and perfect the mechanism of a free and open market and a national market system to provide the Exchange with authority to facilitate a Trading Halt Auction following a MWCB Halt. The Exchange continues to believe that DMM-facilitated Trading Halt Auctions following a MWCB Halt provide the greatest opportunity for fair and orderly reopenings of securities, and would therefore continue to provide DMMs an opportunity to reopen securities before effectuating an Exchange-facilitated Trading Halt Auction. The proposal would provide the Exchange with another tool during volatile markets to reopen securities before 3:50 p.m. so that continuous

applied to these securities priced under $10.00, they would have opened at a price between $0.15 and $1.00 away from the Auction Reference Price.

[21] As noted above, the Exchange has not facilitated any Auctions for any of the DMM firms that have returned staff to the Trading Floor.

[22] Because SPY is priced based on the securities included in the S&P 500 Index, the Exchange believes that SPY's price as compared to its prior day's closing price is indicative of the scope of market-wide volatility leading into the open of the Core Trading Session.

[23] *See* NYSE Arca Rule 7.35–E(a)(5) and NYSE American Rule 7.35E(a)(5).

[24] 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78f(b)(5).

trading may resume before leading into the close. The Exchange further believes that it is not appropriate to provide that the Exchange would automatically facilitate reopening auctions at 3:30 p.m. There may be facts and circumstances where DMMs would be able to reopen all securities before 3:50 p.m., but that the DMM-facilitated process may not have completed by 3:30 p.m. The Exchange would take those facts and circumstances into account before invoking the proposed relief.

Wider Auction Collars for a Trading Halt Auction Following a MWCB Halt

The Exchange believes that it would remove impediments to and perfect the mechanism of a free and open market and a national market system to widen the Auction Collars for an Exchange-facilitated Trading Halt Auction following a MWCB Halt. Such widened Auction Collars would provide the Exchange with more flexibility to respond to any market-wide declines that may continue following a MWCB Halt if the Exchange were to facilitate a Trading Halt Auction following such halt. The Exchange cannot predict if and when the U.S. equities market will experience market-wide declines that would trigger a MWCB Halt again. However, if such market-wide volatility were to occur, the Exchange believes that the widened Auction Collars would promote fair and orderly reopenings following a MWCB Halt by providing a wider price range at which the Exchange could facilitate such a reopening, thereby allowing more buy and sell interest to participate in such Auction.

DMM Interest and Exchange-Facilitated Auctions

As noted above, beginning March 19, 2020, the Exchange began facilitating auctions as provided for under Rule 7.35C for the first time, and then, beginning March 23, 2020, when the Trading Floor was temporarily closed to reduce the spread of COVID–19, began facilitating Auctions on behalf of all DMM firms. Based on that experience, the Exchange added Commentary .03 to Rule 7.35C, which is in effect only for a temporary period while the Trading Floor is closed. The Exchange believes that it would remove impediments to and perfect the mechanism of a free and open market and a national market system to make the changes described in Commentary .03 to Rule 7.35C permanent because it would allow DMMs to maintain continuity with reasonable depth in their assigned securities immediately following an Exchange-facilitated Auction.

As described above, the Exchange is proposing that DMM Interest would continue to not participate in an Exchange-facilitated Auction that results in a trade. As noted above, under both the current Rule and temporary Commentary .03, DMM Interest does not participate in an Exchange-facilitated Auction that results in a trade in part to prevent wash-trade sales of previously-entered DMM buy and sell interest and therefore reduces DMM units' risk. It also protects the fair and orderly operation of such Auctions because such DMM Interest may be at stale prices, and therefore could impact pricing of the Auction in a manner that does not reflect up-to-date trading interest. For this reason, the Exchange believes it would continue to promote fair and orderly Auctions for DMM Interest not to participate in an Exchange-facilitated Auction that results in a trade.

By contrast, the Exchange believes that the proposed change that DMM Interest would be included in an Exchange-facilitated Auction that results in a quote would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would promote fair and orderly resumption of trading by allowing DMM Interest to be considered as part of the opening quote. A security only opens on a quote when there are no buy and sell orders that can be crossed at a single price. Accordingly, when a security opens on a quote, the DMM has an immediate obligation to maintain a two-sided quote and to provide continuity and depth. Including DMM interest in an Exchange-facilitated Auction that results in a quote would assist DMMs in meeting those obligations.

The Exchange believes it would remove impediments to and perfect the mechanism of a free and open market and a national market system not to automatically cancel DMM Interest following an Exchange-facilitated Auction because it would provide DMMs with the opportunity to provide passive liquidity immediately following an Exchange-facilitated Auction, thereby reducing volatility while still limiting DMM risk. Similarly, the Exchange believes that because DMM Interest would not be participating in an Exchange-facilitated Auction that results in a trade, it would remove impediments to and perfect the mechanism of a free and open market and a national market system to cancel DMM Interest that would be marketable against unexecuted orders because, if not cancelled, such interest could trade at a price that would not be consistent with the Auction Price or opening or reopening quote determined in the Exchange-facilitated Auction. The proposed changes would also remove impediments to and perfect the mechanism of a free and open market because DMM Interest that, following an Exchange-facilitated Auction, would be priced through the Auction Price or Auction Collars, as applicable, would be cancelled in the same manner that other unexecuted orders would be cancelled.

The Exchange further believes that the proposed changes to Rules 7.35C(a) and (g) would remove impediments to and perfect the mechanism of a free and open market and a national market system because the Exchange observed improved performance following Exchange-facilitated Auctions after the Exchange implemented Commentary .03 to Rule 7.35C. Accordingly, should circumstances ever arise again that would require the Exchange to facilitate any Auctions, which, based on pre-pandemic experience, would likely be rare, the Exchange believes that these proposed changes would improve the performance of Exchange-facilitated Auctions by enabling better engagement by the DMMs in both the Auction and the immediate after-market while still limiting DMM risk.

Updated Auction Reference Price for Exchange-Facilitated Core Open Auctions

The Exchange believes that the proposal to change the Auction Reference Price for Exchange-facilitated Core Open Auctions would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would reduce the potential number of securities that would be subject to a collared Exchange-facilitated Core Open Auction, including when there is significant overnight market-wide volatility. Commentary .04 to Rule 7.35C sought to achieve this goal by widening the Auction Collars, but as noted above, these temporary widened Auction Collars would not prevent an Exchange-facilitated Core Open Auction from being subject to an Auction Collar when there has been significant overnight market-wide volatility. The Exchange believes that aligning the Auction Reference Price more closely with the anticipated opening price by using the midpoint of the Auction NBBO as the Auction Reference Price (or Official Closing Price of the prior Trading Day if no Auction NBBO) would reduce the potential for an Exchange-facilitated Core Open Action to be subject to an Auction Collar on all trading days, including when there is

significant overnight market-wide volatility. The Exchange further believes that this proposed rule change would reduce the potential number of securities that would open at a price that may not represent the current value of the security due to unfilled marketable auction interest, while still preserving investor protections by preventing significantly dislocated openings. This proposed rule change would therefore promote the fair and orderly operation of Exchange-facilitated Core Open Auctions by allowing such securities to open at a price that is consistent with the buy and sell interest in the security, which would also allow more buy and sell interest to participate in such Auction.

The Exchange notes that this proposed change is not novel and is based on how NYSE Arca and NYSE American determine the Auction Reference Price for their respective electronic Core Open Auctions. Accordingly, this proposed change would align how Auction Reference Prices are determined for electronic Exchange-facilitated Auctions across NYSE, NYSE Arca, and NYSE American.

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 proposed rule change is not designed to address any competitive issues but rather would make permanent the Exchange's temporary Commentaries .01–.03 to Rule 7.35C, which have been in effect for a temporary period while the Trading Floor is temporarily closed due to COVID–19. This proposed rule change is designed to provide the Exchange with additional tools for when it facilitates an Auction, including by allowing for an Exchange-facilitated Trading Halt Auction following a MWCB Halt so that a security can be reopened before leading into the close, providing the DMMs with additional functionality to allow them to maintain price continuity with reasonable depth in their assigned securities following an Exchange-facilitated Auction, and aligning the Auction Reference Price for an Exchange-facilitated Core Open Auction with the Auction Reference Price used for NYSE Arca and NYSE American electronic Core Open Auctions. More specifically, the proposed rule change does not implicate any intramarket competition concerns because the only market participants on the Exchange with the obligation to facilitate Auctions are DMMs, and all DMMs would be subject to this rule change. The proposed rule change does not implicate any intermarket competition concerns because it relates to how the Exchange would facilitate Auctions in Exchange-listed securities.

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

Within 45 days of the date of publication of this notice in the **Federal Register**, or 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 self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the 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–NYSE–2020–89 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–2020–89. 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–2020–89, and should be submitted on or before December 3, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24986 Filed 11–10–20; 8:45 am]

BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Advisers Act Release No. 5624/803–00252]

Arena Holdings Management LLC

November 5, 2020.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an exemptive order under Section 202(a)(11)(H) of the Investment Advisers Act of 1940 (''Advisers Act'').

Applicant: Arena Holdings Management LLC (the ''Applicant'').

Relevant Advisers Act Sections: Exemption requested under Section 202(a)(11)(H) of the Advisers Act from Section 202(a)(11) of the Advisers Act.

Summary of Application: The Applicant requests that the Commission issue an order declaring it to be a person not within the intent of Section 202(a)(11) of the Advisers Act, which defines the term ''investment adviser.''

Filing Dates: The application was filed on November 13, 2019 and amended on August 4, 2020.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on November 30, 2020, and should be accompanied by proof of service on Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicant: Arena Holdings Management LLC, *jbergman@brickpatel.com.*

FOR FURTHER INFORMATION CONTACT: Asaf Barouk, Attorney-Adviser, at 202–551–4029 or Parisa Haghshenas, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website either at *http://www.sec.gov/rules/iareleases.shtml* or by calling (202) 551–8090.

Applicant's Representations

1. The Applicant is a multi-generational, single-family office that provides or intends to provide services to the family and descendants of Roopa Dewan. The Applicant is wholly owned by Family Clients and is exclusively controlled (directly and indirectly) by one or more Family Members and/or Family Entities in compliance with Rule 202(a)(11)(G)–1 (the ''Family Office Rule''). For purposes of the application, the term ''Dewan Family'' means the lineal descendants of Roopa Dewan, their spouses or spousal equivalents, and all other persons and entities that qualify as ''Family Clients'' as defined in paragraph (d)(4) of the Family Office Rule. Unless otherwise indicated, capitalized terms herein have the same meaning as defined in the Family Office Rule.

2. The Applicant provides both advisory and non-advisory services (collectively, the ''Services'') to members of the Dewan Family. Any Service provided by the Applicant that relates to investment advice about securities or may otherwise be construed as advisory in nature is considered an ''Advisory Service.''

3. The Applicant represents that: (i) Each of the persons served by the Applicant is a Family Client (*i.e.,* the Applicant has no investment advisory clients other than Family Clients as required by paragraph (b)(1) of the Family Office Rule); (ii) the Applicant is owned and controlled in a manner that complies in all respects with paragraph (b)(2) of the Family Office Rule; and (iii) the Applicant does not hold itself out to the public as an investment adviser as required by paragraph (b)(3) of the Family Office Rule. At the time of this Application, Applicant provides Advisory Services solely to Family Clients, including primarily to pooled investment vehicles that are wholly owned, directly or indirectly, by one or more natural persons that are Family Clients and operated for the sole benefit of those clients.

4. In addition to the Family Clients, the Applicant desires to provide Services (including Advisory Services) to the siblings of a spouse of a lineal descendant of Roopa Dewan (which descendant is the founder and Chief Executive Officer of Applicant) and their spouses and descendants (the ''Additional Family Clients'').

5. The Additional Family Clients do not have an ownership interest in the Applicant. The Applicant represents that the assets beneficially owned by Family Members and/or Family Entities (excluding the Additional Family Clients) would make up at least 95% of the total assets for which the Applicant provides Advisory Services.

6. The Applicant represents that the Additional Family Clients have important familial ties to and are an integral part of the Dewan Family. The Applicant maintains that including the Additional Family Clients into the definition of ''family'' for this purpose simply recognizes and memorializes the familial ties and intra-familial relationships that already exist, and have existed for at least 25 years and that the inclusion of the Additional Family Clients as members of the Dewan Family for which the Applicant may provide Services would be consistent with the existing familial relationship among the family members.

The Applicant's Legal Analysis

1. Section 202(a)(11) of the Advisers Act defines the term ''investment adviser'' to mean ''any person who, for compensation, engages in the business of advising others, either directly or through publications or writings, as to the value of securities or as to the advisability of investing in, purchasing, or selling securities, or who, for compensation and as part of a regular business, issues or promulgates analyses or reports concerning securities . . .''

2. The Applicant falls within the definition of an investment adviser under Section 202(a)(11). The Family Office Rule provides an exclusion from the definition of investment adviser for which the Applicant is currently eligible but would no longer qualify if the Applicant provides Services to the Additional Family Clients. Because the Applicant has regulatory assets under management of more than $100 million, it is not prohibited from registering with the Commission under Section 203A(a) of the Advisers Act. In sum, absent relief, if the Applicant opted to render Services to the Additional Family Clients, the Applicant would be required to register under Section 203(a) of the Advisers Act, notwithstanding that (i) the Applicant does not hold itself out to the public as an investment adviser and does not market non-public offerings to persons or entities that are not Family Clients, (ii) the Applicant is wholly owned by Family Clients and controlled by Feroz Dewan who is a member of the Dewan Family, in accordance with paragraph (b)(2) of the Family Office Rule; and (iii) the Applicant is a ''family office'' for the Dewan Family and will not offer its Advisory Services to anyone other than Family Clients and the Additional Family Clients.

3. The Applicant submits that its proposed relationship with the Additional Family Clients does not change the nature of the office into that of a commercial advisory firm. In addition, the Applicant notes that if the siblings of Mrs. Dewan were the siblings of a lineal descendant, rather than the siblings of a spouse of a lineal descendant, there would be no question that each of them would be a Family Member, and their retirement assets would similarly fall within the definition of Family Client. The Applicant states that in requesting the order, the Applicant is not attempting to expand its operations or engage in any level of commercial activity to which the Advisers Act is designed to apply. There would only be two natural persons and their spouses and

descendants who are not Family Members to whom the Applicant would provide Advisory Services if relief were granted. The Applicant estimates that if the Additional Family Clients' assets were managed by the Applicant, the assets owned by the Additional Family Clients would represent less than five percent (5%) of the Applicant's assets under management. From the perspective of the Dewan Family, allowing the Applicant to provide Services to the Additional Family Clients is consistent with the existing familial relationship among family members.

4. The Applicant also submits that there is no public interest in requiring the Applicant to be registered under the Advisers Act. The Applicant states that the office is a private organization that was formed to be the ''family office'' for the Dewan Family and that the office does not have any public clients. The Applicant maintains that the office's Advisory Services are exclusively tailored to the needs of the Extended Dewan Family. The Applicant argues that the provision of Advisory Services to the Additional Family Clients, does not create any public interest that would require the office to be registered under the Advisers Act that is different in any manner than the considerations that apply to a ''family office'' that complies in all respects with the Family Office Rule.

5. The Applicant argues that although the Family Office Rule largely codified the exemptive orders that the Commission had previously issued before the enactment of the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Commission recognized in proposing the rule that the exact representations, conditions, or terms contained in every exemptive order could not be captured in a rule of general applicability. The Commission noted that family offices would remain free to seek a Commission exemptive order to advise an individual or entity that did not meet the proposed family client definition, and that certain issues would be more appropriately addressed through an exemptive order process where the Commission can consider the specific facts and circumstances, than through a rule of general applicability.

6. The Applicant maintains that, based on its circumstances—desiring to provide Advisory Services to certain Additional Family Clients who are relatives that have been considered and treated as family members for twenty-five (25) years and whose status as clients of the office would not change the nature of the office's operations to that of a commercial advisory business—an exemptive order is appropriate based on the Applicant's specific facts and circumstances.

7. For the foregoing reasons, the Applicant requests an order declaring it to be a person not within the intent of Section 202(a)(11) of the Advisers Act. The Applicant submits that the order is necessary and appropriate, in the public interest, consistent with the protection of investors, and consistent with the purposes fairly intended by the policy and provisions of the Advisers Act.

The Applicant's Conditions

1. The Applicant will offer and provide Advisory Services only to Family Clients and to the Additional Family Clients, who generally will be deemed to be, and be treated as if they were, Family Clients; provided, however, that the Additional Family Clients will be deemed to be, and treated as if they were, Family Members for purposes of paragraph (b)(1) and for purposes of paragraph (d)(4)(vi) of the Family Office Rule.

2. The Applicant will at all times be wholly owned by Family Clients and exclusively controlled (directly or indirectly) by one or more Family Members and/or Family Entities (excluding the Additional Family Clients' Family Entities) as defined in paragraph (d)(5) of the Family Office Rule.

3. At all times the assets beneficially owned by Family Members and/or Family Entities (excluding the Additional Family Clients' Family Entities), will account for at least 95% of the assets for which the Applicant provides Advisory Services.

4. The Applicant will comply with all the terms for exclusion from the definition of investment adviser under the Advisers Act set forth in the Family Office Rule except for the limited exception requested by this Application.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24956 Filed 11–10–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90368; File No. SR–DTC–2020–801]

Self-Regulatory Organizations; The Depository Trust Company; Notice of No Objection To Advance Notice To Amend Rule 4

November 6, 2020.

On September 9, 2020, The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') advance notice SR–DTC–2020–801 (''Advance Notice'') 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'') [3] to amend Rule 4 of the Rules, By-Laws and Organization Certificate of DTC (the ''Rules''). The Advance Notice was published for comment in the **Federal Register** on October 20, 2020,[4] and the Commission has not received comments regarding the changes proposed in the Advance Notice. This publication serves as notice of no objection to the Advance Notice.

I. The Advance Notice

A. Background

DTC is the central securities depository (''CSD'') for substantially all corporate and municipal debt and equity securities available for trading in the United States.[5] As a covered clearing agency that provides CSD services,[6] DTC provides a central

[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] Securities Exchange Act Release No. 90169 (October 14, 2020), 85 FR 66666 (October 20, 2020) (SR–DTC–2020–801) (''Notice of Filing'').

[5] Each capitalized term not otherwise defined herein has its respective meaning as set forth in DTC's rules, including, but not limited to, the Rules, By-Laws and Organization Certificate of DTC (the ''Rules'') and the DTC Settlement Service Guide (the ''Settlement Guide''), available at *http://www.dtcc.com/legal/rules-and-procedures.aspx.* The Settlement Guide is a Procedure of DTC filed with the Commission that, among other things, operationalizes and supplements the DTC Rules that relate to settlement.

[6] A covered clearing agency is defined as a registered clearing agency that provides the services of a central counterparty (''CCP'') or CSD. *See* 17 CFR 240.17Ad–22(a)(5). CSD services means services of a clearing agency that is a securities depository as described in Section 3(a)(23)(A) of the Exchange Act. *See* 17 CFR 240.17Ad–22(a)(3). Specifically, the definition of a clearing agency includes, in part, ''any person, such as a securities depository that (i) acts as a custodian of securities

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location in which securities may be immobilized, and interests in those securities are reflected in accounts maintained for its Participants, which are financial institutions such as brokers or banks.[7] DTC does not provide central counterparty services and therefore does not become party to its Participants' transactions or guarantee settlement on behalf of its Participants.[8]

DTC provides settlement services for virtually all broker-to-broker equity and listed corporate and municipal debt securities transactions in the U.S., as well as institutional trades, money market instruments and other financial obligations. For end-of-day net funds settlement, the DTC settlement system records money debits and credits to Participant settlement accounts throughout a Business Day.[9] At the end of a Business Day, a Participant's settlement account will have a net debit (*i.e.,* the sum of all money charges to a Participant's account exceeds the sum of all money credits), net credit (*i.e.,* the sum of all money credits to a Participant's account exceeds the sum of all money charges), or zero balance. This final balance will determine whether the Participant has an obligation to pay or to be paid as part of the process of DTC completing settlement on that Business Day. A Participant that fails to pay its net debit balance and therefore defaults on its settlement obligations on a Business Day will not have paid for the securities processed for delivery versus payment, and the securities will not be credited to its account.

DTC represents that there may be circumstances in which the amount of settlement payments received or available to DTC on a Business Day is not sufficient to pay all Participants with an end-of-day net credit balance on that Business Day (a ''settlement gap'').[10] A settlement gap could occur on a Business Day as a result of a Participant Default, where a Participant fails to pay its settlement obligation (a ''default gap''). A settlement gap could also occur on a Business Day as a result of causes other than a Participant Default (a ''non-default gap''). Examples of a non-default gap could include a scenario in which the funds required to complete settlement are not available to DTC due to an operational or data issue arising at DTC or at a Participant or Settling Bank, a cyber incident, or other business disruption.[11] According to DTC, its failure to complete settlement on a given Business day could cause significant market-wide effects.[12]

B. The Participants Fund and Rule 4

The Participants Fund is prefunded and represents the aggregate of the deposits that each DTC Participant is required to make under DTC's Rules.[13] The Rules provide for a minimum deposit to the Participants Fund, and Participants with higher levels of activity that impose greater liquidity risk to the DTC settlement system have proportionally larger required deposits.[14] DTC has stated that the Participants Fund is a mutualized pre-funded liquidity and loss resource, and that DTC does not have an obligation to repay the Participants Fund and the application of the Participants Fund does not convert to a loss.[15] Once DTC applies the Participants Fund, the Participants are required, upon the demand of DTC, to replenish their shares of the Participants Fund to satisfy their minimum deposits.[16] DTC further represents that the principal purpose of the Participants Fund is to be one of the foundational liquidity resources available to DTC to fund a shortfall in order to complete settlement on a Business Day.[17]

Currently, Section 4 of Rule 4 provides that, if there is a Defaulting Participant and the amount charged to the Actual Participants Fund Deposit of the Defaulting Participant pursuant to Section 3 of Rule 4 [18] is not sufficient to complete settlement, DTC may apply the Actual Participants Fund Deposits of Participants other than the Defaulting Participant (each, a ''non-defaulting Participant''), and apply such other liquidity resources as may be available to DTC, including, but not limited to, the End-of-Day Credit Facility.[19] DTC recognizes that currently, certain provisions of Rule 4 might be construed to narrow the scope of use of the Participants Fund (and any other liquidity resources) for settlement to a

in connection with a system for the central handling of securities whereby all securities of a particular class or series of any issuer deposited within the system are treated as fungible and may be transferred, loaned, or pledged by bookkeeping entry without physical delivery of securities certificates, or (ii) otherwise permits or facilitates the settlement of securities transactions or the hypothecation or lending of securities without physical delivery of securities certificates.'' 15 U.S.C. 78c(a)(23)(A).

[7] *See, e.g.,* Securities Exchange Act Release No. 20221 (September 23, 1983), 48 FR 45167, 45168 (October 3, 1983) (File No. 600–1) (''A securities depository is a ''custodial'' clearing agency that operates a centralized system for the handling of securities certificates. Depositories accept deposits of securities from broker-dealers, banks, and other financial institutions; credit those securities to the depositing participants *(sic)* accounts; and, pursuant to participant's *(sic)* instructions, effect book-entry movements of securities. The physical securities deposited with a depository are held in a fungible bulk; each participant or pledgee having an interest in securities of a given issue credited to its account has a pro rata interest in the physical securities of the issue held in custody by the securities depository in its nominee name. Depositories collect and pay dividends and interest to participants for securities held on deposit. Depositories also provide facilities for payment by participants to other participants in connection with book-entry deliveries of securities. . . .'').

[8] A clearing agency that provides central counterparty services interposes itself between the counterparties to securities transactions, acting functionally as the buyer to every seller and the seller to every buyer. 17 CFR 240.17Ad–22(a)(2).

[9] Credits to a Participant settlement account arise from deliveries versus payment, receipt of payment orders, principal and interest distributions in respect of securities held, intraday settlement progress payments and any other items or transactions that give rise to a credit. Debits to a Participant settlement account are primarily due to receives versus payment, as well as other types of charges to the account permitted under the Rules. *See* Notice of Filing, *supra* note 4, 85 FR at 66667.

[10] *See id.*

[11] DTC is subject to a number of regulatory requirements related to its operational and cyber risks, including Rule 17Ad–22(e)(17) and Regulation Systems Compliance and Integrity. DTC's overall approach to operational risk is summarized in its Disclosure Framework, available at *https://www.dtcc.com/legal/policy-and-compliance.* Among other things, DTC manages its operational risk pursuant to the Clearing Agency Operational Risk Management Framework, which the Commission approved in a separate rule filing. *See* Securities Exchange Act Release No. 81745 (September 28, 2017), 82 FR 46332 (October 4, 2017) (SR–DTC–2017–014).

[12] *See* Notice of Filing, *supra* note 4, 85 FR at 66667 (citing, *e.g.,* Rule 9(B), *supra* note 5, which states: ''Each Participant and the Corporation shall settle the balance of the Settlement Account of the Participant on a daily basis in accordance with these Rules and the Procedures. Except as provided in the Procedures, the Corporation shall not be obligated to make any settlement payments to any Participants until the Corporation has received all of the settlement payments that Settling Banks and Participants are required to make to the Corporation.'').

[13] *See* Rule 4 (Participants Fund and Participants Investment), *supra* note 5.

[14] *See id.*

[15] Securities Exchange Act Release No. 83950 (August 27, 2018), 83 FR 44393 (August 30, 2018) (SR–DTC–2017–804).

[16] *See* Section 4 of Rule 4 (Participants Fund and Participants Investment), *supra* note 5.

[17] *See* Notice of Filing, *supra* note 4, 85 FR at 66668 (citing DTC's Settlement Guide which provides that the Participants Fund creates liquidity and collateral resources to support the business of DTC and to cover losses and liabilities incident to that business).

[18] Section 3 of Rule 4 provides that if a Participant is obligated to DTC pursuant to the Rules and the Procedures and fails to satisfy any such obligation, DTC shall, to the extent necessary to eliminate such obligation, apply some or all of the Actual Participants Fund Deposit of such Participant to such obligation to satisfy the Participant Default. *See* Section 3 of Rule 4, *supra* note 5.

[19] Section 2 of Rule 4 provides that ''End-of-Day Credit Facility'' is any credit facility maintained by DTC for the purpose of funding the end-of-day settlement of transactions processed through the facilities of DTC. *See* Section 2 of Rule 4, *supra* note 5. *Also see* Securities Exchange Act Release No. 80605 (May 5, 2017), 82 FR 21850 (May 10, 2017) (SR–DTC–2017–802; NSCC–2017–802) (renewing the committed revolving credit facility of DTC and National Securities Clearing Corporation).

default gap only.[20] In order to ensure that DTC may use the Participants Fund and other liquidity resources to fund a settlement gap regardless of its cause, DTC has proposed revising Rule 4, as discussed below.

C. Description of Proposed Changes

DTC states that Section 4 of Rule 4 does not address the use of the Participants Fund to complete settlement when there is a non-default gap and could be construed as limiting the pro rata application of the Participants Fund to fund a settlement gap to default scenarios.[21] DTC further represents that, on each Business Day, settlement occurs during a tight timeframe, in conjunction with the Federal Reserve's National Settlement Service and Fedwire.[22] If there is a delay with the receipt or disbursement of funds for settlement, DTC would need to address those problems quickly in order to complete settlement on that Business Day.[23]

In the Advance Notice, DTC describes the proposed changes to address this situation and expressly ensure that the Participants Fund could be used to complete settlement in the event of a non-default gap. First, DTC proposes to amend Section 4 of Rule 4 to state that (i) the Participants Fund, (ii) the existing retained earnings or undivided profits of DTC, and (iii) any other liquidity resources as may be available (including, but not limited to, the End-of-Day Credit Facility), would be available to DTC as liquidity resources to fund settlement on a Business Day, regardless of whether the settlement gap is a default gap or a non-default gap. The proposal would state that DTC may apply its available resources to fund settlement, in such order and in such amounts as it determines, in its sole discretion. Second, DTC proposes to provide that a determination to apply the Participants Fund shall be made by either the Chief Executive Officer, Chief Risk Officer, Chief Financial Officer, a member of any management committee, Treasurer or any Managing Director as may be designated by the Chief Risk Officer from time to time. The proposal also states that the Board of Directors (or an authorized Committee thereof) shall be promptly informed of the determination.[24] Third, DTC proposes to make certain clarifying and conforming changes, including to clarify that a Participant's pro rata share of an application of the Participants Fund would be the same whether there is a default gap or a non-default gap, and to make minor changes for conformity and readability.

II. Discussion and Recommendation

Although the Clearing Supervision Act does not specify a standard of review for an advance notice, the stated purpose of the Clearing Supervision Act is instructive: 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 (''SIFMUs'') and strengthening the liquidity of SIFMUs.[25]

Section 805(a)(2) of the Clearing Supervision Act authorizes the Commission to prescribe regulations containing risk management standards for the payment, clearing, and settlement activities of designated clearing entities engaged in designated activities for which the Commission is the supervisory agency.[26] Section 805(b) of the Clearing Supervision Act provides the following objectives and principles for the Commission's risk management standards prescribed under Section 805(a):[27]

- To promote robust risk management;
- To promote safety and soundness;
- To reduce systemic risks; and
- To support the stability of the broader financial system.

Section 805(c) provides, in addition, that the Commission's risk management standards may address such areas as risk management and default policies and procedures, among others areas.[28]

The Commission has adopted risk management standards under Section 805(a)(2) of the Clearing Supervision Act and Section 17A of the Exchange Act (the ''Clearing Agency Rules'').[29] The Clearing Agency Rules require, among other things, each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for its operations and risk management practices on an ongoing basis.[30] As such, it is appropriate for the Commission to review advance notices against the Clearing Agency Rules and the objectives and principles of these risk management standards as described in Section 805(b) of the Clearing Supervision Act. As discussed below, the Commission believes the proposal in the Advance Notice is consistent with the objectives and principles described in Section 805(b) of the Clearing Supervision Act,[31] and in the Clearing Agency Rules, in particular Rule 17Ad–22(e)(1), (e)(2)(i) and (v), and (e)(7).[32]

A. Consistency With Section 805(b) of the Clearing Supervision Act

The Commission believes that the Advance Notice is consistent with the stated objectives and principles of Section 805(b) of the Clearing Supervision Act,[33] because the changes proposed in the Advance Notice are consistent with promoting robust risk management, promoting safety and soundness, reducing systemic risks, and supporting the broader financial system.

First, the Commission believes that the proposal is consistent with promoting robust risk management. DTC proposes to amend Section 4 of Rule 4 to provide expressly for the pro rata application of the Participants Fund, retained earnings, and any other liquidity resources, including DTC's credit facility, to any settlement gap, including a non-default gap. As noted above, settlement occurs during a tight timeframe on each Business Day. If there is a delay with the receipt or disbursement of funds for settlement, it would need to be addressed quickly in order to complete settlement on that Business Day. The proposal would clarify which resources DTC can access and use in the most time-efficient and effective manner to ensure settlement.[34]

[20] *See* Notice of Filing, *supra* note 4, 85 FR at 66668.

[21] *See* Notice of Filing, *supra* note 4, 85 FR at 66669.

[22] *See id.; see also,* Settlement Guide at 19–20, *supra* note 5.

[23] *See* Notice of Filing, *supra* note 4, 85 FR at 66669.

[24] The requirement that DTC would also promptly notify the Commission in the event that the Participants Fund were used to complete settlement would remain unchanged.

[25] *See* 12 U.S.C. 5461(b).

[26] 12 U.S.C. 5464(a)(2).

[27] 12 U.S.C. 5464(b).

[28] 12 U.S.C. 5464(c).

[29] 17 CFR 240.17Ad–22. *See* Securities Exchange Act Release No. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11). *See also* Securities Exchange Act Release No. 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14) (Standards for Covered Clearing Agencies). DTC is a ''covered clearing agency,'' as defined in Rule 17Ad–22(a)(5). *See supra* note 6.

[30] *Id.*

[31] 12 U.S.C. 5464(b).

[32] 17 CFR 240.17Ad–22(e)(1) and (e)(2)(i).

[33] 12 U.S.C. 5464(b).

[34] The Commission further believes that use of the Participants Fund may be the most efficient method of completing settlement at the end of a Business Day on a tight timeframe, as it generally consists of cash which, pursuant to DTC's Investment Policy, must be held in demand deposit, savings or checking bank accounts that provide same day access to funds. *See* Exchange Act Release No. 88513 (March 30, 2020), 85 FR 19047, 19048 (April 3, 2020). The Commission observes that, as a general matter, it likely could take more time to

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Moreover, the proposal would specify the particular DTC personnel whose approval could authorize the use of the Participants Fund to finance a settlement gap. The Commission believes that the proposal is designed to allow DTC to take timely and effective action to fund a settlement gap, regardless of whether it is a default or non-default gap, and therefore complete settlement, by identifying and applying appropriate liquidity resources, which is consistent with the promotion of robust risk management.

Second, the Commission believes that the proposal is consistent with the promotion of safety and soundness of DTC and, by extension, the broader financial system. As stated above, the proposal would expressly provide that DTC may use the Participants Fund and other specified resources as a liquidity resources in the event of a settlement gap. With this proposal, DTC would expressly state how it would manage the potential liquidity risk that may arise from both the default of a Participant as well as a non-default event, including operational issues at DTC, a Participant, or a Settling Bank. With the proposal, DTC would be better positioned to timely complete settlement if a default or non-default gap arises. Accordingly, the Commission believes that the proposal is consistent with the promotion of safety and soundness.

Finally, the Commission believes that the proposal is consistent with reducing systemic risks and supporting the stability of the broader financial system. With clear authority to use the Participants Fund and other resources to address both a default and non-default settlement gap, DTC should be better positioned to access sufficient liquidity, and thus be better able to manage its liquidity risks in the event of a settlement gap. DTC is a SIFMU and serves as the only central securities depository in the United States, settling virtually all broker-to-broker equity and listed corporate and municipal debt securities transactions in the United States, as well as institutional trades, money market instruments and other financial obligations. This access to liquidity during a stress event would help mitigate any risk to settlement finality due to DTC having insufficient funds to meet payment obligations to its Participants. As such, access to this liquidity would help to strengthen the liquidity of DTC and mitigate potential risks to settlement finality, thereby reducing systemic risks and supporting the stability of the broader financial system.

For the reasons stated above, the Commission believes the changes proposed in the Advance Notice are consistent with Section 805(b) of the Clearing Supervision Act.[35]

B. Consistency With Rule 17Ad–22(e)(1)

Rule 17Ad–22(e)(1) under the Act requires that DTC establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for a well-founded, clear, transparent, and enforceable legal basis for each aspect of its activities in all relevant jurisdictions.[36]

As discussed above, current Section 4 of Rule 4 does not address the use of the Participants Fund or other liquidity resources to complete settlement when there is a non-default gap, and DTC is concerned that it could be construed as limiting the pro rata application of the Participants Fund to fund a settlement gap to default scenarios. The proposal would amend Rule 4 to expressly state that the Participants Fund, DTC's retained earnings, and other liquidity resources may be used by DTC to fund a settlement gap to complete settlement on a Business Day, whether the settlement gap is the result of a Participant Default or otherwise. In addition, the proposal makes clarifying and conforming changes and provides governance regarding the application of the Participants Fund.

The Commission believes that the above changes are designed to ensure greater certainty in the Rules regarding what resources would be available to DTC to complete settlement in the event of a settlement gap. The proposal would provide a clear, transparent and enforceable legal basis for DTC to apply the Participants Fund, retained earnings, or other liquidity resources to any settlement gap. It would also clarify that a Participant's pro rata share of an application of the Participants Fund would be the same whether there is a default gap or a non-default gap, and expressly state that DTC may apply its available resources to fund settlement, in such order and in such amounts as it determines, in its sole discretion.

Therefore, the Commission believes the proposal is designed to help ensure that DTC's Rules remain well-founded, transparent, and legally enforceable in all relevant jurisdictions, consistent with Rule 17Ad–22(e)(1) under the Act.[37]

C. Consistency With Rule 17Ad–22(e)(2)(i) and (v)

Rule 17Ad–22(e)(2) under the Act requires, in part, that DTC establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for governance arrangements that (i) are clear and transparent, and (v) specify clear and direct lines of responsibility.[38]

As discussed above, the proposal would provide that a determination to apply the Participants Fund shall be made by either the Chief Executive Officer, Chief Risk Officer, Chief Financial Officer, a member of any management committee, Treasurer or any Managing Director as may be designated by the Chief Risk Officer from time to time. The proposal would also provide that the Board of Directors (or an authorized Committee thereof) shall be promptly informed of the determination. With this proposal, the Rules would expressly define who would be responsible for making the determination to apply the Participants Fund to a settlement gap and would require that the Board of Directors (or its authorized Committee) would be informed of such determination promptly.

Therefore, the Commission believes the proposal is designed to provide for governance arrangements regarding the use of the Participants Fund to complete settlement that are clear and transparent and specify clear and direct lines of responsibility, consistent with Rule 17Ad–22(e)(2)(i) and (v) under the Act.[39]

D. Consistency With Rule 17Ad–22(e)(7)(i)

Rule 17Ad–22(e)(7)(i) under the Act requires, in part, that a covered clearing agency, like DTC, establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively measure, monitor, and manage the liquidity risk that arises in or is borne by the covered clearing agency, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity, by maintaining sufficient liquid resources to effect same-day settlement of payment obligations with a high degree of confidence under a wide range of foreseeable stress scenarios.[40]

As described above, the proposal would clarify that the Participants Fund and other resources may be applied by

access retained earnings or draw down on the credit facility.

[35] 12 U.S.C. 5464(b).

[36] 17 CFR 240.17Ad–22(e)(1).

[37] *Id.*

[38] 17 CFR 240.17Ad–22(e)(2)(i) and (v).

[39] *Id.*

[40] 17 CFR 240.17Ad–22(e)(7)(i).

DTC to fund settlement in the event of a default or non-default gap. The proposed change is designed to help ensure that DTC is able to manage its settlement and funding flows on a timely basis and effect same day settlement of payment obligations in certain foreseeable stress scenarios.

Therefore, the Commission believes that the proposal is reasonably designed to help DTC effectively manage liquidity risk in a timely manner to complete settlement, and accordingly is consistent with Rule 17Ad–22(e)(7)(i).[41]

III. Conclusion

It is therefore noticed, pursuant to Section 806(e)(1)(I) of the Clearing Supervision Act, that the Commission does not object to Advance Notice (SR–DTC–2020–801) and that DTC is authorized to implement the proposed change as of the date of this notice or the date of an order by the Commission approving proposed rule change SR–DTC–2020–011, whichever is later.

By the Commission.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–25006 Filed 11–10–20; 8:45 am]

BILLING CODE 8011–01–P

[41] *Id.*

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90355; File No. SR–NASDAQ–2020–017]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend Nasdaq Rule 5704

November 5, 2020.

On July 23, 2020, The Nasdaq Stock Market LLC (''Exchange'' or ''Nasdaq'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend certain listing requirements relating to maintaining a minimum number of beneficial holders and minimum number of shares outstanding. The proposed rule change was published for comment in the **Federal Register** on August 7, 2020.[3]

On September 10, 2020, pursuant to Section 19(b)(2) of the Exchange Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] The Commission has received no comments on the proposed rule change. The Commission is issuing this order to institute proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act[6] to determine whether to approve or disapprove the proposed rule change.

I. Description of the Proposal

The Exchange proposes to amend Nasdaq Rule 5704 to: (1) Remove the requirement that, twelve months after the commencement of trading on the Exchange, a series of Exchange Traded Fund Shares must have 50 or more beneficial holders; and (2) replace its existing minimum number of shares requirement with a requirement that each series of Exchange Traded Fund Shares have a sufficient number of shares outstanding at the commencement of trading to facilitate the formation of at least one creation unit.[7]

The Exchange believes that the requirement that a series of Exchange Traded Fund Shares listed on the Exchange must have at least 50 beneficial shareholders is no longer necessary. The Exchange believes that the requirements of Rule 6c–11 under the Investment Company Act of 1940 (''1940 Act''), coupled with the existing creation and redemption process, mitigate the potential lack of liquidity that, according to the Exchange, the shareholder requirement was intended to address.[8] The Exchange further believes that requiring at least one creation unit to be outstanding at the commencement of trading, together with the daily portfolio transparency and other enhanced disclosure requirements of Rule 6c–11 under the 1940 Act,[9] will facilitate an effective arbitrage mechanism and provide market participants and investors with sufficient transparency into the holdings of the underlying portfolio, and ensure that the trading price in the secondary market remains in line with the value per share of a fund's portfolio.

Specifically with respect to arbitrage, the Exchange states that the arbitrage mechanism relies on the fact that shares of the Fund can be created and redeemed and that shares of the Fund are able to flow into or out of the market when the price of the Fund is not aligned with the net asset value per share of the portfolio. The resulting buying and selling of the shares of the Fund, as well as the underlying portfolio components, generally causes the market price and the net asset value per share to converge. In addition, the Exchange states that the proper functioning of the arbitrage mechanism is reliant on the presence of authorized participants (''APs'') that are eligible to facilitate creations and redemptions with the fund and support the liquidity of the fund. As a result, the Exchange believes that the AP is able to buy and sell Exchange Traded Fund Shares from both the fund and investors. Because Exchange Traded Fund Shares can be created and redeemed ''in-kind'' and do not have an upper limit of the number of shares that can be outstanding, an AP can fulfill customer orders or take advantage of arbitrage opportunities regardless of the number of shares currently outstanding. Thus, the Exchange believes that, unlike common stock, the liquidity of Exchange Traded Fund Shares is not dependent on the number of shares currently outstanding or the number of shareholders, but on the availability of APs to transact in the Exchange Traded Fund Shares primary market.

To support these contentions, the Exchange provides information, during a two-month observation period, regarding how closely two funds—the SPY and QQQ—tracked their respective underlying indexes, as well as data regarding creation and redemption activity in those two funds during the same observation period. The Exchange asserts that a symbiotic relationship exists between the disclosure requirements of Rule 6c–11 under the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89464 (August 4, 2020), 85 FR 48012 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 89823, 85 FR 57895 (September 16, 2020). The Commission designated November 5, 2020 as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] Currently, Nasdaq Rule 5704(b)(1)(A) provides that the Exchange will establish a minimum number of Exchange Traded Fund Shares required to be outstanding at the time of commencement of trading on the Exchange.

[8] In contrast, Nasdaq believes that the shareholder requirement as it relates to common stock is a measure of liquidity designed to help assure that there will be sufficient investor interest and trading to support price discovery once a security is listed. *See id.* at 48012, n.6.

[9] As an example, the Exchange notes that Rule 6c–11(c)(1)(vi) requires additional disclosure if the premium or discount is in excess of 2% for more than seven consecutive days, so that there would be transparency to investors in the event that the trading value and the underlying portfolio deviate for an extended period of time, which could indicate an inefficient arbitrage mechanism.

1940 Act, the ability of the AP to create and redeem shares of a fund, and the functioning of the arbitrage mechanism that helps to ensure that the trading price in the secondary market is at fair value. According to the Exchange, this renders the need for a shareholder requirement as duplicative and unnecessary.

The Exchange further believes that, in order for fund redemptions to be executed in support of the arbitrage mechanism, it is appropriate that, in lieu of the minimum number of shareholders requirement, the fund have a sufficient number of shares outstanding in order to facilitate the formation of at least one creation unit on an initial and continued listing basis. The Exchange claims that the existence of the creation and redemption process, daily portfolio transparency, as well as a sufficient number of shares outstanding to allow for the formation of at least one creation unit, ensures that market participants are able to redeem shares and thereby support the proper functioning of the arbitrage mechanism. According to the Exchange, of the more than 350 funds currently listed on Nasdaq that would be eligible to be listed under Nasdaq Rule 5704, only two had a single creation unit outstanding. The remaining funds have, on average, shares outstanding equal to approximately 300 creation units.

In addition, the Exchange states that its surveillance program for, and its ability to halt trading in, Exchange Traded Fund Shares provide for additional investor protections by further mitigating any abnormal trading that would affect the prices of Exchange Traded Fund Shares.

II. Proceedings To Determine Whether To Approve or Disapprove SR–NASDAQ–2020–017 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act [10] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved.

Pursuant to Section 19(b)(2)(B) of the Exchange Act,[11] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of and input concerning the proposed rule change's consistency with the Exchange Act and, in particular, Section 6(b)(5) of the Exchange Act, which requires, among other things, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.'' [12]

The Commission has consistently recognized the importance of the minimum number of holders and other similar requirements in exchange listing standards. Among other things, such listing standards help ensure that exchange listed securities have sufficient public float, investor base, and trading interest to provide the depth and liquidity necessary to promote fair and orderly markets.[13]

As discussed above, the Exchange is proposing to: (1) Remove the listing requirement that, following the initial twelve-month period after commencement of trading of a series of Exchange Traded Fund Shares on the Exchange, such series have at least 50 beneficial holders, and (2) replace its existing minimum number of shares requirement with a requirement that each series of Exchange Traded Fund Shares have a sufficient number of shares outstanding at the commencement of trading to facilitate the formation of at least one creation unit.[14] In support of its proposal, the Exchange asserts that the minimum number of beneficial holders requirement is no longer necessary because the requirements of Rule 6c–11 under the 1940 Act, coupled with the existing creation and redemption process, mitigate the potential lack of liquidity that Nasdaq believes the beneficial holders requirement was intended to address. The Exchange, however, does not explain in any detail the basis for this view, particularly if a series of Exchange Traded Fund Shares is permitted to have a very small number of beneficial holders. For example, while the Exchange provides data with respect to two widely-held and highly liquid funds, it does not address how the arbitrage mechanism will assure Exchange Traded Fund Shares with very few holders or very few active APs will effectively support fair and orderly markets. The Exchange also does not discuss potential inefficiencies in the arbitrage mechanism that might occur with illiquid Exchange Traded Fund Shares that have very few holders, and the impact that would have on the ability of the arbitrage mechanism to effectively mitigate the risks of manipulation. Further, the Exchange does not address the impact of creation unit size on the efficiency of the arbitrage mechanism across the spectrum of Exchange Traded Fund Shares (*e.g.,* illiquid Exchange Traded Fund Shares with very few holders and a large creation unit size). The Exchange provides no data or analysis to support its position, other than with respect to the SPY and QQQ, two highly liquid and widely held Exchange Traded Fund Shares, and the number and size of the creation units for existing Exchange Traded Fund Shares.

The Exchange provides no specific arguments to support the proposed elimination of its existing minimum number of shares requirement. While the Exchange proposes to replace that requirement with a requirement that each series of Exchange Traded Fund Shares have a sufficient number of shares outstanding at the commencement of trading to facilitate the formation of at least one creation unit, the Exchange does not explain why this is an appropriate substitute for its existing standards. Creation unit sizes could be highly variable, since they are determined at the discretion of the issuer of Exchange Traded Fund Shares. The Exchange has not articulated how this new standard would effectively support fair and orderly markets, address the risks of manipulation, and otherwise be consistent with Section 6(b)(5) and other relevant provisions of the Exchange Act for Exchange Traded

[10] 15 U.S.C. 78s(b)(2)(B).

[11] *Id.*

[12] 15 U.S.C. 78f(b)(5).

[13] *See, e.g.,* Securities Exchange Act Release No. 57785 (May 6, 2008), 73 FR 27597 (May 13, 2008) (SR–NYSE–2008–17) (stating that the distribution standards, which includes exchange holder requirements ''. . . should help to ensure that the [Special Purpose Acquisition Company's] securities have sufficient public float, investor base, and liquidity to promote fair and orderly markets''); Securities Exchange Act Release No. 86117 (June 14, 2019), 84 FR 28879 (June 20, 2018) (SR–NYSE–2018–46) (disapproving a proposal to reduce the minimum number of public holders continued listing requirement applicable to Special Purpose Acquisition Companies from 300 to 100).

[14] In support of its proposal, Nasdaq states that it would require that a sufficient number of shares to be outstanding at ''all times'' to facilitate the formation of at least one creation unit. *See* Notice, *supra* note 3, 85 FR at 48012. However, proposed Nasdaq Rule 5704(b)(1)(A) establishes that requirement ''at the time of commencement of trading on Nasdaq,'' making it an initial and not a continued listing standard.

Fund Shares with only a single and relatively small creation unit outstanding. The Exchange also has proposed to limit this requirement to a single determination at the commencement of trading, and has not explained the impact of fewer shares potentially being outstanding thereafter. Further, the Exchange has proposed to require that there be a sufficient number of shares outstanding to ''facilitate the formation of'' at least one creation unit, and has not explained how this standard differs from a requirement that the number of shares outstanding at least equals one creation unit.

Finally, the Exchange takes the position that its surveillance procedures and trading halt authority would mitigate any abnormal trading that would affect Exchange Traded Fund Shares prices in the secondary market. The Exchange, however, does not explain in any detail the basis for this view, or how specifically its existing procedures would effectively mitigate the risks addressed by the minimum number of beneficial holders and minimum number of shares requirements the Exchange is proposing to eliminate.

Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization ['SRO'] that proposed the rule change.'' [15] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding, and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the applicable rules and regulations.[16]

For these reasons, the Commission believes it is appropriate to institute proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act to determine whether the proposal should be approved or disapproved.

IV. Commission's Solicitation of Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Exchange Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4, any request for an opportunity to make an oral presentation.[17]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by December 3, 2020. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by December 17, 2020 The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice,[18] in addition to any other comments they may wish to submit about the proposed rule change.

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–2020–017 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–2020–017. 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–NASDAQ–2020–017 and should be submitted by December 3, 2020. Rebuttal comments should be submitted by December 17, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

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[15] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[16] *See id.*

[17] Section 19(b)(2) of the Exchange Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[18] *See supra* note 3.

[19] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90359; File No. SR–NASDAQ–2020–073]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Temporary Supplementary Material .13 (Temporary Extension of the Limited Period for Registered Persons To Function as Principals) Under Nasdaq Rule 1.1210

November 5, 2020.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on October 29, 2020, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

(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 adopt temporary Supplementary Material .13 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under Exchange Rule 1.1210 of General 4 (Registration Requirements).

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.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt temporary Supplementary Material .13 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under Exchange Rule 1.1210 of General 4 (Registration Requirements). The proposed rule change would extend the 120-day period that certain individuals can function as a principal without having successfully passed an appropriate qualification examination through December 31, 2020,[4] and would apply only to those individuals who were designated to function as a principal prior to September 3, 2020. This proposed rule change is based on a filing recently submitted by the Financial Regulatory Authority, Inc. (''FINRA'')[5] and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

In response to COVID–19, earlier this year FINRA began providing temporary relief by way of frequently asked questions (''FAQs'')[6] to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.[7]

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04[8] prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination.[9] On May 19, 2020, FINRA extended the relief to pass the appropriate examination until June 30, 2020. Most recently, on June 29, 2020, FINRA again extended the temporary relief providing that individuals who were designated to function as principals under FINRA Rule 1210.04 prior to May 4, 2020, would be given until August 31, 2020, to pass the appropriate principal qualification examination.

One of the impacts of COVID–19 continues to be serious interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations.[10] Although Prometric has begun reopening test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.[11] Furthermore, Prometric has had to close some reopened test centers due to incidents of COVID–19 cases. The initial nationwide closure in March along with the inability to fully reopen all Prometric test centers due to COVID–19 have led to a significant backlog of individuals who are waiting to sit for FINRA examinations.[12]

In addition, firms are continuing to experience operational challenges with much of their personnel working from home due to shelter-in-place orders, restrictions on businesses and social activity imposed in various states, and adherence to other social distancing guidelines consistent with the recommendations of public health officials.[13] As a result, firms continue to face potentially significant disruptions to their normal business operations that may include a limitation of in-person activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID–19. Such potential disruptions may be further exacerbated and may even affect client services if firms cannot continue to keep principal positions filled as they may have difficulty finding other qualified individuals to transition into these roles or may need to reallocate employee time and resources away from other critical responsibilities at the firm.

These ongoing, extenuating circumstances make it impracticable for members to ensure that the individuals whom they have designated to function in a principal capacity, as set forth in Exchange Rule 1.1210.04, are able to successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule, or to find other

[4] If the Exchange seeks to provide additional temporary relief from the rule requirements identified in this proposed rule change beyond December 31, 2020, the Exchange will submit a separate rule filing to further extend the temporary extension of time.

[5] *See* Securities Exchange Act Release No. 89732 (September 1, 2020), 85 FR 55535 (September 8, 2020) (SR–FINRA–2020–026) (''FINRA Filing''). The Exchange notes that the FINRA Filing also provides temporarily relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

[6] *See https://www.finra.org/rules-guidance/key-topics/covid-19/faq#qe.*

[7] At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. At this time, not all of these Prometric test centers have reopened at full capacity.

[8] Exchange Rule 1.1210.04 is the corresponding rule to FINRA Rule 1210.04.

[9] FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. Exchange Rule 1.1210.04 provides the same allowance to members.

[10] Information about the continued impact of COVID–19 on FINRA-administered examinations is available at *https://www.finra.org/rules-guidance/key-topics/covid-19/faq#qe.*

[11] Information from Prometric about its safety practices and the impact of COVID–19 on its operations is available at *https://www.prometric.com/corona-virus-update. See also supra* note 10.

[12] Although an online test delivery service has been launched to help address the backlog, the General Securities Principal Examination (Series 24) is not available online. *See supra* note 10.

[13] *See, e.g.,* Centers for Disease Control and Prevention, How to Protect Yourself & Others, *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.*

qualified staff to fill this position. The ongoing circumstances also require individuals to be exposed to the health risks associated with taking an in-person examination, because the General Securities Principal (Series 24) Examination is not available online. Therefore, the Exchange is proposing to continue the temporary relief provided through the FINRA FAQs by adopting Rule 1.1210.13 to extend the 120-day period during which an individual can function as a principal before having to pass an applicable qualification examination until December 31, 2020.[14] The proposed rule change would apply only to those individuals who were designated to function as a principal prior to September 3, 2020. Any individuals designated to function as a principal on or after September 3, 2020, would need to successfully pass an appropriate qualification examination within 120 days.

The Exchange believes that this proposed continued extension of time is tailored to address the needs and constraints on a member's operations during the COVID–19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID–19 on members by providing continued flexibility so that members can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by the member's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as Exchange rules.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[15] in general, and furthers the objectives of Section 6(b)(5) of the Act,[16] 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 proposed rule change is intended to minimize the impact of COVID–19 on member operations by extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under Exchange Rule 1.1210.04 until December 31, 2020. The proposed rule change does not relieve members from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable Exchange rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID–19 pandemic, the Exchange believes that the proposed rule change is a sensible accommodation that will continue to afford members the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is intended to provide temporary relief given the impacts of the COVID–19 pandemic crisis and to also maintain consistency with the rules of other self-regulatory organizations (''SROs'') with respect to the registration requirements applicable to members and their registered personnel. In that regard, the Exchange believes that any burden on competition would be clearly outweighed by providing members with temporary relief in this unique environment while also ensuring clear and consistent requirements applicable across SROs and mitigating any risk of SROs implementing different standards in these important areas. In its filing, FINRA provides an abbreviated economic impact assessment maintaining that the changes are necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID–19 pandemic that is equally applicable to the changes the Exchange proposes.[17] The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

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 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[18] and Rule 19b–4(f)(6)[19] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the temporary proposed rule change is based on a recent rule change by FINRA and is intended to harmonize Nasdaq's registration rules with those of FINRA to promote uniform standards across the securities industry.[20] The Exchange states that it will also help minimize the impact of the COVID–19 outbreak on Nasdaq members' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. The ongoing extenuating circumstances of the COVID–19 pandemic make it impractical to ensure that individuals designated to act in principal capacities are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules. Shelter-in-place orders, quarantining, restrictions on business and social activity and adherence to other social distancing guidelines

[14] *See also supra* note 4.

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] FINRA Filing, 85 FR at 55537.

[18] 15 U.S.C. 78s(b)(3)(A).

[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. Nasdaq has satisfied this requirement.

[20] *See* FINRA Filing, 85 FR at 55538.

consistent with the recommendation of public officials remain in place in various states.[21] Further, the Exchange states that Prometric test centers have experienced serious interruptions in the administration of FINRA qualification examinations, resulting in a backlog of individuals waiting to take these examinations. Following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.[22] FINRA has launched an online test delivery service to help address this backlog. However, the General Securities Principal (Series 24) Examination is not available online. The Exchange states that the temporary proposed rule change will provide needed flexibility to ensure that these positions remain filled and is tailored to address the constraints on members' operations during the COVID–19 pandemic without significantly compromising critical investor protection.[23]

The Commission also notes that the proposal provides only temporary relief from the requirement to pass certain qualification examinations within the 120-day period in the rules. As proposed, this relief would extend the 120-day period that certain individuals can function as principals through December 31, 2020. The Exchange has also stated that if it requires temporary relief from the rule requirements identified in this proposal beyond December 31, 2020, it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.[24] For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.[25] Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[26]

[21] *See supra* note 13.

[22] *See supra* notes 10 and 11. The Exchange states that Prometric has also had to close some reopened test centers due to incidents of COVID–19 cases.

[23] The Exchange states that members remain subject to the continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as Exchange rules.

[24] *See supra* note 4.

[25] As noted above by the Exchange, this proposed temporary change is based on a recent filing by FINRA that the Commission approved with a waiver of the 30-day operative delay. *See* FINRA Filing, 85 FR at 55538.

[26] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–2020–073 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–2020–073. 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, on business days between the hours of 10:00 a.m. and 3:00 p.m., located at 100 F Street NE, Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq. 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–2020–073 and should be submitted on or before December 3, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24967 Filed 11–10–20; 8:45 am]

BILLING CODE 8011–01–P

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90356; File No. SR–CboeBZX–2020–082]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule To Eliminate the Listing Fee Waiver for Issuers of Certain ETPs

November 5, 2020.

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 November 4, 2020, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') 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

The Exchange is proposing to amend Rule 14.13(b)(2)(C) related to the listing of exchange traded products (''ETPs'')[3] on the Exchange. Specifically, the Exchange is proposing to eliminate Rule 14.13(b)(2)(C)(iii) related to Auction Fee Listings, as defined below, and to make several other corresponding amendments to Rule 14.13(b)(2)(C).

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] As defined in Rule 11.8(e)(1)(A), the term ''ETP'' means any security listed pursuant to Exchange Rule 14.11.

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 is proposing to amend Rule 14.13(b)(2)(C) related to the listing of exchange traded products (''ETPs'')[4] on the Exchange. Specifically, the Exchange is proposing to eliminate Rule 14.13(b)(2)(C)(iii) related to Auction Fee Listings, as defined below, and to make several other corresponding amendments to Rule 14.13(b)(2)(C).[5]

Auction Fee Listings

Currently, Rule 14.13(b)(2)(C)(iii) provides that any issuer that has an average daily auction volume combined between the opening and closing auctions on the Exchange across all of an issuer's ETPs listed on the Exchange that exceeds 500,000 shares (an ''Auction Fee Listing''), there is no annual listing fee for that issuer's ETPs listed on the Exchange. Any ETP that is not an Auction Fee Listing, a Legacy Listing,[6] a New Listing,[7] an Outcome Strategy ETP,[8] or a Transfer Listing[9] is currently charged an annual listing fee based on the consolidated average daily volume (''CADV'') of the ETP in the fourth quarter of the preceding calendar year, which ranges from $5,000 to $7,000 annually and decreases as the CADV of an ETP increases, a model that is generally designed to reflect the additional revenue that an individual ETP listed on the Exchange creates for the Exchange as its CADV increases. The Exchange is proposing to eliminate Rule 14.13(b)(2)(C)(iii) and the concept of the Auction Fee Listing from its rules. As such, the Exchange is proposing that ETPs under Rule 14.13(b)(2)(C)(iii) that were previously not charged an annual listing fee will be charged an annual listing fee pursuant to the fees table in current Rule 14.13(b)(2)(C)(v)[10] beginning on January 4, 2021, the first trading day of the applicable year.[11]

The Exchange is also proposing to make certain corresponding changes, including deleting a reference to ''Auction Fee Listing'' under current Rule 14.13(b)(2)(C)(v) and changing the numbering associated with Rules 14.13(b)(2)(C)(iv) and (v) to 14.13(b)(2)(C)(iii) and (iv), respectively.

Implementation Date

As noted above, the Exchange intends to implement these amendments to its fee schedule on January 4, 2021, the first trading day of the upcoming year for which an ETP will be billed for applicable annual listing fees pursuant to Rule 14.13(b)(2)(C).[12] The Exchange will announce to its Members the implementation of the rule change prior to its January 4, 2021 implementation date.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[13] Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) and 6(b)(5) of the Act,[14] in that it provides for the equitable allocation of reasonable dues, fees and other charges among issuers and it does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed deletion of Rule 14.13(b)(2)(C)(iii) to eliminate the Auction Fee Listing is a reasonable, fair and equitable, and not unfairly discriminatory allocation of fees and other charges because it would apply equally for all issuers and all ETPs. The pricing for Auction Fee Listings was originally designed to help the Exchange attract and retain listings from issuers of ETPs that had a collectively large auction volume. As the Exchange has continued to grow its ETP listing business, it has determined that such an incentive program is no longer necessary and that such ETPs should instead be subject to the standard annual listing fees on the Exchange, which are generally based on the CADV of the ETP, pursuant to current Rule 14.13(b)(2)(C)(v).[15] Such a change will create a fee structure that will generally apply on a product by product basis instead of across all of an issuer's ETP listings on the Exchange, which will allow the Exchange to charge issuers in a manner more directly related to the incremental costs associated with the initial and continued listing of ETPs on the Exchange.

The Exchange believes that this is a reasonable, fair and equitable, and not unfairly discriminatory allocation of fees and other charges because such standard fees are generally designed to reflect the additional revenue that an individual ETP listed on the Exchange creates for the Exchange through executions occurring in the auctions and additional shares executed on the Exchange. Listing exchanges generally receive an outsized portion of intraday trading activity and receive all auction volume for ETPs listed on the exchange. The higher the CADV for an ETP, the greater the likely income the Exchange will receive based on outsized intraday

[4] As defined in Rule 11.8(e)(1)(A), the term ''ETP'' means any security listed pursuant to Exchange Rule 14.11.

[5] The Exchange initially filed the proposed fee change on November 2, 2020.

[6] As defined in Rule 14.13(b)(2)(C)(i), a ''Legacy Listing'' is an ETP listed on the Exchange prior to January 1, 2019.

[7] As defined in Rule 14.13(b)(2)(C)(ii), a ''New Listing'' is an ETP during its first calendar year listed on the Exchange or an ETP that has been listed for fewer than three calendar months on the ETP's first trading day of the year.

[8] As defined in current Rule 14.13(b)(2)(C)(iv) (Rule 14.13(b)(2)(C)(iii), as amended beginning January 4, 2021), an ''Outcome Strategy ETP'' is an ETP where the issuer lists multiple ETPs that are each designed to provide (i) a pre-defined set of returns; (ii) over a specified outcome period; (iii) based on the performance of the same underlying instrument; and (iv) each employ the same outcome strategy for achieving the pre-defined set of returns.

[9] As defined in Rule 14.13(b)(2)(C)(ii) [*sic*], a ''Transfer Listing'' is an ETP that transfers its listing from another national securities exchange to the Exchange.

[10] Rule 14.13(b)(2)(C)(iv), as amended beginning January 4, 2021.

[11] The Exchange notes that if ETPs are Legacy Listings, New Listings, Outcome Strategy ETPs, and Transfer Listings, then they will be subject to those applicable annual fees as described in current Rule 14.13(b)(2)(C)(i), (ii) and (iv).

[12] The Exchange notes that although this proposal may take effect upon filing with the Commission pursuant to Section 19(b)(3)(A)(ii) of the Act and paragraph (f)(2) of Rule 19b–4 thereunder, the Exchange may choose for such change to be effective on a date other than the filing date.

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(4) and (5).

[15] *See supra* notes 10 and 11.

trading activity and auction volume for such ETP. This structure is designed to reward the issuer of an ETP for such additional revenue brought to the Exchange as CADV increases, which the Exchange believes creates a more equitable and appropriate fee structure for issuers based on the revenue and expenses associated with listing ETPs on the Exchange. With this in mind, the Exchange believes that that it is reasonable, fair and equitable, and not unfairly discriminatory allocation of fees and other charges to charge lower fees for ETPs with a higher CADV.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. With respect to the proposed elimination of Auction Fee Listings for ETPs, the Exchange does not believe that the changes burden competition, but instead, enhance competition, as it is intended to increase the revenue of the Exchange's listing program in order to better compete. Further, the standard fees that will apply on a going forward basis are directly related to the amount of revenue that the Exchange receives from ETPs listed on the Exchange. As such, the proposal is a competitive proposal designed to enhance pricing competition among listing venues and implement pricing for listings that better reflects the revenue and expenses associated with listing ETPs on the Exchange.

The Exchange does not believe the proposed amendments would burden intramarket competition as they would be available to all issuers uniformly.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [16] and paragraph (f) of Rule 19b–4 thereunder.[17] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is 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–CboeBZX–2020–082 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–CboeBZX–2020–082. 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–CboeBZX–2020–082 and should be submitted on or before December 3, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24965 Filed 11–10–20; 8:45 am]

BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f).

[18] 17 CFR 200.30–3(a)(12).

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36434]

The Elk River Railroad, Inc.—Merger Exemption—The Buffalo Creek Railroad Company

On August 27, 2020, The Elk River Railroad, Inc. (TERRI), a Class III rail carrier, filed a petition under 49 U.S.C. 10502 seeking an exemption from the prior approval requirements of 49 U.S.C. 11323–25 to authorize the merger of The Buffalo Creek Railroad Company (BCR), a Class III rail carrier, with and into TERRI, which is the surviving corporation. Because the merger took place in 1995, TERRI is seeking after-the-fact authority and asks that the requested exemption be granted with retroactive effect. For the reasons discussed below, the Board will grant TERRI's petition for an exemption authorizing its merger with BCR but will deny the request to make the exemption retroactive.

Background

According to the petition, William T. Bright (Bright) is the sole owner of TERRI, a West Virginia corporation that acquired a rail line previously owned and operated by CSX Transportation, Inc.[1] (Pet. 1–3.) In 1992, BCR, at that time a noncarrier also owned by Bright, acquired the rail line of the Buffalo Creek and Gauley Railroad Company (BC&G) pursuant to authority granted by the Board's predecessor, the Interstate Commerce Commission (ICC),[2] and

[1] *See Elk River R.R.—Lease, Operation & Acquis. Exemption—Line of CSX Transp., Inc.,* FD 31497 (ICC served July 26, 1989) (authorizing TERRI to acquire a line of railroad between milepost 6.2, at or near Gilmer, and milepost 67.2, at or near Hartland, in Gilmer, Braxton, and Clay Counties, W. Va.).

[2] *See Buffalo Creek R.R.—Acquis. & Operation Exemption—Buffalo Creek & Gauley R.R.,* FD 31968 (ICC served Feb. 11, 1992) (authorizing BCR to acquire from BC&G an 18.6-mile rail line extending from a junction point at Dundon (milepost 62.2 on

Bright obtained authority to control BCR as a rail carrier.[3] (Pet. 3–4.)

TERRI states that in December 1995, ''[d]ue to an inadvertent oversight and lack of knowledge that additional agency approval was necessary,'' BCR was merged with and into TERRI, the surviving corporation, without prior agency authorization as required under 49 U.S.C. 11323–25. (Pet. 4–5.) TERRI explains that, had it ''been aware of its obligation to obtain additional agency authorization, it would have timely filed a verified notice of exemption under 49 CFR 1180.2(d)(3) prior to consummating the merger.'' (*Id.* at 5.) In its petition, TERRI disclaims any intention ''to flout the law,'' as it ''only became aware of the need for such authorization as part of current Counsel's due diligence relating to the imminent and expected sale'' of BC&G to the State of West Virginia. (*Id.*) To address this oversight, TERRI seeks expedited consideration of its petition under 49 U.S.C. 10502 for an exemption from the prior approval requirements of 49 U.S.C. 11323–25 to authorize its 1995 merger with BCR and seeks retroactive effect.

Discussion and Conclusions

Under 49 U.S.C. 11323(a)(1), the merger of two rail carriers into one corporation for the ownership, management, or operation of the previously separately owned properties requires prior approval of the Board. When a transaction does not involve the merger or control of at least two Class I railroads, it is governed by 49 U.S.C. 11324(d). However, under 49 U.S.C. 10502(a), the Board must exempt a transaction or service from regulation upon finding that: (1) Regulation is not necessary to carry out the rail transportation policy (RTP) of 49 U.S.C. 10101; and (2) either (a) the transaction or service is of limited scope, or (b) regulation is not needed to protect shippers from the abuse of market power.

Here, an exemption from the prior approval requirements of sections 11323–25 is consistent with section 10502(a). Detailed scrutiny of this transaction is not necessary to carry out the RTP here. An exemption from the application process would promote a fair and expeditious regulatory decision-making process, minimize the need for Federal regulatory control, encourage honest and efficient management of railroads, and result in the expeditious handling of this proceeding. *See* 49 U.S.C. 10101(2), (9), (15). Other aspects of the RTP would not be adversely affected.

Regulation of this transaction is not needed to protect shippers from the abuse of market power.[4] At the time of the 1995 merger, TERRI and BCR already were commonly controlled by Bright, and indeed, as TERRI points out, the transaction likely would have qualified for the class exemption for transactions within a corporate family under 49 CFR 1180.2(d)(3) had it been timely sought. Moreover, the record indicates there has been no loss of rail competition, no adverse change in the competitive balance in the transportation market, and no change in the level of service to any shippers because, as TERRI explains in its petition, the BC&G rail line does not connect with another rail line other than TERRI's at Dundon, W. Va., and has not carried any traffic in over twenty years. (Pet. 6.)

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, precludes the Board from imposing labor protection for Class III rail carriers receiving authority under sections 11324–25. Accordingly, the Board may not impose labor protective conditions here because TERRI and BCR were both Class III carriers at the time of the merger.

This transaction is categorically excluded from environmental review under 49 CFR 1105.6(c)(1) and from the historic reporting requirements under 49 CFR 1105.8(b).

As stated above, TERRI seeks an exemption with retroactive effect, arguing that its failure to obtain prior approval or an exemption for its merger with BCR was ''an inadvertent oversight'' and ''was in no way intended to flout the law[.]'' (Pet. 5.) Although the Board on occasion has granted authority retroactively,[5] it generally disfavors retroactive grants of authority.[6] As TERRI provides no explanation as to why retroactive authority is needed, the Board declines to grant retroactive authority here.

It is ordered:

1. Under 49 U.S.C. 10502, the Board exempts from the prior approval requirements of 49 U.S.C. 11323–25 BCR's merger with and into TERRI.

2. Notice of the exemption will be published in the **Federal Register**.

3. The exemption will be effective on the service date of this decision.

Decided: November 5, 2020.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2020–25016 Filed 11–10–20; 8:45 am]

BILLING CODE 4915–01–P

the TERRI line; milepost 0 on the BC&G line) to Widen (milepost 18.6 on the BC&G line) in Clay County, W. Va.).

[3] *See Bright—Control Exemption—Buffalo Creek R.R.,* FD 31969, slip op. at 3 (ICC served Mar. 9, 1992) (granting an exemption for Bright to control BCR). Bright placed the stock of BCR in an independent voting trust before BCR acquired the BC&G line in order to avoid controlling BCR as a rail carrier before obtaining his ICC authority to do so. *See id.* at 1; (Pet. 3–4).

[4] Because the Board concludes that regulation is not needed to protect shippers from the abuse of market power, it is unnecessary to determine whether the proposed transaction is limited in scope. *See* 49 U.S.C. 10502(a).

[5] *See, e.g., Grand Elk R.R.—Acquis. of Incidental Trackage Rights Exemption—Norfolk S. Ry.,* FD 35187 (Sub-No. 1) et al., slip op. at 4 (STB served Nov. 20, 2017) (after having previously denied a request for retroactive authority, reopening the proceeding to make exemption retroactive in light of changed circumstances).

[6] *See, e.g., Ark.-Okla. R.R.—Acquis. & Operation Exemption—Okla.,* FD 36323, slip op. at 3 (STB served Sept. 19, 2019) (declining a request for retroactive authority and stating that the Board ''generally disfavors retroactive grants of authority'').

SUSQUEHANNA RIVER BASIN COMMISSION

Grandfathering (GF) Registration Notice

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists Grandfathering Registration for projects by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: October 1–31, 2020.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists GF Registration for projects, described below, pursuant to 18 CFR 806, subpart E for the time period specified above:

Grandfathering Registration Under 18 CFR Part 806, Subpart E

1. Danville Borough Municipal Authority—Public Water Supply System, GF Certificate No. GF–202010119, Danville Borough, Montour County, Pa.; Susquehanna River; Issue Date: October 13, 2020.

2. Pennsylvania Department of Corrections—State Correctional Institute at Camp Hill, GF Certificate No. GF–202010120, Lower Allen Township, Cumberland County, Pa.; Cedar Run and consumptive use; Issue Date: October 13, 2020.

3. Pennsylvania Department of Corrections—State Correctional Institute at Dallas, GF Certificate No. GF–202010121, Jackson Township, Luzerne County, Pa.; Well 1 and consumptive use; Issue Date: October 13, 2020.

4. Joseph and Susan Tallman—Joseph and Susan Tallman Farm, GF Certificate No. GF–202010122, Porter Township, Schuylkill County, Pa.; Wiconisco Creek; Issue Date: October 13, 2020.

5. Port Royal Municipal Authority—Public Water Supply System, GF Certificate No. GF–202010123, Turbett Township, Juniata County, Pa.; Wells 1, 3, 4, and 5; Issue Date: October 15, 2020.

6. Pennsylvania Fish & Boat Commission—Huntsdale State Fish Hatchery, GF Certificate No. GF–202010124, Penn Township, Cumberland County, Pa.; Northline/Knaubs, McManus, and Springs 3, 4, 5, 6, 7, and 9; Issue Date: October 15, 2020.

7. Centre Hall Borough—Centre Hall Borough Waterworks, GF Certificate No. GF–202010125, Centre Hall Borough and Potter Township, Centre County, Pa.; Wells 8 and 9; Issue Date: October 15, 2020.

8. Henry Reiner—Reiner Farms, GF Certificate No. GF–202010126, Upper Mahantongo Township, Schuylkill County, Pa.; Mahantongo Creek—Pivot and Mahantongo Creek—Reel; Issue Date: October 15, 2020.

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806 and 808.

Dated: November 5, 2020.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2020–24957 Filed 11–10–20; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Commission Meeting

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: The Susquehanna River Basin Commission will conduct its regular business meeting on December 11, 2020, from Harrisburg, Pennsylvania. Details concerning the matters to be addressed at the business meeting are contained in the Supplementary Information section of this notice. Also the Commission published a document in the **Federal Register** on October 7, 2020, concerning its public hearing on November 5, 2020, in Harrisburg, Pennsylvania.

DATES: The meeting will be held on Friday, December 11, 2020, at 9 a.m.

ADDRESSES: The meeting will be conducted telephonically from the Susquehanna River Basin Commission, 4423 N. Front Street, Harrisburg, PA 17110.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: 717–238–0423; fax: 717–238–2436.

SUPPLEMENTARY INFORMATION: The business meeting will include actions or presentations on the following items: (1) Adoption of a policy to incentivize the use of impaired waters; (2) adoption of an updated regulatory program fee schedule; (3) adoption of a general permit for groundwater remediation projects; (4) ratification/approval of contracts/grants; (5) a report on delegated settlements; and (6) Regulatory Program projects.

This agenda is complete at the time of issuance, but other items may be added, and some stricken without further notice. The listing of an item on the agenda does not necessarily mean that the Commission will take final action on it at this meeting. When the Commission does take final action, notice of these actions will be published in the **Federal Register** after the meeting. Any actions specific to projects will also be provided in writing directly to project sponsors.

Due to the COVID–19 orders, the meeting will be conducted telephonically and there will be no physical public attendance. The public is invited to attend the Commission's business meeting by telephone conference and may do so by dialing Conference Call # 1–888–387–8686, the Conference Room Code # 9179686050. Written comments pertaining to items on the agenda at the business meeting may be mailed to the Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, Pennsylvania 17110–1788, or submitted electronically through *www.srbc.net/about/meetings-events/business-meeting.html.* Such comments are due to the Commission on or before December 9, 2020. Comments will not be accepted at the business meeting noticed herein.

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: November 5, 2020.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2020–24958 Filed 11–10–20; 8:45 am]

BILLING CODE 7040–01–P

TENNESSEE VALLEY AUTHORITY

Sunshine Act Meetings

TIME AND DATE: 10 a.m. on November 13, 2020.

PLACE: Please use the following link for the live stream of meeting: *https://bcove.video/2ThhkTb*.

STATUS: Open, via live streaming only.

MATTERS TO BE CONSIDERED:

Meeting No. 20–04

The TVA Board of Directors will hold a public meeting on November 13, 2020. Due to the ongoing risks associated with the COVID–19 outbreak, the meeting will be conducted via teleconference. The meeting will be called to order at 10 a.m. ET to consider the agenda items listed below. TVA Board Chair John Ryder and TVA management will answer questions from the news media following the Board meeting.

Public health concerns also require a change to the Board's public listening session. Although in-person comments from the public are not feasible, the Board is encouraging those wishing to express their opinions to submit written comments that will be provided to the Board members before the November 13 meeting. Written comments can be submitted through the same online system used to register to speak at previous listening sessions.

Agenda

1. Approval of minutes of the August 27, 2020, Board Meeting
2. Report from President and CEO
3. Report of the Finance, Rates, and Portfolio Committee
   A. FY 2021 Financial Plan and Budget
   B. Electric Vehicle Charging—Policy and Pricing
4. Report of the People and Performance Committee
   A. Fiscal Year 2020 Performance and Compensation
   B. Fiscal Year 2021 Corporate Goals
5. Report of the Audit, Risk, and Regulation Committee
   A. Extension of Pandemic Relief Delegation
6. Report of the Nuclear Oversight Committee
7. Report of the External Relations Committee
8. Information Items

A. Executive Order 13950
B. Strategic Assessment Review
C. Policy on Requests to Use the TVA Transmission System

CONTACT PERSON FOR MORE INFORMATION: For more information: Please call Jim Hopson, TVA Media Relations at (865) 632–6000, Knoxville, Tennessee. Anyone who wishes to comment on any of the agenda in writing may send their comments to: TVA Board of Directors, Board Agenda Comments, 400 West Summit Hill Drive, Knoxville, Tennessee 37902.

Dated: November 6, 2020.

Sherry A. Quirk,

General Counsel.

[FR Doc. 2020–25153 Filed 11–9–20; 4:15 pm]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0414]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Recording of Aircraft Conveyances and Security Documents

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 to renew an information collection. The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 23, 2020. The collection involves a lienholder returning an AC Form 8050–41, Notice of Recordation—Aircraft Security Conveyance with Part II—Release completed to the Civil Aviation Registry, Aircraft Registration Branch (Registry), to release a recorded lien. This information is necessary to show satisfaction of a recorded lien.

DATES: Written comments should be submitted by December 14, 2020.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Bonnie Lefko by email at: *Bonnie.Lefko@faa.gov;* phone: 405–954–7461.

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: 2120–0043.

Title: Recording of Aircraft Conveyances and Security Documents.

Form Numbers: AC Form 8050–41, Notice of Recordation.

Type of Review: Renewal.

Background: The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 23, 2020 (85 FR 22784). Statute provides for establishing and maintaining a system for the recording of security conveyances affecting title to, or interest in U.S. civil aircraft and qualified engines, propellers, and/or spare part locations, and for recording of releases relating to those conveyances. A lienholder submits a lien against aircraft and/or qualified engines, propellers, and/or spare part locations to the Registry for recording. The Registry records the lien and sends an AC Form 8050–41, Notice of Recordation—Aircraft Security Conveyance, to the lienholder. When the lien is ready for release, the lienholder completes Part II—Release at the bottom of the form and returns it to the Registry as official notification that the lien has been satisfied.

Respondents: Any aircraft, propeller, engine or spare parts location lienholder, who has received the Notice of Recordation from the Registry, and is releasing the subject lien.

Frequency: On occasion.

Estimated Average Burden per Response: 1 hour.

Estimated Total Annual Burden: During FY 2019 the FAA received 22,370 release notifications for a total time burden of 22,370 hours.

Issued in Oklahoma City, OK on November 5, 2020.

Bonnie Lefko,

Program Analyst, Civil Aviation Registry, Aircraft Registration Branch, AFB–711.

[FR Doc. 2020–24952 Filed 11–10–20; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION

[Docket No. NHTSA–2020–0102]

Request for Information: Impaired Driving Technologies

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for information.

SUMMARY: This notice requests information from interested parties to help inform the agency on available or late stage technology under development for impaired driving detection and mitigation. It also fulfills the Joint Explanatory Statement accompanying the Further Consolidated Appropriations Act, 2020, Public Law 116–94 (2020), which directs NHTSA to facilitate the sharing of information and the implementation and integration of impaired driving technology across the automotive industry.

DATES: Comments must be received on or before January 11, 2021.

ADDRESSES: You may submit comments identified by the docket number in the heading of this document or by using any of the following methods:

- *Electronic submissions:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility. M–30, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* 1–202–493–2251.

Instructions: Comments submitted to the docket should not include any sensitive personal information or confidential business information. Each submission must include the Agency name and the Docket number for this Notice. Note that all comments submitted to the docket, will be posted without change to *http://www.regulations.gov* including any personal information provided. Please see the Privacy Act heading below.

If you wish to voluntarily submit confidential business information, you should submit two copies of your

complete submission electronically to the Chief Counsel, NHTSA, at the address given below under **FOR FURTHER INFORMATION CONTACT**, with one copy containing the information you claim to be confidential business information, and one copy from which the claimed confidential business information has been deleted. In addition, you should submit one copy, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information to the Chief Counsel, you should follow the procedures set forth in 49 CFR part 512, and include a cover letter setting forth the information specified in our confidential business information regulation, along with the certification required by the regulation. 49 CFR part 512. In addition, you must clearly mark the top of each page of a document containing confidential business information with the word ''CONFIDENTIAL.''

• *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 *http://www.dot.gov/privacy.html.*

• *Docket:* For access to the docket to read comments received, go to *http://www.regulations.gov* or the street address listed above. To be sure someone is there to help you, please call 202–366–9322 before coming. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: Robert Ritter, Office of Impaired Driving and Occupant Protection Division, Office of Research and Program Development, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, NPD–100, Room W44–243, Washington, DC 20590. Mr. Ritter's phone number is 202–493–0019, and his email address is *Robert.Ritter@dot.gov.*To submit confidential business information to the Chief Counsel: Daniel Rabinovitz, Office of Chief Counsel, National Highway Traffic Safety Administration, *Daniel.Rabinovitz@dot.gov*.

SUPPLEMENTARY INFORMATION: In 2008, the National Highway Traffic Safety Administration (NHTSA) entered into a Cooperative Agreement with the Automotive Coalition for Traffic Safety (ACTS)—representing the majority of automobile manufacturers—to assess and develop alcohol detection technologies that prevent the operation of a vehicle when the driver's blood alcohol concentration (BAC) exceeds the legal limit. This collaborative research partnership is known as the Driver Alcohol Detection System for Safety (DADSS) program. Over the years, the DADSS program made progressive improvements in the development of two in-vehicle technologies that target measuring breath or blood alcohol levels and could help prevent alcohol-impaired drivers from operating their vehicles: A breath-based and a touch-based system. As the DADSS technology progressed, NHTSA also became aware of some market-based driver monitoring systems, some of which may also play a role in addressing safety risks associated with impaired driving.

NHTSA is interested in better understanding the state of technologies in impaired driving detection and mitigation, particularly those targeting alcohol-impaired driving.

Request for Information: This notice requests information to inform NHTSA about the capabilities, limitations, and maturity of currently available technologies or those under advanced stages of development that target impaired driving. The Joint Explanatory Statement accompanying the Further Consolidated Appropriations Act, 2020, Public Law 116–94 (2020), requires NHTSA to facilitate the sharing of this information and the implementation and integration of impaired driving technology across the automotive industry. NHTSA plans to conduct further research on such technologies. To ensure a comprehensive review of these technologies, NHTSA requests interested parties to submit information to the Agency on related technologies that are being researched, developed, or marketed. More specifically, NHTSA seeks information about technologies that can detect degrees of driver impairment through a range of approaches including (1) technologies that can monitor driver action, activity, behavior, or responses, such as vehicle movements during lane keeping, erratic control, or sudden maneuvers; (2) technologies that can directly monitor driver impairment (*e.g.,* breath, touch-based detection through skin); (3) technologies that can monitor a driver's physical characteristics, such as eye tracking or other measures of impairment; and (4) technologies or sensors that aim direct measurement of a driver's physiological indicators that are already linked to forms of impaired driving (*e.g.,* BAC level for alcohol-impaired driving).

NHTSA is interested in information about product specifications; impairment measurement metrics, methods, and systems; impairment classification approaches and capabilities; availability of test results and data that support system capabilities and limitations; advanced sensors; and other technologies that could be used in a vehicle to detect impaired drivers.

Input is also requested about whether and how systems have been validated to date, including human factors issues and user acceptance of proposed approaches. Further, NHTSA requests information on the range of active intervention these technologies are targeted to support in vehicles based on the type and level of impairment estimated, or measured, by the system with respect to the system's confidence in such assessment.

Responses most useful to NHTSA would include specific information about the product capabilities and limitations, the state of its development, its availability and/or current uses. Examples of useful information include vendor contact information; information related to product's marketed capabilities; a description of the approach the technology uses to detect, estimate, or measure driver impairment; product specifications, including physical dimensions, accuracy, tolerance limits, performance characteristics such as temperature limitations, vehicle integration feasibility, and part-life in the automotive environment; closest Technology Readiness Level (TRL) of the technology based on best practices described in the General Accounting Office *Technology Readiness Assessment Guide* (*https://www.gao.gov/assets/710/703694.pdf*); any publicly shareable information related to the cost ranges for the unit, its installation, as well as lifetime maintenance; any data related to studies that targeted usability and user acceptance; known technology defeat strategies users may employ; and impairment detection and impairment differentiation capabilities (alcohol-impaired, drug-impaired, distracted, drowsy, etc.), including false-positive and false-negative detection rates. Additionally, NHTSA would like to know how existing technologies have been evaluated in laboratory or field tests or in operational deployments and how positive impairment data was utilized in those studies.

NHTSA encourages commenters to provide information in common file

formats, such as Microsoft Word, pdf, or plain text and limit responses to no more than 10 pages, not including appendices.

Authority: 23 U.S.C. 403.

Issued in Washington, DC, under authority delegated by 49 CFR 1.95 and 49 CFR 501.8.

Nanda Narayanan Srinivasan,

Associate Administrator, Research and Program Development.

[FR Doc. 2020–24951 Filed 11–10–20; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Modifications to Special Permit

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before November 27, 2020.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on October 29, 2020.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA

Application No.	Applicant	Regulation(s) affected	Nature of the Special Permits thereof
7573–M	Department of Defense (Military Surface Deployment & Distribution Command).	172.1, 175.1	To modify the special permit to update references to the new AFMAN manual. (mode 4)
9232–M	Department of Defense US Army (Military Surface Deployment & Distribution Command).	Parts 172 and 175	To modify the special permit to update references to the new AFMAN manual. (modes 4, 5)
14313–M	Airgas USA LLC	172.203(a), 172.301(c), 173.302a(b), 180.205.	To modify the special permit to authorize an additional UE test system to re-qualify certain DOT and permitted cylinders. (modes 1, 2, 3, 4, 5)
16146–M	Department of Defense (Military Surface Deployment & Distribution Command).	171.22(e), 172.101(j)	To modify the permit to reference update references to the 24 series of the Air Force regulations. (mode 4)
20851–M	Call2Recycle, Inc.	172.200, 172.600, 172.700(a).	To modify the special permit to authorize the transportation of end-of-life lithium batteries up to 1,200 Wh to be shipped in PG II fiberboard boxes. (mode 1)
20904–M	Piston Automotive, LLC	172.101(j), 173.185(b)(5)	To modify the special permit to authorize the use of alternative packaging which complies with § 173.185(b)(5) and Packing Instruction 965 Section 1A.2. (mode 4)

[FR Doc. 2020–24989 Filed 11–10–20; 8:45 am]

BILLING CODE 4909–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Actions on Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on special permit applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before December 14, 2020.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety

Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 2, 2020.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
		SPECIAL PERMITS DATA—Granted	
11156–M	Orica USA Inc	173.212(b), 173.62(c)	To modify the special permit to authorize an alternative bag closure (glued seam).
12706–M	Hexagon Ragasco As	173.304(a), 173.335(a)	To modify the special permit to add additional Division 2.2 hazmat.
13220–M	Entegris, Inc	173.302, 173.302c	To modify the special permit to harmonize internal pressure limits and test pressures with UN Model Regulations.
16311–M	Thai Air Attache		To modify the permit to include Div 1.4 materials that are in a quantity that exceed the package limitations in Column (9B) of the 172.101 HMT.
16318–M	Technical Chemical Company	173.304(d), 173.167(a)	To modify the special permit to authorize an additional 2.1 hazmat.
20274–M	Bollore Logistics USA Inc	172.101(j), 172.300, 172.400, 173.301, 173.302a(a)(1), 173.304a(a)(2).	To modify the special permit to add an additional 2.3 hazmat.
20851–M	Call2Recycle, Inc	172.200, 172.600, 172.700(a)	To modify the special permit to authorize rail transport.
20904–M	Piston Automotive, LLC	172.101(j)	To modify the special permit to authorize a change to the packaging of the battery assembly.
21049–N	Ferrellgas, L.P	180.205(c)	To authorize the transportation in commerce of 2,338 filled cylinders that had not been requalified before the requalification became due.
21072–N	Isotek Systems, LLC	173.417(b)(1), 173.427(a)(3), 173.453(d).	To authorize the transportation in commerce of radioactive material in alternative packaging.
21074–N	Zhejiang Meenyu Can Industry Co., Ltd.	173.304(a), 173.304(d)	To authorize the manufacture, mark, sale and use of a non-refillable, non-DOT specification inside metal container similar to a DOT specification 2Q.
21081–M	Romeo Systems, Inc	172.102, 173.185(b)	To modify the special permit to authorize a new variant of the approved batteries and cells.
21093–N	Orbital Sciences LLC	172.101(j)(2), 173.185(a)(1), 173.185(b)(3)(i).	To authorize the transportation in commerce of the low production lithium metal battery identified as Model No.9ER20P–20B, manufactured by Orion HIT, which are specifically designed for space flight, as Class 9 without passing UN T.6—Impact Test.
21094–N	Umbra Lab, Inc	173.185(a)(1), 173.185(b)	To authorize the transportation of prototype lithium batteries contained in equipment (spacecraft).
21095–N	Suterra LLC	173.306(i)(1)	To authorize the transportation in commerce of limited quantities of aerosols for which the completed package exceeds 66 lbs gross weight.
21099–N	StageFX, Inc	173.64	To authorize the use of the 2018 APA Standard 87–1C: Standard for the Construction, Classification, Approval, and Transportation of Entertainment Industry and Technical (EI&T) Pyrotechnics for classification of pyrotechnic materials.
21101–N	United States Aviation Co	172.101(j), 172.200, 172.301(c), 172.302(c), 175.30.	To authorize the transportation in commerce of hazardous materials by helicopter in amounts that exceed the maximum net quantity in the HMR.
21105–M	US EPA Region 5	172.102(c)(1), 173.185(f)(1), 173.185(f)(3).	To modify the special permit to authorize layering fire suppressant between a layer of button cells rather than around each individual cell.
21117–N	Spaceflight, Inc	173.185(a), 173.185(e)	To authorize the transportation in commerce of low production lithium batteries contained in spacecraft.
21119–N	Spaceflight, Inc	173.185(a), 173.185(e)	To authorize the transportation in commerce of spacecraft containing hazardous materials.
21123–N	General Defense Corp	172.101(j), 172.204(c)(3)	To authorize the transportation in commerce of certain Class 1 materials that are forbidden for air transportation by cargo-only aircraft.

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
SPECIAL PERMITS DATA—Denied			
21035–N	Volkswagen Ag	172.101(j)	To authorize the transportation in commerce of lithium ion batteries exceeding 35 kg by cargo only aircraft.
21096–N	Pacira Cryotech, Inc	171.23, 173.306(j)	To authorize the transportation in commerce of receptacles, small that have a oxidizer subsidiary hazard under 49 CFR 173.306(j).
21103–N	Kalitta Air, LLC	172.200, 172.300, 172.400, 175.30.	To authorize the transportation in commerce of certain hazardous materials by cargo aircraft without shipping papers, marking and labeling, and information to the pilot-in-command.
SPECIAL PERMITS DATA—Withdrawn			
21118–N	Royal Thai Air Force	172.101(j), 172.204(c)(3), 173.27(b)(2), 173.27(b)(3), 177.848(f).	To authorize the transportation in commerce of explosives by cargo aircraft which is forbidden in the regulations. (mode 4).

[FR Doc. 2020–24990 Filed 11–10–20; 8:45 am]
BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for New Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before December 14, 2020.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 02, 2020.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21125–N	CTS Cylinder Sales LLC	180.209(a), 180.209(b)(1)	To authorize the transportation in commerce of certain hazardous materials in DOT Specification 3AL cylinders manufactured from aluminum allow 6061–T6 that are requalified every ten years rather than every five years using 100% ultrasound examination. (modes 1, 2).
21127–N	Sodastream USA Inc.	178.35(b)(1), 178.70(e)	To authorize the manufacture of cylinders by a foreign entity without requiring Independent Inspection Agency inspection and analysis. (modes 1, 2, 3).
21129–N	Alliant Techsystems Operations LLC.	173.301, 173.302, 178.56(c), 178.56(g), 178.56(i), 178.56(j), 178.56(k), 178.56(m).	To authorize the transportation in commerce of non-DOT specification pressure vessels which incorporate a class 1 component. (mode 1).
21133–N	Securaplane Technologies, Inc..	172.102(b)(2)	To authorize the transportation in commerce of lithium ion batteries by cargo-only aircraft at a state of charge exceeding 30%. (mode 4).
21134–N	GATX Corporation	179.100–4, 179.200–4	To authorize the use of certain jacketed DOT specification tank cars that have been repaired pursuant to Applicant's Jacket Patch Procedure. (mode 2).
21135–N	JohnDow Industries, Inc.	178.503(a)	To authorize the marking of specification packagings that were mismarked with an incorrect specification. (mode 1).

SPECIAL PERMITS DATA—Continued

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
21136–N	Cimarron Composites, LLC.	173.302(a)(1)	To authorize the manufacture, mark, sale, and use fiber reinforced composite cylinders with non-load sharing plastic liners in compliance with UN/ISO11515: 2013, Type 4. (modes 1, 2, 3).
21137–N	DGM Italia Srl	172.101(j)	To authorize the transportation in commerce of lithium ion batteries exceeding 35 kg by cargo-only aircraft. (mode 4).

[FR Doc. 2020–24991 Filed 11–10–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Fiscal Service

Bureau of the Fiscal Service; Notice of Rate To Be Used for Federal Debt Collection, and Discount and Rebate Evaluation

AGENCY: Bureau of the Fiscal Service, Fiscal Service, Treasury.

ACTION: Notice of rate to be used for Federal debt collection, and discount and rebate evaluation.

SUMMARY: The Secretary of the Treasury is responsible for computing and publishing the percentage rate that is used in assessing interest charges for outstanding debts owed to the Government (The Debt Collection Act of 1982, as amended). This rate is also used by agencies as a comparison point in evaluating the cost-effectiveness of a cash discount. In addition, this rate is used in determining when agencies should pay purchase card invoices when the card issuer offers a rebate. Notice is hereby given that the applicable rate for calendar year 2021 is 1.00 percent.

DATES: January 1, 2021 through December 31, 2021

FOR FURTHER INFORMATION CONTACT: Department of the Treasury, Bureau of the Fiscal Service, Payment Management, E-Commerce Division (LC–RM 349B), 3201 Pennsy Drive, Building E, Landover, MD 20785 (Telephone: 202–874–9428).

SUPPLEMENTARY INFORMATION: The rate reflects the current value of funds to the Treasury for use in connection with Federal Cash Management systems and is based on investment rates set for purposes of Public Law 95–147, 91 Stat. 1227 (October 28, 1977). Computed each year by averaging Treasury Tax and Loan (TT&L) investment rates for the 12-month period ending every September 30, rounded to the nearest whole percentage, for applicability effective each January 1. Quarterly revisions are made if the annual average, on a moving basis, changes by 2 percentage points. The rate for calendar year 2021 reflects the average investment rates for the 12-month period that ended September 30, 2020.

Authority: 31 U.S.C. Section 3717.

Ronda L. Kent,

Assistant Commissioner, Payment Management and Chief Disbursing Officer.

[FR Doc. 2020–25018 Filed 11–10–20; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Exempt Organization Forms: 990, 990–BL, 990–EZ, 990–N, 990–PF, 990–T, 990–W, 990 SCH E, 990 SCH I, 990 SCH M, 990 SCH D, 990 SCH F, 990 SCH H, 990 SCH J, 990 SCH K, 990 SCH R, 990/990–EZ SCH A, 990/990–EZ SCH C, 990/990–EZ SCH G, 990/990–EZ SCH L, 990/990–EZ SCH N, 990/990–EZ SCH O, 990/990–EZ/990–PF SCH B, 1023, 1023–EZ, 1023-Interactive, 1024, 1024–A, 1028, 1120–POL, 4720, 5578, 5884–C, 6069, 6497, 8038, 8038–B, 8038–CP, 8038–G, 8038–GC, 8038–R, 8038–T, 8038–TC, 8282, 8328, 8330, 8453–E.O., 8453–X, 8718, 8868, 8870, 8871, 8872, 8879–E.O., 8886–T, 8899, and Related Attachments

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 proposed and continuing information collections, as required by the Paperwork Reduction Act of 1995 (PRA). This notice requests comments on all forms used by tax-exempt organizations: Forms 990, 990–BL, 990–EZ, 990–N, 990–PF, 990–T, 990–W, 990 SCH E, 990 SCH I, 990 SCH M, 990 SCH D, 990 SCH F, 990 SCH H, 990 SCH J, 990 SCH K, 990 SCH R, 990/990–EZ SCH A, 990/990–EZ SCH C, 990/990–EZ SCH G, 990/990–EZ SCH L, 990/990–EZ SCH N, 990/990–EZ SCH O, 990/990–EZ/990–PF SCH B, 1023, 1023–EZ, 1023-Interactive, 1024, 1024–A, 1028, 1120–POL, 4720, 5578, 5884–C, 6069, 6497, 8038, 8038–B, 8038–CP, 8038–G, 8038–GC, 8038–R, 8038–T, 8038–TC, 8282, 8328, 8330, 8453–E.O., 8453–X, 8718, 8868, 8870, 8871, 8872, 8879–E.O., 8886–T, 8899 related and all attachments to these forms (see the Appendix-A to this notice). With this notice, the IRS is also announcing significant changes to (1) the manner in which tax forms used by tax-exempt organizations will be approved under the PRA and (2) its method of estimating the paperwork burden imposed on all tax-exempt organizations.

DATES: Written comments should be received on or before January 11, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha Brinson, at (202) 317–5753, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION: *Related Internal Revenue Service and the Department of Treasury Guidance:*

Pub 1075, EE–111–80 (TD 8019—Final) Public Inspection of Exempt Organization Return

TD 8033 (TEMP) Tax Exempt Entity Leasing (REG–209274–85)

Revenue Procedure 98–19, Exceptions to the notice and reporting requirements of section 6033(e)(1) and the tax imposed by section 6033(e)(2)

REG–246256–96 (Final TD 8978) Excise Taxes on Excess Benefit Transactions

T.D. 8861, Private Foundation Disclosure Rules

Notice 2006–109—Interim Guidance Regarding Supporting Organizations and Donor Advised Funds
Disclosure by taxable party to the tax-exempt entity
Reinstatement and Retroactive Reinstatement for Reasonable Cause (Rev. Proc. 2014–11) and Transitional Relief for Small Organizations (Notice 2011–43) under IRC § 6033(j)
TD 8086—Election for $10 Million Limitation on Exempt Small Issues of Industrial Development Bonds; Supplemental Capital Expenditure Statements (LR–185–84 Final)
Arbitrage Restrictions and Guidance on Issue Price Definition for Tax Exempt Bonds
TD 8712 (Final), Definition of Private Activity Bonds; TD 9741, General Allocation and Accounting Regulations Under Section 141; Remedial Actions for Tax-Exempt Bonds
FI–28–96 (Final) Arbitrage Restrictions on Tax-Exempt Bonds
REG–121475–03 (TD 9495-Final) Qualified Zone Academy Bonds: Obligations of States and Political Subdivisions
Notice 2009–26, Build America Bonds and Direct Payment Subsidy Implementation
Notice 2012–48: Tribal Economic Development Bonds
TD 7925 7952—Indian Tribal Governments Treated As States For Certain Purposes
Revenue Procedure 97–15, Section 103—Remedial Payment Closing Agreement Program
T.D. 8802—Certain Asset Transfers to a Tax-Exempt Entity
TD 7852—Registration Requirements with Respect to Debt Obligations (NPRM, LR–255–82)
Notice 2007–70—Charitable Contributions of Certain Motor Vehicles, Boats, and Airplanes. Reporting requirements under Sec. 170(f)(12)(D)
TD 8124—Time and Manner of Making Certain Elections Under the Tax Reform Act of 1986
Publication 1075 Tax Information Security Guidelines for Federal, State and Local Agencies

Today, over 70 percent of all tax-exempt organization returns other than Form 990–N and all Forms 990–N are prepared using software by the taxpayer or with preparer assistance.

These are forms used by tax-exempt organizations taxpayers. These include Forms *990, 990–PF, 990–N, and 990–T,* and related schedules tax-exempt organizations attach to their tax returns (see Appendix-A to this notice). In addition, there are numerous regulations, notices and Treasury Decisions that are covered by the burden estimate provided in this notice. (See Appendix B for a list).

Taxpayer Compliance Burden

Tax compliance burden is defined as the time and money taxpayers spend to comply with their tax filing responsibilities. Time-related activities include recordkeeping, tax planning, gathering tax materials, learning about the law and what you need to do, and completing and submitting the return. Out-of-pocket costs include expenses such as purchasing tax software, paying a third-party preparer, and printing and postage. Tax compliance burden does not include a taxpayer's tax liability, economic inefficiencies caused by sub-optimal choices related to tax deductions or credits, or psychological costs.

Proposed PRA Submission to OMB

Title: Returns of Organization Exempt from Income Tax Under Section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code.

OMB Number: 1545–0047.

Form Numbers: Forms 990, 990–EZ, 990–PF, 990–N, 990–T and all attachments to these forms and related forms (see the Appendix-A to this notice).

Abstract: OMB number 1545–0047 reports the estimated burden incurred by tax-exempt organizations to meet their tax-compliance-related reporting requirements. The estimate is preliminary and reflects only the change in burden related to technical adjustments related to updating the number of affected taxpayers to reflect the FY2020 forecast.

Current Actions: There have been changes in regulatory guidance related to various forms approved under this approval package during the past year. There has been additions and removals of forms included in this approval package. It is anticipated that these changes will have an impact on the overall burden and cost estimates requested for this approval package, however these estimates were not finalized at the time of release of this notice. These estimated figures are expected to be available by the release of the 30-comment notice from Treasury. This approval package is being submitted for renewal purposes only.

Affected Public: Tax-Exempt Organizations.

Estimated Number of Respondents: 1,606,200.

Total Estimated Time: 52.45 million hours.

Estimated Time per Respondent: 32.7 hours.

Total Estimated Out-of-Pocket Costs: $1.50 billion.

Estimated Out-of-Pocket Cost per Respondent: $932.

Total Estimated Monetized Burden: $4.17 billion.

Estimated Total Monetized Burden per Respondent: $2,595.

Note: Amounts below are for FY2021. Reported time and cost burdens are national averages and do not necessarily reflect a ''typical'' case. Most taxpayers experience lower than average burden, with taxpayer burden varying considerably by taxpayer type. Detail may not add due to rounding.

FISCAL YEAR 2021 ICB ESTIMATES FOR FORM 990 SERIES OF RETURNS AND RELATED FORMS AND SCHEDULES

	FY 20		FY 21
Number of Taxpayers	1,413,200	193,000	1,606,200
Burden in Hours	50,450,000	2,000,000	52,450,000
Burden in Dollars	1,297,300,000	199,200,000	1,496,500,000
Monetized Total Burden	3,594,400,000	422,600,000	4,017,000,000

Note: FY: 21 is most recent approved burden estimates for OMB number—1545–0047.

FISCAL YEAR 2020 FORM 990 SERIES TAX COMPLIANCE COST ESTIMATES

	Form 990	Form 990–EZ	Form 990–PF	Form 990–T	Form 990–N
Projections of the Number of Returns to be Filed with IRS	315,762	232,345	118,192	198,798	741,133
Estimated Average Total Time (Hours)	85	45	47	40	2

FISCAL YEAR 2020 FORM 990 SERIES TAX COMPLIANCE COST ESTIMATES—Continued

	Form 990	Form 990–EZ	Form 990–PF	Form 990–T	Form 990–N
Estimated Average Total Out-of-Pocket Costs	$2,600	$500	$2,000	$1,500	$10
Estimated Average Total Monetized Burden	$8,000	$1,200	$3,900	$4,400	$30
Estimated Total Time (Hours)	26,760,000	10,500,000	5,510,000	8,040,000	1,630,000
Estimated Total Out-of-Pocket Costs (*Note.* Totals may not add due to rounding.)	$835,700,000	$127,500,000	$236,200,000	$290,300,000	$6,800,000

Note. Amounts above are for FY2020. Reported time and cost burdens are national averages and don't necessarily reflect a ''typical'' case. Most taxpayers experience lower than average burden, with taxpayer burden varying considerably by taxpayer type. Detail may not add due to rounding.

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 as long as 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 will 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: November 6, 2020.

Martha R. Brinson,

IRS Tax Analyst.

Appendix-A

Number	Title	Description
990		Return of Organization Exempt From Income Tax.
990	BL	Information and Initial Excise Tax Return for Black Lung Benefit Trusts and Certain Related Persons.
990	EZ	Short Form Return of Organization Exempt From Income Tax.
990	N	Electronic Notice (e-Postcard) for Tax-Exempt Organizations Not Required to File Form 990 or Form 990EZ.
990	PF	Return of Private Foundation or Section 4947(a)(1) Trust Treated as Private Foundation.
990	T	Exempt Organization Business Income Tax Return and Proxy Tax.
990	W	Estimated Tax on Unrelated Business Taxable Income for Tax-Exempt Organizations.
990	990–EZ, 990–PF SCH B	Schedule of Contributors.
990	OR 990–EZ SCH A	Public Charity Status and Public Support.
990	OR 990–EZ SCH C	Political Campaign and Lobbying Activities.
990	OR 990–EZ SCH E	Schools.
990	OR 990–EZ SCH G	Supplemental Information Regarding Fundraising or Gaming Activities.
990	OR 990–EZ SCH L	Transactions With Interested Persons.
990	OR 990–EZ SCH N	Liquidation, Termination, Dissolution, or Significant Disposition of Assets.
990	OR 990–EZ SCH O	Supplemental Information to Form 990 or 990–EZ.
990	SCH D	Supplemental Financial Statements.
990	SCH F	Statement of Activities Outside the United States.
990	SCH H	Hospitals.
990	SCH I	Grants and Other Assistance to Organizations, Governments, and Individuals in the United States.
990	SCH J	Compensation Information.
990	SCH K	Supplemental Information on Tax-Exempt Bonds.
990	SCH M	Noncash Contributions.
990	SCH R	Related Organizations and Unrelated Partnerships.
1023		Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code.
1023	EZ	Streamlined Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code.
1023	I	Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code.
1024		Application for Recognition of Exemption Under Section 501(a).
1024	A	Application for Recognition of Exemption Under Section 501(c)(4) of the Internal Revenue Code.
1028		Application for Recognition of Exemption Under Section 521 of the Internal Revenue Code.
1120	POL	U.S. Income Tax Return for Certain Political Organizations.
4720		Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code.
5578		Annual Certification of Racial Nondiscrimination for a Private School Exempt From Federal Income Tax.
5884	C	Work Opportunity Credit for Qualified Tax-Exempt Organizations Hiring Qualified Veterans.
6069		Return of Excise Tax on Excess Contributions to Black Lung Benefit Trust Under Section 4953 and Computation of Section 192 Deduction
6497		Information Return of Nontaxable Energy Grants or Subsidized Energy Financing.
8038		Information Return for Tax-Exempt Private Activity Bond Issues.

Number	Title	Description
8038	B	Information Return for Build America Bonds and Recovery Zone Economic Development Bonds.
8038	CP	Return for Credit Payments to Issuers of Qualified Bonds.
8038	G	Information Return for Government Purpose Tax-Exempt Bond Issues.
8038	GC	Consolidated Information Return for Small Tax-Exempt Government Bond Issues.
8038	R	Request for Recovery of Overpayment Under Arbitrage Rebate Provisions.
8038	T	Arbitrage Rebate and Penalty in Lieu of Arbitrage Rebate.
8038	TC	Information Return for Tax Credit and Specified Tax Credit Bonds as the result of the new Hire bill.
8282		Donee Information Return.
8328		Carry forward Election of Unused Private Activity Bond Volume.
8330		Issuer's Quarterly Information Return for Mortgage Credit Certificates (MCCs).
8453	EO	Exempt Organization Declaration and Signature for Electronic Filing.
8453	X	Political Organization Declaration for Electronic Filing of Notice of Section 527 Status.
8718		User Fee for Exempt Organization Determination Letter Request.
8868		Application for Automatic Extension of Time To File an Exempt Organization Return.
8870		Information Return for Transfers Associated With Certain Personal Benefit Contracts.
8871		Political Organization Notice of Section 527 Status.
8872		Political Organization Report of Contributions and Expenditures.
8879	EO	IRS e-file Signature Authorization for an Exempt Organization.
8886	T	Disclosure by Tax-Exempt Entity Regarding Prohibited Tax Shelter Transaction.
8899		Notice of Income From Donated Intellectual Property.

Appendix-B

Title/Description

EE–111–80 (TD 8019—Final) Public Inspection of Exempt Organization Return

TD 8033 (TEMP) Tax Exempt Entity Leasing (REG–209274–85)

Revenue Procedure 98–19, Exceptions to the notice and reporting requirements of section 6033(e)(1) and the tax imposed by section 6033(e)(2)

REG–246256–96 (Final TD 8978) Excise Taxes on Excess Benefit Transactions

T.D. 8861, Private Foundation Disclosure Rules

Notice 2006–109—Interim Guidance Regarding Supporting Organizations and Donor Advised Funds

Disclosure by taxable party to the tax-exempt entity

Reinstatement and Retroactive Reinstatement for Reasonable Cause (Rev. Proc. 2014–11) and Transitional Relief for Small Organizations (Notice 2011–43) under IRC § 6033(j)

TD 8086—Election for $10 Million Limitation on Exempt Small Issues of Industrial Development Bonds; Supplemental Capital Expenditure Statements (LR–185–84 Final)

Arbitrage Restrictions and Guidance on Issue Price Definition for Tax Exempt Bonds

TD 8712 (Final), Definition of Private Activity Bonds; TD 9741, General Allocation and Accounting Regulations Under Section 141; Remedial Actions for Tax-Exempt Bonds

FI–28–96 (Final) Arbitrage Restrictions on Tax-Exempt Bonds

REG–121475–03 (TD 9495-Final) Qualified Zone Academy Bonds: Obligations of States and Political Subdivisions

Notice 2009–26, Build America Bonds and Direct Payment Subsidy Implementation

Notice 2012–48: Tribal Economic Development Bonds

TD 7925—Indian Tribal Governments Treated As States For Certain Purposes

Revenue Procedure 97–15, Section 103—Remedial Payment Closing Agreement Program

T.D. 8802—Certain Asset Transfers to a Tax-Exempt Entity

TD 7852—Registration Requirements with Respect to Debt Obligations (NPRM, LR–255–82)

Notice 2007–70—Charitable Contributions of Certain Motor Vehicles, Boats, and Airplanes. Reporting requirements under Sec. 170(f)(12)(D)

TD 8124—Time and Manner of Making Certain Elections Under the Tax Reform Act of 1986

Publication 1075 Tax Information Security Guidelines for Federal, State and Local Agencies

[FR Doc. 2020–25012 Filed 11–10–20; 8:45 am]

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FEDERAL REGISTER

Vol. 85 Thursday,

No. 219 November 12, 2020

Part II

Department of the Treasury

Internal Revenue Service

26 CFR Parts 1 and 301

Guidance Related to the Allocation and Apportionment of Deductions and Foreign Taxes, Foreign Tax Redeterminations, Foreign Tax Credit Disallowance Under Section 965(g), Consolidated Groups, Hybrid Arrangements and Certain Payments Under Section 951A; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[TD 9922]

RIN 1545–BP21; 1545–BP22

Guidance Related to the Allocation and Apportionment of Deductions and Foreign Taxes, Foreign Tax Redeterminations, Foreign Tax Credit Disallowance Under Section 965(g), Consolidated Groups, Hybrid Arrangements and Certain Payments Under Section 951A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations that provide guidance relating to the allocation and apportionment of deductions and creditable foreign taxes, the definition of financial services income, foreign tax redeterminations, availability of foreign tax credits under the transition tax, the application of the foreign tax credit limitation to consolidated groups, adjustments to hybrid deduction accounts to take into account certain inclusions in income by a United States shareholder, conduit financing arrangements involving hybrid instruments, and the treatment of certain payments under the global intangible low-taxed income provisions.

DATES: *Effective Date:* These regulations are effective on January 11, 2021.

Applicability Dates: For dates of applicability, see §§ 1.245A(e)–1(h)(2), 1.704–1(b)(1)(ii)(*b*)(*1*), 1.861–8(h), 1.861–9(k), 1.861–12(k), 1.861–14(k), 1.861–17(h), 1.861–20(i), 1.881–3(f), 1.904–4(q), 1.904–6(g), 1.904(b)–3(f), 1.904(g)–3(l), 1.905–3(d), 1.905–4(f), 1.905–5(f), 1.951A–7(d), 1.954–1(h), 1.954–2(i), 1.960–7, 1.965–9, 1.1502–4(f), and 301.6689–1(e).

FOR FURTHER INFORMATION CONTACT: Concerning § 1.245A(e)–1, Andrew L. Wigmore, (202) 317–5443; concerning §§ 1.861–8, 1.861–9(b), 1.861–12, 1.861–14, 1.861–17, and 1.954–2(h), Jeffrey P. Cowan, (202) 317–4924; concerning §§ 1.704–1, 1.861–9(e), 1.904–4(e), 1.904(b)–3, 1.904(g)–3, 1.1502–4, and 1.1502–21, Jeffrey L. Parry, (202) 317–4916; concerning §§ 1.861–20, 1.904–4(c), 1.904–6, 1.960–1, and 1.960–7, Suzanne M. Walsh, (202) 317–4908; concerning § 1.881–3, Richard F. Owens, (202) 317–6501; concerning §§ 1.965–5 and 1.965–9, Karen J. Cate, (202) 317–4667; concerning §§ 1.905–3, 1.905–4, 1.905–5, 1.954–1, 301.6227–1, and 301.6689–1, Corina Braun, (202) 317–5004; concerning § 1.951A–2, Jorge M. Oben, at (202) 317–6934 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

I. Rules Relating to Foreign Tax Credits

On December 7, 2018, the Department of the Treasury (the ''Treasury Department'') and the IRS published proposed regulations (REG–105600–18) relating to foreign tax credits in the **Federal Register** (83 FR 63200) (the ''2018 FTC proposed regulations''). The 2018 FTC proposed regulations addressed several significant changes that the Tax Cuts and Jobs Act (Pub. L. 115–97, 131 Stat. 2054, 2208 (2017)) (the ''TCJA'') made with respect to the foreign tax credit rules and related rules for allocating and apportioning deductions in determining the foreign tax credit limitation. Certain provisions of the 2018 FTC proposed regulations relating to §§ 1.78–1, 1.861–12(c)(2), and 1.965–7 were finalized as part of TD 9866, published in the **Federal Register** (84 FR 29288) on June 21, 2019.

The remainder of the 2018 FTC proposed regulations were finalized on December 17, 2019 in TD 9882, published in the **Federal Register** (84 FR 69022) (the ''2019 FTC final regulations''). On the same date, the Treasury Department and the IRS published proposed regulations (REG–105495–19) relating to foreign tax credits in the **Federal Register** (84 FR 69124) (the ''2019 FTC proposed regulations''). The 2019 FTC proposed regulations related to changes made by the TCJA and other foreign tax credit issues. Correcting amendments to the 2019 FTC final regulations and the 2019 FTC proposed regulations were published in the **Federal Register** on May 15, 2020, see 85 FR 29323 (2019 FTC final regulations) and 85 FR 29368 (2019 FTC proposed regulations). A public hearing on the proposed regulations was held on May 20, 2020.

On November 7, 2007, the **Federal Register** published temporary regulations (TD 9362) at 72 FR 62771 and a notice of proposed rulemaking by cross-reference to the temporary regulations at 72 FR 62805 relating to sections 905(c), 986(a), and 6689 of the Internal Revenue Code (''Code''). Portions of these temporary regulations were finalized in the 2019 FTC final regulations, while certain portions were reproposed in the 2019 FTC proposed regulations.

This document contains final regulations (the ''final regulations'') addressing the following issues: (1) The allocation and apportionment of deductions under sections 861 through 865, including rules on the allocation and apportionment of expenditures for research and experimentation (''R&E''), stewardship, legal damages, and certain deductions of life insurance companies; (2) the allocation and apportionment of foreign income taxes; (3) the interaction of the branch loss and dual consolidated loss recapture rules with section 904(f) and (g); (4) the effect of foreign tax redeterminations of foreign corporations, including for purposes of the application of the high-tax exception described in section 954(b)(4) (and for purposes of determining tested income under section 951A(c)(2)(A)(i)(III)), and required notifications under section 905(c) to the IRS of foreign tax redeterminations and related penalty provisions; (5) the definition of foreign personal holding company income under section 954; (6) the application of the foreign tax credit disallowance under section 965(g); and (7) the application of the foreign tax credit limitation to consolidated groups.

II. Rules Relating to Hybrid Deduction Accounts, Hybrid Instruments Used in Conduit Financing Arrangements, and Certain Payments Under Section 951A

On December 28, 2018, the Treasury Department and the IRS published proposed regulations (REG–104352–18) relating to hybrid arrangements, including hybrid arrangements to which section 245A(e) applies, in the **Federal Register** (83 FR 67612) (the ''2018 hybrids proposed regulations''). Those regulations were finalized as part of TD 9896, published in the **Federal Register** (85 FR 19802) on April 8, 2020 (the ''2020 hybrids final regulations''). On the same date, the Treasury Department and the IRS published proposed regulations (REG–106013–19) in the **Federal Register** (85 FR 19858) (the ''2020 hybrids proposed regulations''). Correcting amendments to the 2020 hybrids final regulations and the 2020 hybrids proposed regulations were published in the **Federal Register** on August 4, 2020, August 11, 2020, and August 12, 2020. See 85 FR 47027 (2020 hybrids final regulations), 85 FR 48485 (2020 hybrids proposed regulations), and 85 FR 48651 (2020 hybrids final regulations).

The 2020 hybrids proposed regulations address hybrid deduction accounts under section 245A(e), hybrid instruments used in conduit financing arrangements under section 881, and certain payments under section 951A (relating to global intangible low-taxed income). The Treasury Department and

the IRS received written comments with respect to the 2020 hybrids proposed regulations. All written comments received in response to the 2020 hybrids proposed regulations are available at *www.regulations.gov* or upon request. A public hearing on the 2020 hybrids proposed regulations was not held because there were no requests to speak.

This document contains final regulations addressing the following issues: (1) The reduction to a hybrid deduction account under section 245A(e) by reason of an amount included in the gross income of a domestic corporation under section 951(a) or 951A(a) with respect to a controlled foreign corporation (''CFC''); (2) the treatment of a hybrid instrument as a financing transaction for purposes of the conduit financing rules under section 881; and (3) the treatment under section 951A of certain prepayments made to a related CFC after December 31, 2017, and before the CFC's first taxable year beginning after December 31, 2017.

III. Scope of Provisions and Comments Discussed in This Preamble

This rulemaking finalizes, without substantive change, certain provisions in the 2019 FTC proposed regulations and the 2020 hybrids proposed regulations with respect to which the Treasury Department and IRS did not receive any comments. See, for example, § 1.904(b)–3, § 1.904(g)–3, § 1.951A–2(c)(6), § 1.951A–7(d), § 1.1502–4, or § 301.6689–1. These provisions are generally not discussed in this preamble.

Comments received that do not pertain to the 2019 FTC proposed regulations or the 2020 hybrids proposed regulations, or that are otherwise outside the scope of this rulemaking, are generally not addressed in this preamble but may be considered in connection with future guidance projects.

Summary of Comments and Explanation of Revisions

I. Rules Under Section 245A(e) To Reduce Hybrid Deduction Accounts

A. Overview

Section 245A(e) was added to the Code by the TCJA. Section 245A(e) and the 2020 hybrids final regulations neutralize the double non-taxation effects of a hybrid dividend or tiered hybrid dividend by either denying the section 245A(a) dividends received deduction with respect to the dividend or requiring an inclusion under section 951(a)(1)(A) with respect to the dividend, depending on whether the dividend is received by a domestic corporation or a CFC. The 2020 hybrids final regulations require that certain shareholders of a CFC maintain a hybrid deduction account with respect to each share of stock of the CFC that the shareholder owns, and provide that a dividend received by the shareholder from the CFC is a hybrid dividend or tiered hybrid dividend to the extent of the sum of those accounts. A hybrid deduction account with respect to a share of stock of a CFC reflects the amount of hybrid deductions of the CFC that have been allocated to the share, reduced by the amount of hybrid deductions that gave rise to a hybrid dividend or tiered hybrid dividend.

The 2020 hybrids proposed regulations generally reduced a hybrid deduction account with respect to a share of stock of a CFC by three categories of amounts included in the gross income of a domestic corporation with respect to the share, including an ''adjusted subpart F inclusion'' or an ''adjusted GILTI inclusion'' with respect to the share. See proposed § 1.245A(e)–1(d)(4)(i)(B)(*1*) and (*2*). An adjusted subpart F inclusion or an adjusted GILTI inclusion with respect to a share is intended to measure, in an administrable manner, the extent to which a domestic corporation's inclusion under section 951(a)(1)(A) (''subpart F inclusion'') or inclusion under section 951A (''GILTI inclusion amount'') attributable to the share is likely ''included in income'' in the United States—that is, taken into account in income and not offset by, for example, foreign tax credits associated with the inclusion and, in the case of a GILTI inclusion amount, the deduction under section 250(a)(1)(B).

The final regulations retain the basic approach and structure of the 2020 hybrids proposed regulations that reduced hybrid deduction accounts, with certain revisions. Part I.B of this Summary of Comments and Explanation of Revisions discusses the revisions as well as comments received that relate to these rules.

B. Computation of Adjusted Subpart F Income Inclusion and Adjusted GILTI Inclusion

1. In General

Comments suggested several refinements or clarifications to the computation of an adjusted subpart F inclusion or adjusted GILTI inclusion with respect to a share of stock of a CFC, generally so that the adjusted subpart F inclusion or adjusted GILTI inclusion more closely reflects the extent that the subpart F inclusion or GILTI inclusion amount is in fact included in income in the United States.

2. Section 904 Limitation

Under the 2020 hybrids proposed regulations, an adjusted subpart F inclusion or adjusted GILTI inclusion with respect to a share of stock is computed by taking into account foreign income taxes that, as a result of the application of section 960(a) or (d), are likely to give rise to deemed paid credits eligible to be claimed by the domestic corporation with respect to the subpart F inclusion or adjusted GILTI inclusion. See proposed § 1.245A(e)–1(d)(4)(ii)(A) and (B). To minimize complexity, the 2020 hybrids proposed regulations did not take into account any limitations on foreign tax credits when computing foreign income taxes that are likely to give rise to deemed paid credits. See proposed § 1.245A(e)–1(d)(4)(ii)(D). A comment suggested that the final regulations take into account the limitation under section 904.

The Treasury Department and the IRS agree with the comment for computing an adjusted GILTI inclusion. Foreign income taxes that by reason of section 904 do not currently give rise to deemed paid credits eligible to be claimed with respect to the GILTI inclusion amount are not creditable in another year through a carryback or carryover. See section 904(c). Thus, there is generally no ability for such excess foreign income taxes to reduce the extent that an amount taken into account in income by the domestic corporation is included in income in the United States. The final regulations therefore provide that such foreign income taxes are not taken into account when computing an adjusted GILTI inclusion. See § 1.245A(e)–1(d)(4)(ii)(D)(*2*)(*iii*) and (G). If the application of this rule results in circularity or ordering rule issues, a taxpayer may, solely for purposes of computing the adjusted GILTI inclusion, apply any reasonable method to compute the amount of foreign income taxes the creditability of which is limited by section 904.[1]

[1] For example, in certain cases the section 904 limitation may be affected by the extent to which section 245A(e) applies to a dividend paid by the CFC (in particular, in connection with allocating and apportioning deductions under §§ 1.861–8 through 1.861–20); the application of section 245A(e) to the dividend may depend on the extent to which a hybrid deduction account is reduced by reason of an adjusted GILTI inclusion; and the adjusted GILTI inclusion may in turn depend on the section 904 limitation. In such a case, to avoid circularity issues, a taxpayer may compute the section 904 limitation for purposes of determining the adjusted GILTI inclusion by, for instance, using simultaneous equations, or applying an ordering rule pursuant to which, solely for purposes of

Continued

The final regulations do not adopt a similar rule for computing an adjusted subpart F inclusion. This is because foreign income taxes that by reason of section 904 do not currently give rise to deemed paid credits eligible to be claimed with respect to the subpart F inclusion may become creditable in another year under section 904(c). Consequently, for example, the foreign income taxes could in a later year reduce the extent that an amount is included in income in the United States, and could thus inappropriately result in an outcome similar to the one that would have occurred had the foreign income taxes given rise to deemed paid credits in the year of the subpart F inclusion and thereby reduced the extent that the subpart F inclusion was subject to tax in the United States at the full statutory rate. The Treasury Department and the IRS have determined that special rules to prevent such results would be complex or burdensome as they would require, for instance, tracking the creditability of the foreign income taxes over prior or later years (potentially through a 10-year period), and then adjusting the hybrid deduction account as the foreign income taxes become creditable.

3. Section 250 Deduction

Under the 2020 hybrids proposed regulations, an adjusted GILTI inclusion is computed by taking into account the portion of the deduction allowed under section 250 by reason of section 250(a)(1)(B) that the domestic corporation is likely to claim with respect to the GILTI inclusion amount. See proposed § 1.245A(e)–1(d)(4)(ii)(B). The 2020 hybrids proposed regulations did not take into account any limitations on the deduction under section 250(a)(2)(B). See id. A comment suggested that the final regulations take into account the taxable income limitation under section 250(a)(2).

The Treasury Department and the IRS agree with the comment, because taking into account the taxable income limitation results in an adjusted GILTI inclusion that more closely reflects the extent to which the GILTI inclusion amount is included in income in the United States. The final regulations thus provide a rule to this effect. See § 1.245A(e)–1(d)(4)(ii)(B) and (H). Similar to the rule discussed in Part I.B.2 of this Summary of Comments and Explanation of Revisions (related to the section 904 limitation), a taxpayer may, solely for purposes of computing an adjusted GILTI inclusion, apply any reasonable method to compute the extent to which the portion of a deduction allowed under section 250 by reason of section 250(a)(1)(B) is limited under section 250(a)(2)(B).

4. Limit on Reduction of a Hybrid Deduction Account

The 2020 hybrids proposed regulations provided a limit to ensure that an adjusted subpart F inclusion or adjusted GILTI inclusion with respect to a share of stock of a CFC does not reduce the hybrid deduction account by an amount greater than the hybrid deductions allocated to the share for the taxable year multiplied by a fraction, the numerator of which is the subpart F income or tested income, as applicable, of the CFC for the taxable year and the denominator of which is the CFC's taxable income. See proposed § 1.245A(e)–1(d)(4)(i)(B)(*1*)(*ii*) and (d)(4)(i)(B)(*2*)(*ii*). In cases in which the CFC's taxable income is zero or negative, the 2020 hybrids proposed regulations prevented distortions to the fraction—which would otherwise occur because the fraction would involve dividing by zero or a negative number—by providing that the fraction is considered to be zero. See proposed § 1.245A(e)–1(d)(4)(i)(B)(*1*)(*ii*) and (d)(4)(i)(B)(*2*)(*ii*).

Distortions to the fraction could also occur if the CFC's taxable income is greater than zero but less than its subpart F income or tested income (due to losses in one category of income) because, absent a rule to address, the fraction would be greater than one. The final regulations eliminate these distortions by modifying the fraction so that the numerator and denominator only reflect items of gross income. See § 1.245A(e)–1(d)(4)(i)(B)(*1*)(*ii*) and (d)(4)(i)(B)(*2*)(*ii*).

5. Clarifications

Comments recommended that the final regulations clarify whether an adjusted subpart F inclusion or adjusted GILTI inclusion can be negative and result in an increase to the hybrid deduction account (that is, whether the hybrid deduction account can be reduced by a negative amount). The final regulations clarify that an adjusted subpart F inclusion or adjusted GILTI inclusion cannot be negative and thus cannot result in an increase to the hybrid deduction account. See § 1.245A(e)–1(d)(4)(ii)(A) and (B).

A comment also recommended that the final regulations clarify whether the computation of an adjusted subpart F inclusion takes into account an amount that the domestic corporation includes in gross income by reason of section 964(e)(4). As noted in the comment, an amount that the domestic corporation includes in gross income by reason of section 964(e)(4) is in many cases offset by a 100 percent dividends received deduction under section 245A(a), and thus no portion of the amount is included in income in the United States (that is, taken into account in income and not offset by a deduction or credit particular to the inclusion). The final regulations clarify that the computation of an adjusted subpart F inclusion does not take into account an amount that a domestic corporation includes in gross income by reason of section 964(e)(4), to the extent that a deduction under section 245A(a) is allowed for the amount. See § 1.245A(e)–1(d)(4)(ii)(A).

6. Comments Outside the Scope of the 2020 Hybrids Proposed Regulations

In response to a comment, the 2020 hybrids final regulations clarified that a deduction or other tax benefit may be a hybrid deduction regardless of whether it is used currently under the foreign tax law. See § 1.245A(e)–1(d)(2). The preamble to the 2020 hybrids final regulations explained that even though a deduction or other tax benefit may not be used currently, it could be used in another taxable period and thus could produce double non-taxation. The preamble also noted that it could be complex or burdensome to determine whether a deduction or other tax benefit is used currently and, to the extent not used currently, to track the deduction or other tax benefit and add it to the hybrid deduction account if it is in fact used.

Comments submitted with respect to the 2020 hybrids proposed regulations raised additional issues involving the extent to which a hybrid deduction account should be adjusted based on the availability-for-use of a deduction or other tax benefit under the foreign tax law. These issues include the extent to which (or the mechanism by which) a hybrid deduction account should be adjusted when a deduction or other tax benefit reflected in the account is subsequently disallowed under the foreign tax law (for example, by reason of a foreign audit) or an economically equivalent adjustment is made under the foreign tax law, or the deduction or other tax benefit expires or otherwise cannot be used under the foreign tax law. The Treasury Department and the IRS are studying these comments, which are outside the scope of the 2020 hybrids proposed regulations, and may address these issues in a future guidance project.

determining the adjusted GILTI inclusion, the section 904 limitation is determined without regard to the application of section 245A(e) (as well as any other provision the application of which depends on the extent to which section 245A(e) applies).

II. Allocation and Apportionment of Deductions and the Calculation of Taxable Income for Purposes of Section 904(a)

A. Stewardship Expenses, Litigation Damages Awards and Settlement Payments, Net Operating Losses, Interest Expense, and Other Expenses

1. Stewardship Expenses

The 2019 FTC proposed regulations made several changes to the rules for allocating and apportioning stewardship expenses, which are generally expenses incurred to oversee a related corporation. Although the 2019 FTC proposed regulations did not change the definition of stewardship expenses, the regulations did provide that expenses incurred with respect to partnerships are treated as stewardship expenses. The 2019 FTC proposed regulations also expanded the types of income to which stewardship expenses are allocated to include not only dividends but also other inclusions received with respect to stock. The 2019 FTC proposed regulations further provided that stewardship expenses are to be apportioned based on the relative values of stock held by a taxpayer, as computed for purposes of allocating and apportioning the taxpayer's interest expense. Additionally, the preamble to the 2019 FTC proposed regulations requested comments regarding how to distinguish stewardship expenses from supportive expenses.

Several comments addressed the definition of stewardship expenses. Some comments recommended that the current regulations' definition be retained without changes. One comment recommended that, because stewardship is among those activities that are not treated as providing a benefit to a related party under the section 482 regulations, such expenses should be treated as supportive expenses. Another recommended that the definition of stewardship expenses be narrowed to apply solely to expenses that result from oversight with respect to foreign subsidiaries or non-affiliated domestic entities. Comments also requested clarification on how to identify and distinguish between stewardship and supportive expenses and sought greater flexibility in identifying stewardship expenses. One comment recommended that further guidance be left to a separate project.

The final regulations generally retain the existing definition of stewardship expenses as either duplicative or shareholder activities as described in § 1.482–9(l)(3)(iii) or (iv). Therefore, stewardship expenses either duplicate an expense incurred by the related entity without providing an additional benefit to that entity or are incurred primarily to protect the taxpayer's investment in another entity or to facilitate the taxpayer's compliance with its own reporting, legal or regulatory requirements. In contrast, supportive expenses are typically incurred in order to enhance the income-producing capabilities of the taxpayer itself, and so are definitely related and allocable to all, or broad classes, of the taxpayer's gross income. See § 1.861–8(b)(3). The fact that expenses attributable to stewardship activities do not provide a benefit to the related party does not mean that the expenses are supportive of all of the taxpayer's income-producing activity. Instead, expenses categorized under §§ 1.861–8(e)(4)(ii) and 1.482–9(l)(3)(iii) and (iv) as stewardship expenses are properly allocated to income generated by the related party (and included in income of the taxpayer as a dividend or other inclusion), rather than to income earned directly by the taxpayer.

Comments recommended that the definition of stewardship expenses be expanded to include expenses incurred with respect to branches and disregarded entities, in addition to corporations and partnerships. The Treasury Department and the IRS agree that stewardship expenses can also be incurred with respect to all business entities (whether foreign or domestic) as described in § 301.7701–2(a) and not only those business entities that are classified as corporations or partnerships for Federal income tax purposes. Therefore, the final regulations at § 1.861–8(e)(4)(ii)(A) provide that stewardship expenses incurred with respect to oversight of disregarded entities are also subject to allocation and apportionment under the rules of § 1.861–8(e)(4). However, the Treasury Department and the IRS have determined that it is inappropriate to extend the definition of stewardship expense to include oversight expenses incurred with respect to an unincorporated branch of the taxpayer, since the branch's income is income of the taxpayer itself, not income of a separate entity in which the taxpayer is protecting its investment, and any reporting, legal or regulatory requirements that apply to an unincorporated branch of the taxpayer apply to the taxpayer itself.

Comments also requested that the final regulations make clear that stewardship expenses can be allocated and apportioned to income and assets of all affiliated and consolidated group members, noting that a portion of the dividends and stock with respect to domestic affiliates may be treated as exempt income or assets under section 864(e)(3) and § 1.861–8(d)(2)(ii) and excluded from the apportionment formula, which could reduce apportionment of expenses to U.S. source income. In response to the comments, the final regulations at § 1.861–8(e)(4)(ii)(A) provide that the affiliated group rules in § 1.861–14 do not apply for purposes of allocating and apportioning stewardship expenses. As a result, stewardship expenses incurred by one member of an affiliated group in order to oversee the activities of another member of the group are allocated and apportioned by the investor taxpayer on a separate entity basis, with reference to the investor's stock in the affiliated member. See § 1.861–8(e)(4)(ii)(A). Furthermore, in response to comments, the final regulations at § 1.861–8(e)(4)(ii)(C) provide that the exempt income and asset rules in section 864(e)(3) and § 1.861–8(d)(2) do not apply for purposes of apportioning stewardship expenses.

Comments were also received regarding the rules for allocating stewardship expenses solely to income arising from the entity for which the stewardship expenses are being incurred in order to protect that investment. One comment argued that the rule in the prior final regulations for allocating stewardship expenses solely to dividend income should be retained and should not be expanded to include inclusions such as those under the GILTI rules. In contrast, another comment agreed with the approach to expand allocation to include shareholder-level inclusions such as GILTI inclusions in light of the changes made by the TCJA.

The Treasury Department and the IRS have determined that allocating stewardship expenses to all types of income derived from ownership of the entity, rather than solely dividend income, is appropriate because dividends do not fully capture all of the statutory and residual groupings to which income from stock is assigned. Limiting the allocation of stewardship expenses only to dividends would preclude allocation to stock in a CFC or passive foreign investment company (''PFIC'') whose income gave rise only to subpart F, GILTI, or PFIC inclusions, even if the expense clearly relates to overseeing activities that generate income in the CFC or PFIC that give rise to such inclusions. Therefore, the Treasury Department and IRS agree with the comment supporting the expansion of stewardship expense allocation in

proposed § 1.861–8(e)(4)(ii)(B) to include shareholder-level inclusions.

One comment recommended adding dividends eligible for a section 245A deduction to the list of income inclusions to which stewardship expenses are allocable. The existing regulations are already clear, however, that stewardship expenses are allocable to dividends. This allocation is not affected by the fact that dividends may qualify for the deduction under section 245A, which does not convert the dividends into exempt or excluded income for purposes of allocating and apportioning deductions. See § 1.861–8(d)(2)(iii)(C). To the extent that stewardship expense is allocated and apportioned to dividend income in the section 245A subgroup, section 904(b)(4) requires certain adjustments to the taxpayer's foreign source taxable income and entire taxable income for purposes of computing the applicable foreign tax credit limitation. Accordingly, the final regulations are not modified in response to the comment.

In response to a request for comments in the 2019 FTC proposed regulations on possible exceptions to the general rule for the allocation and apportionment of stewardship expenses, several comments recommended allowing taxpayers to show that stewardship expense factually relates only to the relevant income of a specific income-producing entity or entities. The Treasury Department and the IRS agree that stewardship expenses may be factually related to the taxpayer's ownership of a specific entity (or entities) and should not be allocated and apportioned to the income derived from all entities in a group without taking into account the factual connection between the stewardship expense and the entity being overseen. Accordingly, the final regulations at § 1.861–8(e)(4)(ii)(B) clarify that at the allocation step (but before applying the apportionment rules), only the gross income derived from entities to which the taxpayer's stewardship expense has a factual connection are included and, in such cases, the apportionment rule applies based on the tax book value of the taxpayer's investment in those particular entities. This approach recognizes that stewardship activities are not fungible in the same manner as interest expense.

With respect to the apportionment of stewardship expenses, several comments recommended retaining the flexibility of the prior final regulations, which provide for several permissible methods of apportionment, or alternatively apportioning stewardship expenses on the basis of gross income, rather than assets. One comment questioned the appropriateness of applying the apportionment rule used for interest expense in the context of stewardship expenses.

The Treasury Department and the IRS have determined that it is appropriate to provide a single, clear rule for the apportionment of stewardship expenses and that the asset-based rule for interest expense apportionment is the most appropriate method. The Treasury Department and the IRS have also determined that an explicit rule provides certainty for both taxpayers and the IRS and will minimize disputes. By definition, stewardship expenses typically relate to protecting the value of the taxpayer's ownership interest in another entity. Therefore, such expenses should be apportioned on the basis of the tax book value (or alternative tax book value) of the taxpayer's interest in the entity (or entities) in question, since that value more closely approximates the income generated by the entity over time, while income distributed from an entity (or entities) and taxed to the owner can vary from year to year and may not properly reflect all the income-generating activity of the entity. Although stewardship activities may be definitely related to indirectly-owned entities, the Treasury Department and the IRS have determined that apportioning stewardship expenses based on the value of an indirectly-owned entity would lead to unnecessary complexity for taxpayers and administrative burdens for the IRS; instead, such expenses are apportioned based on the values of the entities that are owned directly by the taxpayer. See § 1.861–8(e)(4)(ii)(C).

For purposes of determining the value of an entity, the final regulations at § 1.861–8(e)(4)(ii)(C) provide that the value of the stock in an affiliated corporation is characterized as if the corporation were not affiliated and the stock is characterized by the taxpayer in the same ratios in which the affiliate's assets are characterized for purposes of allocating and apportioning the group's interest expense. The final regulations also provide that the tax book value of a taxpayer's investment in a disregarded entity is determined and characterized under the rules that would apply if the entity's stock basis were regarded for purposes of allocating and apportioning the investor taxpayer's interest expense.

2. Litigation Damages Awards, Prejudgment Interest, and Settlement Payments

The 2019 FTC proposed regulations included special rules for the allocation and apportionment of damages awards, prejudgment interest, and settlement payments incurred in settlement of, or in anticipation of, claims for damages arising from product liability, events incident to the production or sale of goods or provision of services, and investor suits. Damages or settlement awards related to product liability, or events incident to the production or sale of goods or provision of services, are allocated to the class of gross income produced by the specific sales of products or services that gave rise to the claims for damages or injury, or to the class of gross income produced by the assets involved in the production or sales activity, respectively. Damages awards related to shareholder suits are allocated to all income of the corporation and apportioned based on the relative values of all of the corporation's assets that produce income in the statutory and residual groupings.

One comment suggested that the proposed rules lacked clearly articulated rationales, in contrast to, for example, the rules for R&E expenditures. The Treasury Department and the IRS have determined that the rules included in the 2019 FTC proposed regulations for specific types of litigation-related expenses are consistent with the general principles of the allocation and apportionment rules, which are based on the factual connection between deductions and the class of gross income to which they relate. See § 1.861–8(b)(1). Accordingly, no change is made in the final regulations in response to this comment. However, the final regulations at § 1.861–8(e)(5)(ii) include a new paragraph heading and a sentence to clarify that the damages rule is not limited to product liability claims.

One comment stated that the 2019 FTC proposed regulations could be interpreted to require a double allocation of deductions to royalty income, for example, if a taxpayer incurs damages from a patent infringement lawsuit and also indemnifies its CFC for damages paid in a separate lawsuit filed against the CFC. The Treasury Department and the IRS have determined that indemnification payments, to the extent deductible, are governed by the generally-applicable rules for allocating and apportioning expenses based on the factual relationship between the deduction and the class of gross income to which the deduction relates. The allocation of separate deductions that are both related to the same class of gross income does not constitute a double allocation. Accordingly, no changes are made in

the final regulations in response to this comment.

The 2019 FTC proposed regulations contained an explicit apportionment rule for damages awards in response to industrial accidents and investor lawsuits, but not for product liability and similar claims. The final regulations add a sentence at § 1.861–8(e)(5)(ii) to clarify that deductions relating to product liability and similar claims are apportioned among the statutory and residual groupings based on the relative amounts of gross income in the relevant class in the groupings in the year the deductions are allowed.

Finally, several comments disagreed with the approach in the 2019 FTC proposed regulations regarding lawsuits filed by investors against a corporation. These comments argued that it is inappropriate to allocate deductions for such payments to income produced by all of the taxpayer's assets, because these expenses can have a closer factual connection to the jurisdiction where the litigation occurs or where the events (for example, any negligence, fraud, or malfeasance) at issue in the lawsuit occurred. Some comments advocated for a more flexible rule, noting that certain shareholder claims may have a very narrow geographic scope, whereas other claims may relate to a broader range of activities.

The Treasury Department and the IRS have determined that it is inappropriate to allocate deductions for payments with respect to investor lawsuits on the basis of the situs of the underlying events or the location of the lawsuit. The purpose of direct investor lawsuits against a company is generally to compensate investors for damages to their investment in the entire company. Even where the underlying misconduct directly relates to only a portion of the taxpayer's business activities, the harm to the investor is generally attributable to the taxpayer's business more generally and, therefore, any damages payment is related to all of the taxpayer's income-producing activities. Moreover, any rule that attempted to quantify the portion of damages or settlements that relate to specific business activities and the portion that relates to more general reputational loss would by its nature be difficult for taxpayers to comply with and for the IRS to administer. Furthermore, the Treasury Department and the IRS disagree with the comments suggesting that award payments should be allocated based on the geographic location in which the lawsuit is filed, which could be governed by contractual terms or choice-of-law rules that have little to no factual relationship to the underlying activities to which the lawsuit relates. Accordingly, the comments are not adopted.

3. Net Operating Loss Deductions

The 2019 FTC proposed regulations clarified the treatment of net operating losses (NOLs) by specifying how the statutory and residual grouping components of an NOL are determined in the taxable year of the loss and by clarifying the manner in which the net operating loss deduction allowed under section 172 is allocated and apportioned in the taxable year in which the deduction is allowed. Comments requested that for purposes of applying § 1.861–8(e)(8) to section 250 as the operative section, NOLs arising in taxable years before the TCJA's enactment of section 250 should not be allocated and apportioned to gross FDDEI. On July 15, 2020, the Treasury Department and the IRS finalized regulations under section 250, which provide that the deduction under section 172(a) is not taken into account in computing FDDEI. See § 1.250(b)–1(d)(2)(ii). Therefore, the comment is moot. However, a sentence is added to the final regulations at § 1.861–8(e)(8)(i) to clarify that in determining the component parts of an NOL, deductions that are considered absorbed in the year the loss arose for purposes of an operative section may differ from the deductions that are considered absorbed for purposes of another provision of the Code that requires determining the components of an NOL. Therefore, for example, a taxpayer's NOL may comprise excess deductions allocated to foreign source general category income for purposes of section 904, even though for purposes of section 172(b)(1)(B)(ii) the NOL is a farming loss comprising excess deductions allocated to U.S. source income from farming.

4. Application of the Exempt Income/Asset Rule to Insurance Companies in Connection With Certain Dividends and Tax-Exempt Interest

The 2019 FTC proposed regulations clarified in proposed § 1.861–8(d)(2)(ii)(B), (d)(2)(v), and (e)(16) the effect of certain deduction limitations on the treatment of income and assets generating dividends-received deductions and tax-exempt interest held by insurance companies for purposes of allocating and apportioning deductions to such income and assets. Specifically, the 2019 FTC proposed regulations provided that in the case of insurance companies, exempt income includes dividends for which a deduction is provided by sections 243(a)(1) and (2) and 245, without regard to the proration rules under section 805(a)(4)(A)(ii) disallowing a portion of the deduction attributable to the policyholder's share of the dividends or any similar disallowance under section 805(a)(4)(D). Similarly, the regulations provided that the term exempt income includes tax-exempt interest without regard to the proration rules.

One comment requested that the final regulations modify § 1.861–8T(d)(2) to permit insurance companies to adjust the amount of income and assets that are exempted in apportioning deductions. The comment asserted that such adjustment is required in order to reflect the addition of section 864(e)(7)(E) and relied on legislative history to a provision in proposed technical corrections legislation (Technical Corrections Act of 1987, H.R. 2636, 100th Cong., section 112(g)(6)(A)) (June 10, 1987)) (the ''1987 bill'') to suggest that Congress intended to create a different result for insurance companies than for other companies.

The 1987 bill, however, was not enacted, and the language in section 864(e)(7)(E) is not the same as the language proposed in the bill. Section 864(e)(7)(E) provides regulatory authority for the Secretary to issue regulations regarding any adjustments that may be appropriate in applying section 864(e)(3) to insurance companies. The legislative history to section 864(e)(7)(E) (which was enacted in 1988) does not contain the same language as did the committee reports from the 1987 bill, and the rule that was proposed in the 1987 bill is contrary to subsequent case law. See *Travelers Insurance Company* v. *United States,* 303 F.3d 1373 (2002). Therefore, the Treasury Department and the IRS have concluded that although section 864(e)(7)(E) provides regulatory authority for a rule applying section 864(e)(3) to insurance companies, there is no indication that Congress intended for Treasury to adopt a rule mirroring the rule in the 1987 bill (which Congress did not enact).

Section 864(e)(3) is clear that exempt income includes income for which a deduction is allowed under sections 243 and 245, and no exception is provided in the statute for insurance companies. Furthermore, as explained in Part I.A.4 of the Explanation of Provisions in the 2019 FTC proposed regulations, a special rule for either tax-exempt interest of a life insurance company or dividends-received deductions and tax-exempt interest of a nonlife insurance company is not appropriate because when a policyholder's share or applicable percentage is accounted for as either a reserve adjustment or a

reduction to losses incurred, no further modification to the generally applicable rules is required to ensure that the appropriate amount of expenses are apportioned to U.S. source income. Instead, the rule suggested by the comment would inappropriately distort the allocation and apportionment of deductions to U.S. source income. Therefore, the comment is not adopted.

5. Treatment of the Section 250 Deduction

One comment requested clarification on the allocation and apportionment of the deduction allowed under section 250 (''section 250 deduction'') with respect to members of a consolidated group. In general, under § 1.1502–50(b), a consolidated group member's section 250 deduction is determined based on the member's share of the sum of all members' positive FDDEI or GILTI. Separate from this determination under § 1.1502–50(b), a taxpayer must also allocate and apportion the section 250 deduction to gross income for purposes of determining its foreign tax credit limitation. For this purpose, in allocating and apportioning the section 250 deduction to statutory and residual groupings, under § 1.861–8(e)(13) the portion of the section 250 deduction attributable to FDII is treated as definitely related and allocable to the specific class of gross income that is included in the taxpayer's FDDEI and then apportioned between the statutory and residual groupings based on the relative amounts of FDDEI in each grouping. In the context of an affiliated group, under § 1.861–14T(c)(1) expenses are generally allocated and apportioned by treating all members of an affiliated group as if they were a single corporation.

In response to the comment requesting clarity on the allocation and apportionment of the section 250 deduction with respect to members of a consolidated group, the final regulations provide that the section 250 deduction is allocated and apportioned as if all members of the consolidated group are treated as a single corporation. See § 1.861–14(e)(4). However, in the case of an affiliated group that is not a consolidated group, the section 250 deduction of a member of an affiliated group is allocated and apportioned on a separate entity basis under the rules of § 1.861–8(e)(13) and (14).

6. Other Requests for Comments on Expense Allocation

The preamble to the 2019 FTC proposed regulations requested comments on whether future regulations should allow taxpayers to capitalize and amortize certain expenses solely for purposes of the rules in § 1.861–9 for allocating and apportioning interest expense in order to better reflect asset values under the tax book value method. One comment was received recommending that such a rule be included with respect to R&E and advertising expenditures. The Treasury Department and the IRS agree with this comment and, accordingly, this rule is included in a notice of proposed rulemaking in the Proposed Rules section of this issue of the **Federal Register** (the ''the 2020 FTC proposed regulations''). See Part V.A of the Explanation of Provisions in the 2020 FTC proposed regulations.

One comment requested that a special rule be adopted in § 1.861–10T to directly allocate certain interest expense related to regulated utility companies. The Treasury Department and the IRS agree that a special rule is warranted, and have included a rule in the 2020 FTC proposed regulations. See Part V.B. of the Explanation of Provisions in the 2020 FTC proposed regulations.

Finally, the preamble to the 2019 FTC proposed regulations requested comments on whether the rules in § 1.861–8(e)(6) for allocating and apportioning state income taxes should be revised in light of changes made by the TCJA and changes to state rules for taxing foreign income. One comment was received requesting that the existing rules, which rely on state law to determine the income to which state taxes relate, be retained. The Treasury Department and the IRS agree that no changes to the rules in § 1.861–8(e)(6) are required at this time.

7. Examples Illustrating Allocation and Apportionment of Certain Expenses of an Affiliated Group of Corporations

Examples 1 through 6 in § 1.861–14T(j) apply the temporary regulations to fact patterns involving affiliated groups of corporations. However, Examples 1 and 4 of § 1.861–14T(j) are no longer consistent with current law, and therefore the final regulations append an informational footnote to § 1.861–14T(j) to reflect this fact. The Treasury Department and the IRS are also studying whether the remaining examples should be modified and whether new examples should be included in future guidance.

B. Partnership Transactions

The 2019 FTC proposed regulations revised §§ 1.861–9(b) and 1.954–2(h)(2)(i) to provide that guaranteed payments for the use of capital described in section 707(c) are treated similarly to interest deductions for purposes of allocating and apportioning deductions under §§ 1.861–8 through 1.861–14, and are treated as income equivalent to interest under section 954(c)(1)(E). These rules were intended to prevent the use of guaranteed payments to avoid the rules under §§ 1.861–9(e)(8) and 1.954–2(h) that apply to partnership debt.

One comment stated that while guaranteed payments for capital are economically similar to interest payments in some respects, guaranteed payments are, for Federal income tax purposes, payments with respect to equity, not debt, and regulations issued under section 707 narrowly circumscribe the situations in which a guaranteed payment is treated as something other than a distributive share of partnership income. The comment recommended that guaranteed payments for capital be treated as interest only in cases when the taxpayer harbors an abusive motive to circumvent the relevant rule.

The Treasury Department and the IRS have determined that guaranteed payments for the use of capital share many of the characteristics of interest payments that a partnership would make to a lender and, therefore, should be treated as interest equivalents for purposes of allocating and apportioning deductions under §§ 1.861–8 through 1.861–14 and as income equivalent to interest under section 954(c)(1)(E). This treatment is consistent with other sections of the Code in which guaranteed payments for the use of capital are treated similarly to interest. See, for example, §§ 1.469–2(e)(2)(ii) and 1.263A–9(c)(2)(iii). In addition, the fact that a guaranteed payment for the use of capital may be treated as a payment attributable to equity under section 707(c), or that a guaranteed payment for the use of capital is not explicitly included in the definition of interest in § 1.163(j)–1(b)(22), does not preclude applying the same allocation and apportionment rules that apply to interest expense attributable to debt, nor does it preclude treating such payments as ''equivalent'' to interest under section 954(c)(1)(E). Instead, the relevant statutory provisions under sections 861 and 864, and section 954(c)(1)(E), are clear that the rules can apply to amounts that are similar to interest.

Finally, a rule that would require determining whether the transaction had an abusive motive would be difficult to administer. Therefore, the comment is not adopted.

C. Treatment of Section 818(f) Expenses for Consolidated Groups

Section 818(f)(1) provides that a life insurance company's deduction for life insurance reserves and certain other deductions (''section 818(f) expenses'') are treated as items which cannot definitely be allocated to an item or class of gross income. When the life insurance company is a member of an affiliated group of corporations, proposed § 1.861–14(h)(1) provided that section 818(f) expenses are allocated and apportioned on a separate company basis.

One comment argued that the separate company approach was inconsistent with the general rule in section 864(e)(6) that expenses other than interest that are not directly allocable or apportioned to any specific income-producing activity are allocated and apportioned as if all members of the affiliated group were a single corporation. The comment also argued that the separate company approach would encourage consolidated groups to use intercompany transactions, such as related party reinsurance arrangements, to shift their section 818(f) expenses and achieve a more desirable foreign tax credit result. The comment advocated that the regulations instead adopt a single entity approach for life insurance companies that operate businesses and manage assets and liabilities on a group basis (a ''life subgroup'' approach).

In contrast, another comment argued that the separate company approach adopted in the proposed regulations was consistent with the fact that life insurance companies are regulated with respect to their reserves, investable assets, and capital. The comment, however, acknowledged that a life subgroup approach may be appropriate in certain cases, such as when an affiliated group of life insurance companies manages similar products on a cross-entity, product-line basis, rather than on an entity-by-entity basis. The comment recommended that final regulations provide a one-time election for taxpayers to choose either the separate company or life subgroup approach for allocating and apportioning section 818(f) expenses.

The Treasury Department and the IRS agree that there are merits and drawbacks to both the separate company and the life subgroup approaches and that a one-time election, as suggested by the comments, should be considered. Therefore, the final regulations at § 1.861–14(h) do not include the separate company rule for section 818(f) expenses. The 2020 FTC proposed regulations instead propose a life subgroup approach as well as a one-time election for taxpayers to choose the separate company approach.

D. Allocation and Apportionment of R&E Expenditures

The 2019 FTC proposed regulations proposed several changes to § 1.861–17, including eliminating the gross income method of apportionment, eliminating the legally-mandated R&E rule, and limiting the class of income to which R&E expenditures could be allocated to gross intangible income reasonably connected with a relevant Standard Industrial Code (SIC) category. In addition, the rule for exclusive apportionment of R&E expenditures was modified by eliminating the possibility of increased exclusive apportionment based on taxpayer-specific facts and circumstances, and by providing that exclusive apportionment applies solely for purposes of section 904.

1. Scope of Gross Intangible Income

Before being revised, § 1.861–17(a) provided that R&E expenditures are related to all income reasonably connected to a broad line of business or SIC code category. The 2019 FTC proposed regulations narrowed and clarified the class of gross income to which R&E expenditures are considered to relate. The 2019 FTC proposed regulations defined the relevant class of gross income as gross intangible income (''GII''), which is defined as all income attributable, in whole or in part, to intangible property, including sales or leases of products or services derived, in whole or in part, from intangible property, income from sales of intangible property, income from platform contribution transactions, royalty income, and amounts taken into account under section 367(d) by reason of a transfer of intangible property. GII does not include dividends or any amounts included in income under section 951, 951A, or 1293.

One comment disagreed with the exclusion from GII of section 951A inclusions. According to this comment, R&E expenditures ultimately benefit foreign subsidiaries such that allocation to income described in section 904(d)(1)(A) (the ''section 951A category'') is appropriate and should not be treated differently from other taxpayer expenses that reduce income in the section 951A category. Other comments generally supported the exclusion of GILTI and other income inclusions from GII on the grounds that a taxpayer incurring R&E expenditures to develop intangible property should be fully compensated for the value of that intellectual property and, conversely, the earnings of CFCs should not reflect returns on intellectual property owned by another person.

The Treasury Department and the IRS have determined that GII should continue to exclude GILTI or other inclusions attributable to ownership of stock in a CFC. As described in § 1.861–17(b), R&E expenditures, whether or not ultimately successful, are incurred to produce intangible property. Under the rules of sections 367(d) and 482, the person incurring the R&E expenditures must be compensated at arm's length when such intangible property is licensed, sold, or otherwise gives rise to income of controlled parties, and it is this income that gives rise to GII. In transactions not involving the direct transfer of intangible property to a related party, the section 482 regulations require compensation for the intangible property embedded in the underlying transaction. See generally § 1.482–1(d)(3)(v). For example, § 1.482–3(f) requires that intangible property embedded in tangible property be accounted for when determining the arm's length price for the transaction. Similarly, § 1.482–9(m) requires that intangible property used in a controlled services transaction be accounted for in determining the arm's length price for the transaction.

In contrast to R&E expenditures giving rise to income required by sections 367(d) and 482, subpart F or GILTI inclusions reflect income earned by a CFC and not the taxpayer incurring the R&E expenditures; the fact that such taxpayer is deemed under section 951 or 951A to have income through an inclusion from a CFC licensee does not mean that such income is a result of the R&E expenditures incurred by the taxpayer, assuming that the CFC pays the taxpayer an arm's length price for the transfer of the intangible property or, in the case of an exchange described in sections 351 or 361, the taxpayer reports the required annual income inclusion.[2] Therefore, including income in the section 951A category in GII would result in a mismatch between the R&E expenditures and the income

[2] To assist in determining an arm's length price in related party transactions, section 14221 of the TCJA and related technical corrections in the 2018 Consolidated Appropriations Act amended sections 482 and 367(d) to clarify the methods that may be applied to determine the value of intangible property and that the definition of intangible property includes workforce, goodwill and going concern value, or other items the value or potential value of which is not attributable to tangible property or the services of any individual. To the extent the comment reflects a concern that arm's length compensation for intangible property has not always been paid under sections 367(d) and 482, the comment raises issues beyond the scope of this rulemaking.

generated by such expenditures. Although (as noted in a comment) R&E expenditures that are ultimately unsuccessful could be viewed as intended to benefit a taxpayer's foreign subsidiaries more broadly, the Treasury Department and the IRS have determined that the GII earned by the taxpayer provides a reasonable proxy for how the taxpayer expects to recover its R&E costs, and providing separate rules for identifying and attributing unsuccessful R&E expenditures to a broader class of income would be unduly burdensome for taxpayers and difficult for the IRS to administer.

Several comments noted that while income in the section 951A category is excluded from GII, income giving rise to foreign-derived intangible income (''FDII'') is included in GII. These comments generally argued that the exclusion from GII of income in the section 951A category and inclusion of amounts included in FDII created a lack of parity between the two provisions even though the methodology and calculations of both are meant to be similar.

The Treasury Department and the IRS disagree with these comments. The allocation and apportionment of R&E expenditures to separate categories for purposes of section 904 as the operative section and the allocation and apportionment of R&E expenditures to FDDEI for purposes of section 250 as the operative section both require identifying the class of income to which the R&E expenditures are attributable. R&E expenditures incurred by a United States shareholder (''U.S. shareholder'') are not allocated and apportioned to income in the section 951A category because such income, which relates to an inclusion of income earned by the CFC, is not a return on the U.S. shareholder's R&E expenditures and, thus, is not included in gross intangible income. In contrast, income giving rise to FDII is earned directly by the same taxpayer that incurs R&E expenditures and may include a return on those R&E expenditures. Income that gives rise to FDII is reduced by ''the deductions (including taxes) properly allocable to such gross income.'' See section 250(b)(3)(A)(ii) and § 1.250(b)–1(d)(2). There is no indication that Congress intended to exclude R&E expenditures from that calculation. Furthermore, because expenses incurred by a CFC are allocated and apportioned to income of the CFC for purposes of computing tested income under section 951A(c)(2)(A)(ii), contrary to the suggestion in the comments, R&E expenditures of the CFC are in fact allocated and apportioned to tested income under § 1.861–17 and reduce the ultimate amount of the taxpayer's GILTI inclusion. Accordingly, the comment is not adopted.

One comment requested modifications to the definition of GII to exclude both acquired intangible property and income from certain platform contribution transactions described in § 1.482–7(b)(1)(ii). According to the comment, income from these items should be excluded from GII because a taxpayer's R&E expenditures could not relate to gross income from intangible property acquired from a different taxpayer (as opposed to developed by the taxpayer), or to gross income from certain platform contributions.

The Treasury Department and the IRS have determined that the comment does not accurately describe the premise on which the R&E allocation and apportionment rules are based. R&E expenditures are not reasonably expected to produce any current income in the taxable year in which the expenditures are incurred, and as the regulations explicitly recognize, the results of R&E expenditures are speculative. Accordingly, R&E expenditures are allocated to a class of currently recognized gross income only because it generally will be the best available proxy for the income that the current expense is reasonably expected to produce in the future. Specifically, although current R&E expense of a taxpayer likely does not directly contribute to gross intangible income currently recognized, it is reasonable to expect that R&E will contribute to GII earned by the taxpayer group in the future. The definition of GII is not intended to require a strict factual connection between the R&E expenditure and GII earned in the taxable year, but merely that the expenditures be ''reasonably connected'' with a class of income. The Treasury Department and the IRS have also determined that requiring the comment's suggested level of explicit factual connection between R&E expenditures and GII would outweigh the administrative benefit and ease of broadly defining GII. Moreover, in cases in which a taxpayer has a valid cost sharing agreement, even though R&E expenditures may be allocated to PCT payments, those expenses are generally apportioned based on sales by the taxpayer or other entities reasonably expected to benefit from current research and experimentation. This ensures that R&E expenditures offset the categories of income included in GII that are expected to benefit from those expenditures. Accordingly, the comment is not adopted.

One comment requested clarification of the definition of GII and specifically that the final regulations provide that the services income included in GII does not include gross income allocated to or from a foreign branch under § 1.904–4(f)(2)(vi) by reason of a disregarded payment for services performed by or for the foreign branch that contribute to earning GII of the taxpayer.

Under § 1.904–4(f)(2)(vi)(B), a disregarded payment from a foreign branch owner to its foreign branch to compensate the foreign branch for the provision of contract R&E services that, if regarded, would be allocable to general category gross intangible income attributable to the foreign branch owner under the principles of §§ 1.861–8 through 1.861–17, would cause the general category GII attributable to the foreign branch owner to be adjusted downward and the GII attributable to the foreign branch and included in foreign branch category income to be adjusted upward. Although a disregarded payment for R&E services does not give rise to gross income for Federal income tax purposes and so does not in and of itself constitute GII, to the extent the disregarded payment results in the reattribution of regarded gross income that is GII from the general category to the foreign branch category (or vice versa), that income is treated as GII in the foreign branch category (or the general category). The final regulations at § 1.861–17(b)(2) clarify that although GII does not include disregarded payments, certain disregarded payments that would be allocable to GII if regarded may result in the reassignment of GII from the general category to the foreign branch category or vice versa. Part II.D.6 of this Summary of Comments and Explanation of Revisions further describes comments regarding R&E expenditures and foreign branches.

One comment sought clarification regarding the portion of product sales derived from intangible property that would be considered GII. The final regulations at § 1.861–17(b)(2) clarify that GII includes the full amount of gross income from sales or leases of products or services, if the income is derived in whole or in part from intangible property. Under the definition of GII, there is no bifurcation or splitting of sales income between a portion attributable to intangible property and other amounts such as distribution or marketing functions. Additionally, the definition of GII has been modified to more clearly delineate between amounts from sales or leases of

products derived from intangible property versus sales or licenses of intangible property itself.

2. Allocation of R&E Expenditures

One comment requested modifications to the general rule that allocates R&E expenditures to GII that is reasonably connected with one or more relevant SIC code categories. The comment noted that in some cases, taxpayers are restricted by law or contract from exploiting research, with the result that the research would only generate income in a particular statutory grouping after several years from the date of the contract. Accordingly, the comment requested that such R&E expenditures be allocated to the statutory or residual grouping of income within GII that corresponds to the market restrictions on the use of the R&E. Alternatively, the comment requested that taxpayers be provided with the option to allocate R&E expenditures in a manner consistent with the taxpayer's books and records to the extent there is a clear factual relationship between the expenditures and a particular category of income.

The Treasury Department and the IRS have determined that it is inappropriate to provide exceptions to the general rule that R&E expenditures are allocated to GII reasonably connected with one or more relevant SIC code categories. The two approaches suggested by the comment are premised on a goal of seeking to ''trace'' R&E expenditures to the actual income that they are expected to produce in the future. However, as discussed in Part II.D.1 of this Summary of Comments and Explanation of Revisions, R&E expenditures are not reasonably expected to produce any current income in the taxable year in which the expenditures are incurred, and the regulations recognize that the results of R&E expenditures are speculative. Instead, § 1.861–17 relies on the use of current year sales as a proxy for the income that the expenses are reasonably expected to produce in the future, in recognition of the fact that it is difficult to ascertain the composition of future income that would be generated from R&E expenditures. This approach generally already takes into account the types of market or legal restrictions described by the comment—to the extent that a taxpayer's sales of products in the same SIC code category are generally restricted to a particular market, these restrictions will be reflected in its sales and therefore are already taken into account under the sales method provided in proposed § 1.861–17. Moreover, rules that specially allocate particular R&E expenditures based on the reasonableness of speculative expectations about sales that may or may not actually arise several years in the future would be very difficult for taxpayers to comply with and for the IRS to administer.

Finally, allowing taxpayers to elect the use of a books-and-records method to allocate R&E expenditures to less than all of a taxpayer's GII would lead to inappropriate results, as taxpayers would only elect such option if the additional information reflected in the taxpayer's books and records improved the tax result; in contrast, the IRS would not have any such information available to it if the taxpayer chose not to make the election. Since this information would generally be in the form of predictions about future income streams, an elective books-and-records rule would create administrability concerns for the IRS, which would have substantial difficulty verifying whether the predictions were reasonable. Accordingly, the comments are not adopted.

One comment recommended that the Treasury Department and the IRS reconsider the elimination of the ''legally mandated R&E'' rule from the 2019 FTC proposed regulations, noting that the rule seemed to be required by section 864(g)(1)(A). As explained in the preamble to the 2019 FTC proposed regulations, the legally mandated R&E rule was eliminated in light of changes to the international business environment and to simplify the regulations, and the comment does not argue the change is inappropriate. Additionally, the comment misstates the application of section 864(g)(1)(A), which is not applicable to the taxable years to which the final regulations apply. See section 864(g)(6). Accordingly, the comment is not adopted.

One comment sought clarification on the allocation of R&E expenditures where research is conducted with respect to more than one SIC code category. The comment noted that the current final regulations at § 1.861–17(a)(2)(iii) mention two digit SIC code categories, or Major Groups in the terminology of the SIC Manual, yet the 2019 FTC proposed regulations omitted references to two digit SIC codes.

The Treasury Department and the IRS have determined that it is appropriate to aggregate some or all three digit SIC categories within the same Major Group, but it is inappropriate to aggregate any three digit SIC categories within different Major Groups. While R&E expenditures are speculative, it is not reasonable to expect R&E conducted for one broad line of business to benefit an unrelated line of business and, therefore, the allocation and apportionment of expenses should not be determined by aggregating different Major Groups. For example, if a taxpayer engages in both the manufacturing and assembling of cars and trucks (SIC code 371) it may aggregate that category with another three digit category in Major Group 37, which includes six other three digit categories (for example, aircraft and parts (SIC code 372) or railroad equipment (SIC code 374)), but taxpayers may not aggregate a three digit SIC code from a Major Group with another three digit SIC code from a different Major Group, except as provided in § 1.861–17(b)(3)(iv) (requiring aggregation of R&E expenditures related to sales-related activities with the most closely related three digit SIC code, other than those within the wholesale and retail trade divisions, if the taxpayer conducts material non-sales-related activities with respect to a particular SIC code). The final regulations are modified accordingly.

3. Exclusive Apportionment of R&E Expenditures

i. Computation of FDII

Several comments argued that if the Treasury Department and the IRS determine that GII should include amounts giving rise to FDII, then the rule in the 2019 FTC proposed regulations in § 1.861–17(c), which limits exclusive apportionment of R&E expenditures solely for purposes of applying section 904 as the operative section, should be revised to also allow for exclusive apportionment for purposes of calculating a taxpayer's FDII deduction. The comments generally argued that the exclusive apportionment provision be applied such that 50 percent of a taxpayer's R&E expenditures should be apportioned to income that is not foreign derived deduction eligible income (''FDDEI'') provided that at least 50 percent of the taxpayer's research activities are conducted in the United States. Comments argued that such an exclusive apportionment rule would encourage R&E activity in the United States, consistent with the general intent of the TCJA to eliminate tax incentives for shifting activity and intellectual property overseas. Additionally, comments asserted that R&E expenditures provide greater value to the location where R&E is performed and that there is a technology ''lag''

before successful products are exported to foreign markets.

The Treasury Department and the IRS have determined that it is not appropriate to apply an exclusive apportionment rule for purposes of computing FDII. As discussed in Part II.D.1 of this Summary of Comments and Explanation of Revisions, R&E expenditures are not reasonably expected to produce any current income in the taxable year in which the expenditures are incurred, and the regulations explicitly recognize that the results of R&E expenditures are speculative. Furthermore, to the extent there is consistently a ''lag'' before a taxpayer's successful products are exported to foreign markets, then such lag should generally be reflected in current year sales of newly successful products (which relate to R&E incurred in prior taxable years) being weighted towards domestic markets. Therefore, the rules' use of current year sales as a proxy for the income that the expense is reasonably expected to produce in the future already takes into account to some extent the potential for a ''lag'' between exploiting intangible property in the domestic market versus foreign markets.

In addition, the Treasury Department and the IRS have determined that nothing in the text of the TCJA or its legislative history suggests that Congress intended that existing rules on allocation and apportionment of R&E expenditures be modified in a way to create particular incentives. Section 250(b)(3) requires determining the deductions that are ''properly allocable'' to deduction eligible income, and § 1.250(b)–1(d)(2) confirms that the general rules under § 1.861–17 apply for purposes of allocating and apportioning R&E expenditures to deduction eligible income and FDDEI. Nothing in the statute or legislative history suggests that any alternative allocation and apportionment rule should apply. Furthermore, adopting an R&E allocation and apportionment rule solely for purposes of increasing the amount of the FDII deduction to incentivize R&E activity (whether or not such expenditures were ''properly'' allocable to non-FDDEI income) would be inconsistent with the United States' position, including as stated in forums such as the OECD's Forum on Harmful Tax Practices, that the FDII regime is not intended to provide a tax inducement to shifting activities or income, but is intended to neutralize the effect of providing a lower U.S. effective tax rate with respect to the active earnings of a CFC of a domestic corporation (through a deduction for GILTI) by also providing a lower effective U.S. tax rate with respect to FDII earned directly by the domestic corporation. Such parity is generally furthered by ensuring that R&E expenditures incurred by a domestic corporation are allocated and apportioned to FDII in the same manner as R&E expenditures incurred by a CFC are allocated and apportioned to tested income that gives rise to GILTI.

Therefore, the final regulations provide that the exclusive apportionment rule is limited to section 904 as the operative section.

ii. Increased Exclusive Apportionment

Two comments recommended reinstating the rule allowing for an increased exclusive apportionment of R&E expenditures. Under the increased exclusive apportionment rule, a taxpayer may establish to the satisfaction of the Commissioner that an even greater amount of R&E expenditures should be exclusively apportioned. One comment indicated that there may be circumstances where an even greater amount of R&E expenditures should be apportioned, such as following the termination of a cost sharing arrangement (''CSA''). Another comment pointed out that the 2019 FTC proposed regulations reduce taxpayer options by eliminating both increased exclusive apportionment and the gross income method.

The Treasury Department and the IRS have determined that a rule allowing for increased exclusive apportionment is not warranted. The facts and circumstances nature of the determination that would be required and the potential for disputes outweigh the benefits of affording taxpayers additional flexibility in rare or unusual cases. Additionally, to the extent that there is a tendency to exploit intellectual property in the same market where the taxpayer conducts R&E, this will already be reflected in current sales, as those in part reflect the results of recently-developed intellectual property. Accordingly, this comment is not adopted.

iii. Mandatory Application of Exclusive Apportionment

Two comments generally objected to the required application of exclusive apportionment for purposes of section 904. According to the comments, in certain situations where a taxpayer has insufficient domestic source gross income to absorb the apportioned R&E expenditures, the resulting overall domestic loss (''ODL'') would reduce foreign source income in each separate category described in § 1.904–5(a)(4)(v), including the section 951A and foreign branch categories, reducing the taxpayer's ability to claim foreign tax credits. The comments recommended that taxpayers either be allowed to elect out of exclusive apportionment or alternatively that it be applied in an amount less than 50 percent of the taxpayer's R&E expenditures. One comment alternatively recommended a modification to the ODL and R&E expenditure rules such that the majority of the amounts otherwise subjected to exclusive apportionment would instead be allocated to income in the general category rather than the section 951A or foreign branch categories.

The TCJA did not modify the operation of section 904(f) or (g) with respect to the section 951A or foreign branch categories, nor is there any indication in the TCJA or legislative history that Congress intended the rules under section 904(f) and (g), or the allocation and apportionment rules under section 861, to apply differently in connection with section 951A or foreign branch category income. To the extent an ODL account is created as the result of a domestic loss offsetting foreign source income in the section 951A or foreign branch category under section 904(f)(5)(D), this reduction is reversed in later years through the recapture provisions in section 904(g)(3), when U.S. source income is recharacterized as foreign source income in the separate categories that were offset by the ODL. Additionally, the Treasury Department and the IRS have determined that the consistent application of the exclusive apportionment rule for purposes of section 904 promotes simplicity and certainty, whereas an optional rule would be more difficult to administer. Accordingly, these comments are not adopted.

4. Elimination of the Gross Income Method

Several comments requested that the gross income method for apportioning R&E expenditures be retained. In general, these comments recommended allowing taxpayers to choose either the gross income method or the sales method rather than being required to utilize only the sales method, including by allowing taxpayers to choose one method for certain operative sections and another method for other operative sections. Some comments asserted that the mandatory use of the sales method would inappropriately allocate and apportion more R&E expenditures to FDDEI than under the gross income method in cases where U.S. taxpayers license their intellectual property for foreign use but sell products directly to

U.S. customers. One comment argued that the sales method could be distortive in certain situations where a taxpayer licenses its intellectual property to entities whose sales are at least partially attributable to self-developed intellectual property. Another comment argued that where a taxpayer's primary type of GII is royalty income, it will be difficult to apportion R&E based on sales numbers and that therefore the gross income method should be maintained.

The Treasury Department and the IRS have determined that, on balance, the sales method results in substantially fewer distortions than the gross income method. Before being modified by these final regulations, taxpayers were permitted to apportion R&E expenditures under either a gross income or sales method. The Explanation of Provisions in the 2019 FTC proposed regulations explained that the gross income method could produce inappropriate, distortive results in certain cases. In particular, distortions could arise because the gross income method looks only to gross income earned directly by the taxpayer. Gross income that is earned by the taxpayer and that is attributable to one grouping (such as U.S. source income) may reflect value unrelated to intangible property, for example gross income from sales that reflect value from marketing or distribution activities of the taxpayer, whereas gross income of such taxpayer that is attributable to another grouping (such as foreign source income) may exclude such non-IP related value due, for example, to the fact that such gross income is earned solely from licensing intangible property to a related party without the performance of any marketing or distribution activities. The distortions arise both because gross income reflects a reduction of gross receipts for cost of goods sold but not for related deductible expenses, and also because the gross income method does not distinguish between gross income earned from customers (for which the gross income generally captures all of the value related to the product or service arising from the IP) versus from related parties (for which gross income generally only captures an intermediate portion of the value of the relevant product or service, which will generally be enhanced by the related party).

In contrast, the sales method provides a consistent, reliable method with fewer distortions than the gross income method. In particular, the sales method focuses on the gross receipts from sales of a product to final customers. This approach is more likely to achieve consistent results in the case of the same or similar final products, and thereby allows for a consistent comparison of value derived from intangible property with respect to each grouping. That is the case regardless of whether the taxpayer chooses to license its intangible property to other persons (including related parties) for purposes of manufacturing final products, or the taxpayer manufactures products itself, and regardless of whether other persons enhance the product with additional value attributable to other intangible property. Therefore, the sales method ensures that differences in supply chain structures do not alter the nature of how R&E expenditures are allocated and apportioned.

Alternatively, some comments recommended modifying the gross income method. One comment recommended modifying the gross income method to more accurately match income to related R&E expenditures by using only gross income that is attributable to the intangible property owned by the taxpayer. However, the Treasury Department and the IRS have determined that it would lead to complexity for taxpayers and administrative burdens for the IRS to seek to accurately determine the share of gross income that is attributable to intangible property when the intangible property is embedded in a final product. In addition, such a rule would be unlikely to result in significantly different results than under the sales method, because the ratio of gross income among groupings that is attributable solely to intangible property is likely to be broadly similar to the ratio of gross receipts from sales within those groupings, since the intangible component of gross income from sales is likely to be determined as a fraction of gross receipts, and such fraction would generally be the same for each grouping.

One comment argued that the gross income method must be included in the final regulations because it is statutorily required under section 864(g)(1). However, section 864(g) is not applicable to the taxable years covered by the final regulations. See section 864(g)(6). Therefore, the comment is not adopted.

Finally, one comment recommended allowing taxpayers to use the gross income method if using the sales method would otherwise cause the taxpayer to have an ODL. The Treasury Department and the IRS have determined that it would be inappropriate to allow for the targeted application of a method solely for the purpose of avoiding the ODL rules, which are statutorily mandated. The regulations under section 861, including § 1.861–17, are premised on associating deductions in as accurate and reasonable a manner as possible with the income to which such deductions relate. It is inconsistent with this overall policy of relating deductions to the relevant income to revise the regulations under section 861 simply to achieve a specific result under an operative section. Accordingly, the final regulations eliminate the gross income method.

5. Application of Sales Method

The 2019 FTC proposed regulations retained the rule in the prior final regulations which provides that for apportionment purposes, the sales method includes certain gross receipts of related and unrelated entities that are reasonably expected to benefit from the taxpayer's R&E expenditures, but does not include the receipts of entities that have entered into a valid CSA with the taxpayer. The 2019 FTC proposed regulations made limited changes to the sales method as it existed under the prior final regulations.

One comment requested guidance on the application of the sales method in the context of foreign branch category income; this comment is discussed in Part II.D.6 of this Summary of Comments and Explanation of Revisions.

Two comments asked for a modification to the treatment of controlled entities that terminate an existing CSA with a taxpayer. Under the sales method, gross receipts from sales of products or the provision of services within a relevant SIC code category by controlled parties of the taxpayer are taken into account when apportioning the taxpayer's R&E expenditures if the controlled party is reasonably expected to benefit from the taxpayer's research and experimentation. Under proposed § 1.861–17(d)(4)(iv), the sales of controlled parties that enter into a valid CSA with a taxpayer are generally excluded from the apportionment formula because the controlled party is not expected to benefit from the taxpayer's R&E expenditures. The comments argued that when a CSA is terminated and a taxpayer licenses newly-developed intangibles to a controlled party, all gross receipts from the controlled party are included in the apportionment formula, even though for some post-termination period the controlled party may benefit more from intangibles created by its own R&E expenditures incurred under the previously-existing CSA rather than from the newly-developed and licensed

intangibles. The comments recommended varying adjustments, including rules specific to CSA terminations or alternatively more generalized adjustments such as the retention of the increased exclusive apportionment rule or the gross income method.

The Treasury Department and the IRS disagree with the comments' characterization of § 1.861–17 as seeking directly to match R&E expenditures with the income that such expenditures generate. According to the comments, following a CSA termination with a controlled party, a taxpayer's current R&E expenditures should not offset the controlled party's royalty payment to the taxpayer because the controlled party's gross receipts would be attributable to the intangibles funded by the controlled party during the period the CSA existed. This assertion assumes that current sales are used to apportion R&E expenditures because they result from a taxpayer's current or recent research and, therefore, it is inappropriate to include gross receipts attributable to the research of a different taxpayer. The regulations, however, are based in part on the acknowledgement that R&E is a speculative, forward-looking activity that often does not result in income or sales in the current year, or even in future years. As discussed in Part II.D.2 of this Summary of Comments and Explanation of Revisions, current sales are nevertheless used because they generally will be the best available proxy for the income R&E expenditures are expected to produce in future years. Accordingly, once a CSA is terminated, it is appropriate to include the sales of a controlled party that previously participated in a CSA if that controlled party is reasonably expected to benefit from the taxpayer's current R&E expenditures to generate future sales. Additionally, the Treasury Department and the IRS have determined that attempting to distinguish between the sales attributable to the controlled party's intangible property and those attributable to intangible property licensed from the taxpayer is generally difficult and uncertain and may often lead to disputes, making such a rule difficult for taxpayers to comply with and burdensome for the IRS to administer. Because those concerns also exist when a taxpayer and a controlled party enter into a CSA, the final regulations also do not adopt comments requesting such a rule in that context. Furthermore, the Treasury Department and the IRS have determined that the tax consequences of terminating a CSA may vary depending on the facts and circumstances and are considering whether it would be appropriate to provide special rules for these transactions, and thus it would not be appropriate to provide special rules in connection with § 1.861–17 until these transactions have undergone further study. Therefore, the comments are not adopted.

Finally, several comments requested a modification to the rule in proposed § 1.861–17(d)(3) and (4) providing that if a taxpayer has previously licensed, sold, or transferred intangible property related to a SIC code category to a controlled or uncontrolled party, then the taxpayer is presumed to expect to do so with respect to all future intangible property related to the same SIC code category. The comments argued that the 2019 FTC proposed regulations' use of the term ''presumption'' suggested that taxpayers would be unable to rebut the presumption in appropriate cases. In response to the comments, the final regulations clarify that taxpayers may rebut the presumption by demonstrating that prior exploitation of the taxpayer's intangible property is inconsistent with reasonable future expectations.

In addition, the final regulations make other revisions to the sales method. First, the final regulations specify under what circumstances the sales or services of uncontrolled or controlled parties are taken into account. In particular, the final regulations specify that the gross receipts are taken into account if the uncontrolled or controlled party is expected to acquire (through license, sale, or transfer) intangible property arising from the taxpayer's current R&E expenditures, products in which such intangible property is embedded or used in connection with the manufacture or sale of such products, or services that incorporate or benefit from such intangible property. Second, the final regulations revise § 1.861–17(d)(4) to refer to sales by controlled parties (which is defined as any person that is related to the taxpayer)), rather than controlled corporations, to clarify that, for example, sales made by a controlled partnership that is reasonably expected to license intangible property from the taxpayer are fully taken into account under the sales method. Finally, the final regulations revise § 1.861–17(f)(3) to provide that if a partnership incurs R&E expenditures (and is not also an uncontrolled party or controlled party described in § 1.861–17(d)(3) or (4)) and makes related sales, then those sales are considered made by the partners in proportion to their distributive shares of gross income attributable to the sales.

6. Foreign Branch Category Income and R&E Expenditures

Two comments addressed the interaction of § 1.861–17 and foreign branch category income. One comment requested that a portion of sales earned by a foreign branch should be attributed to the general category for purposes of apportioning R&E expenditures in circumstances where a foreign branch utilizes intellectual property of the foreign branch owner to earn GII and pays a disregarded royalty to its U.S. owner. Under § 1.904–4(f)(2)(vi)(A), the amount of foreign branch category income would be adjusted downward and the foreign branch owner's general category income would be adjusted upward by the amount of the disregarded royalty. According to the comment, after exclusive apportionment (as applicable), the 2019 FTC proposed regulations would apportion entirely to foreign branch category income the remaining R&E expense, which should instead be apportioned to the general category income originally attributable to the GII of the foreign branch that was reassigned by reason of the disregarded royalty.

The Treasury Department and the IRS have determined that the 2019 FTC proposed regulations, in combination with § 1.904–4(f)(2)(vi), already operate in the manner requested by the comment. Under proposed § 1.861–17(d)(1)(iii), gross receipts are assigned to the statutory grouping (or groupings) or residual grouping to which the GII related to the sale, lease, or service is assigned. Adjustments to the amounts of gross income attributable to a foreign branch by reason of disregarded payments change the separate category grouping to which the gross income is assigned, but do not change the total amount, character, or source of a United States person's gross income. See § 1.904–4(f)(2)(vi)(A). After application of § 1.904–4(f)(2)(vi), GII related to the foreign branch's sales is assigned to the general category in the amount of the disregarded royalty payment, and only the balance of the GII is assigned to the foreign branch category. Accordingly, a proportionate amount of the gross receipts from sales made by the foreign branch to which a disregarded royalty payment would be allocable is assigned to the general and foreign branch categories in the same ratio as the disregarded royalty payment bears to the gross income attributable to the sales. The final regulations in § 1.861–17(d)(1)(iii) clarify that the assignment of gross receipts occurs after gross income in the separate categories is adjusted under § 1.904–4(f)(2)(vi) and

clarify through an example the formula used to reassign gross receipts as a result of a disregarded reallocation transaction. See § 1.861–17(g)(6) (*Example 6*).

The second comment requested changes to the treatment of foreign branches that provide contract R&E services for the benefit of the foreign branch owner. According to the comment, when disregarded payments made by the foreign branch owner in respect of the provision of contract R&E services by a foreign branch cause GII to be reallocated to the foreign branch, R&E expenditures incurred by the foreign branch owner may be apportioned to foreign branch category income in a manner inconsistent with the economics of the branch's activities as a services provider, creating disparate tax results compared to those that would obtain if the services were performed by a CFC. The comment suggested that the foreign branch's regarded costs of providing the research services that give rise to the disregarded payment from the foreign branch owner should reduce the amount of GII that was assigned to the foreign branch category, or more generally that GII should not be assigned to the foreign branch category by reason of disregarded payments for research services.

The Treasury Department and the IRS agree that R&E expenditures, including deductible expenses for the foreign branch's costs in providing research services to the foreign branch owner, may be apportioned to foreign branch category income that is GII, including GII that is treated as attributable to the foreign branch category under § 1.904–4(f)(2)(vi) by reason of disregarded payments from the foreign branch owner compensating the foreign branch for its research services that will generate GII for the foreign branch owner, and that the apportionment is based upon gross receipts assigned to the statutory groupings. However, as noted in § 1.904–4(f)(2)(vi)(A), the reattribution of gross income between the general and foreign branch categories by reason of disregarded payments cannot change the character of a taxpayer's realized gross income. The Treasury Department and the IRS have determined that the different characterization of services income earned by a CFC, which may not be GII, and sales income reflecting GII that is attributed to a foreign branch by reason of disregarded payments for services, results from the Federal income tax treatment of disregarded payments, which do not give rise to gross income, and that it is not appropriate effectively to override the characterization of gross income by modifying the rules for allocating and apportioning recognized R&E expenditures. Accordingly, the comment is not adopted.

7. Contract Research Arrangements

In the Explanation of Provisions in the 2019 FTC proposed regulations, the Treasury Department and the IRS requested comments on whether contract research arrangements involving expenditures that are reimbursed by a foreign affiliate are generally paid or incurred by a U.S. taxpayer such that a deduction under section 174 would be allowable for such expenditures, and whether any special rules for such arrangements should be considered. Generally, the comments received stated that where contract research is performed in the United States and is connected with a U.S.-based multinational's trade or business, a deduction under section 174, rather than section 162, may be appropriate.

The Treasury Department and the IRS have determined that it is beyond the scope of the final regulations to determine whether contract research expenses are, or are not, eligible to be deducted under either section 162 or 174.

8. Amended Returns and Applicability Dates

One comment requested clarification of the applicability date provisions of the § 1.861–17 portion of the 2019 FTC proposed regulations. The comment noted that it was unclear whether a taxpayer that originally elected to apply the gross income method on its 2018 tax return would be eligible to amend its 2018 tax return to apply the sales method. The 2019 FTC final regulations included a provision addressing the binding election contained in former § 1.861–17(e)(1). Under this provision, as modified in the 2019 FTC final regulations at § 1.861–17(e)(3), taxpayers otherwise subject to the binding election were permitted to change their election. On May 15, 2020, correcting amendments to the 2019 FTC final regulations were issued in 85 FR 29323. These amendments make clear that the change in method can occur on an original or an amended return. See also Part VII of this Summary of Comments and Explanation of Revisions for a discussion of the ability for taxpayers to rely on the proposed or final versions of § 1.861–17 for taxable years before the years in which the final regulations are applicable. Accordingly, changes to the applicability date provisions are not necessary in response to this comment.

Finally, one comment requested that the applicability of the regulations under section 250 be deferred until after § 1.861–17 is finalized. Because the applicability of the regulations under section 250 has been deferred until taxable years beginning on or after January 1, 2021, which is consistent with the applicability date of § 1.861–17, the comment is moot. See § 1.250–1(b).

E. Application of Section 904(b) to Net Operating Losses

Proposed § 1.904(b)–3(d)(2) contained a coordination rule providing that for purposes of determining the source and separate category of a net operating loss, the separate limitation loss and overall foreign loss rules of section 904(f) and the overall domestic loss rules of section 904(g) are applied without taking into account the adjustments required under section 904(b). No comments were received on this provision, which is finalized without change.

One comment requested that the final regulations include a rule switching off the application of section 904(b)(4) with respect to pre-2018 U.S. source NOLs that offset foreign source income and created ODL accounts in pre-2018 taxable years, because in certain cases the increase in the denominator of the foreign tax credit limitation fraction required by section 904(b)(4) could limit the utilization of foreign tax credits that would otherwise be allowed by reason of the recapture of the ODL.

Nothing in section 904(b)(4) allows for the rule to be applied differently in cases when a taxpayer recaptures a pre-2018 ODL versus a post-2017 ODL or has no ODL recapture at all. Instead, the adjustments required by section 904(b)(4) apply in all taxable years beginning after 2017. Therefore, the comment is not adopted.

III. Conduit Financing Rules Under § 1.881–3 To Address Hybrid Instruments

A. Overview

The conduit financing regulations in § 1.881–3 allow the IRS to disregard the participation of one or more intermediate entities in a ''financing arrangement'' where such entities are acting as conduit entities, and to recharacterize the financing arrangement as a transaction directly between the remaining parties for purposes of imposing tax under sections 871, 881, 1441 and 1442. In general, a financing arrangement exists when through a series of transactions one person advances money or other property (the financing entity), another

person receives money or other property (the financed entity), the advance and receipt are effected through one or more other persons (intermediate entities), and there are ''financing transactions'' linking each of those parties. See § 1.881–3(a)(2)(i). An instrument that for U.S. tax purposes is stock (or a similar interest, such as an interest in a partnership) is not a financing transaction under the existing conduit financing regulations, unless it is ''redeemable equity'' or is otherwise described in § 1.881–3(a)(2)(ii)(B)(*1*).

The 2020 hybrids proposed regulations expanded the definition of a financing transaction, such that an instrument that for U.S. tax purposes is stock or a similar interest is a financing transaction if: (i) Under the tax law of a foreign country where the issuer is a tax resident or has a taxable presence, such as a permanent establishment, the issuer is allowed a deduction or another tax benefit, including a deduction with respect to equity, for an amount paid, accrued, or distributed with respect to the instrument; or (ii) under the issuer's tax laws, a person related to the issuer is entitled to a refund, including a credit, or similar tax benefit for taxes paid by the issuer upon a payment, accrual, or distribution with respect to the equity interest and without regard to the related person's tax liability in the issuer's jurisdiction. See proposed § 1.881–3(a)(2)(ii)(B)(*1*)(*iv*) and (*v*). The 2020 hybrids proposed regulations relating to conduit financing arrangements were proposed to apply to payments made on or after the date that final regulations are published in the **Federal Register**.

B. Scope of Instruments Treated as Financing Transactions

A comment agreed that a financing transaction should include an instrument that is stock or a similar interest for U.S. tax purposes but debt under the tax law of the issuer's country because, according to the comment, cases of potential conduit abuse are likely to involve ''classic'' hybrid instruments not covered by the types of equity described in § 1.881–3(a)(2)(ii)(B)(*1*). However, the comment recommended that an instrument that is equity for purposes of both U.S. tax law and the issuer's tax law not be treated as a financing transaction, except in limited circumstances, such as if the instrument is issued by a special purpose company formed to facilitate the avoidance of tax under section 881 and the instrument gives rise to a notional deduction or a refund or credit to a related person. According to the comment, the proposed rule that treated an instrument that is equity for both U.S. and foreign tax purposes as a financing transaction was overbroad—as it could deem an operating company to have entered into a financing transaction simply because foreign tax law provides for notional interest deductions or a similar regime of general applicability—or was unclear or vague in certain cases.

If the final regulations were to retain the proposed rules treating other types of equity instruments as financing transactions, the comment requested several clarifications, modifications, and limitations with respect to the rules. These included: (i) Treating an instrument that is equity in a partnership for U.S. tax purposes and under the issuer's tax law as a financing transaction only if the partnership is a hybrid entity that claims treaty benefits; (ii) either eliminating or clarifying the rule providing that an instrument can be a financing transaction by reason of generating tax benefits in a jurisdiction where the issuer has a permanent establishment; and (iii) modifying the applicability date for payments under existing financing arrangements.

Consistent with the comment, the final regulations adopt without substantive change the rule that included as a financing transaction an instrument that is stock or a similar interest (including an interest in a partnership) for U.S. tax purposes but debt under the tax law of the country of which the issuer is a tax resident. See § 1.881–3(a)(2)(ii)(B)(*1*)(*iv*). In addition, the final regulations provide that if the issuer is not a tax resident of any country, such as an entity treated as a partnership under foreign tax law, the instrument is a financing transaction if the instrument is debt under the tax law of the country where the issuer is created, organized, or otherwise established. See id.

The final regulations do not include the rules under the 2020 hybrids proposed regulations that treated as a financing transaction an instrument that is stock or a similar interest for U.S. tax purposes but gives rise to notional interest deductions or other tax benefits (such as a deduction or credit allowed to a related person) under foreign tax law. The Treasury Department and the IRS plan to finalize those rules separately, in order to allow additional time to consider the comments received. In addition, the Treasury Department and the IRS are continuing to study instruments that generate tax benefits in the jurisdiction where the issuer has a permanent establishment and may address these instruments in future guidance.

IV. Foreign Tax Credit Limitation Under Section 904

A. Definition of Financial Services Entity

In order to promote simplification and greater consistency with other Code provisions that have complementary policy objectives, § 1.904–4(e)(2) of the 2019 FTC proposed regulations proposed to define a financial services entity as an individual or a corporation ''predominantly engaged in the active conduct of a banking, insurance, financing, or similar business,'' and proposed to define financial services income as ''income derived in the active conduct of a banking, insurance, financing, or similar business.'' These modified definitions are generally consistent with sections 954(h), 1297(b)(2)(B), and 953(e); the 2019 FTC proposed regulations also included conforming changes to the rules for affiliated groups in proposed § 1.904–4(e)(2)(ii) and partnerships in proposed § 1.904–4(e)(2)(i)(C).

Comments stated that the 2019 FTC proposed regulations increased uncertainty and resulted in the disqualification of certain banks or insurance companies that would qualify as financial services entities under the existing final regulations. Comments also suggested that it was inappropriate to seek to align the relevant definitions in section 904 with those in section 954 because of the differing policies and scope of the two rules. Comments suggested various modifications to more closely align the revisions with the existing approach under § 1.904–4(e), or in the alternative, withdrawing the proposed rules entirely.

The Treasury Department and the IRS have determined that revisions to the financial services entity rules in § 1.904–4(e) continue to be necessary in light of statutory changes made in 2004 (under the American Jobs Creation Act of 2004, Pub. L. 108–357) and the changes to the look-through rules in § 1.904–5 in the 2019 FTC final regulations, which were precipitated by the revisions to section 904(d) under the TCJA. However, the Treasury Department and the IRS have determined the changes to § 1.904–4(e) should be reproposed to allow further opportunity for comment. Therefore, the 2020 FTC proposed regulations contain new proposed regulations under § 1.904–4(e), as well as a delayed applicability date. See Part IX.B. of the Explanation of Provisions in the 2020 FTC proposed regulations.

B. Allocation and Apportionment of Foreign Income Taxes

Proposed § 1.861–20 provided detailed guidance on how to match foreign income taxes with income, particularly in the case of differences in how U.S. and foreign law compute taxable income with respect to the same transactions. Proposed § 1.861–20(c) provided that foreign tax expense is allocated and apportioned among the statutory and residual groupings by first assigning the items of gross income under foreign law (''foreign gross income'') on which a foreign tax is imposed to a grouping, then allocating and apportioning deductions under foreign law to that income, and finally allocating and apportioning the foreign tax among the groupings. See proposed § 1.861–20(c).

Proposed § 1.861–20(d)(2)(ii)(B) provided that if a taxpayer recognizes an item of foreign gross income that is attributable to a base difference, then the item of foreign gross income is assigned to the residual grouping, with the result that no credit is allowed if the tax on that item is paid by a CFC. The proposed regulations provided an exclusive list of items that are excluded from U.S. gross income and that, if taxable under foreign law, are treated as base differences.

Several comments requested that distributions described in sections 301(c)(2) and 733, representing nontaxable returns of capital, be removed from the list of base differences on the grounds that foreign tax on such distributions is more likely to result from timing differences. Some comments argued that the foreign law characterization of the distribution should govern the determination of the income group to which the foreign tax is allocated. Other comments suggested that foreign tax on return of capital distributions should be associated with passive category capital gains, because by reducing basis such distributions may increase the amount of capital gain recognized for U.S. tax purposes in the future.

The purpose of the rules in § 1.861–20, as well as § 1.904–6, is to allocate and apportion foreign income taxes to groupings of income determined under Federal income tax law, and the final regulations at § 1.861–20(d)(1), consistent with the approach in former § 1.904–6, provide that Federal income tax law applies to characterize foreign gross income and assign it to a grouping. Characterizing items solely based on foreign law, with no comparison to the U.S. tax base, would altogether eliminate base differences, which are expressly referenced in section 904(d)(2)(H)(i).

However, the Treasury Department and the IRS have determined that in most cases, a foreign tax imposed on distributions described in sections 301(c)(2) and 733 is likely to represent tax on earnings and profits of the distributing entity that are accounted for at different times under U.S. and foreign tax law, such as earnings of a hybrid partnership, earnings that are accelerated and subsequently eliminated for U.S. tax purposes by reason of a section 338 election, or earnings and profits of lower-tier entities, rather than tax on amounts that are permanently excluded from the U.S. tax base. Although in some cases involving net basis foreign income taxes imposed at the shareholder level, distributions described in sections 301(c)(2) and 733 may reflect a timing difference in the recognition of unrealized gain with respect to the equity of the distributing entity, the Treasury Department and the IRS have determined that these situations are less likely to occur than timing differences in the recognition of earnings subject to withholding taxes because of the prevalence of foreign participation exemption regimes. Moreover, treating the foreign tax on distributions as representing a timing difference on earnings and profits of the distributing entity is more consistent with the general approach in the Code and regulations to the treatment of distributions as representing a tax on the earnings (see, for example, sections 904(d)(3) and (4), and 960(b)) and with treating gain on stock sales as related in part to earnings and profits (see section 1248(a)).

Therefore, these distributions are removed from the list of base differences, and the final regulations at § 1.861–20(d)(3)(ii)(B)(*2*) generally associate a foreign law dividend that gives rise to a return of capital distribution under section 301(c)(2) with hypothetical earnings of the distributing corporation, measured based on the groupings to which the tax book value of the corporation's stock is assigned under the asset method in § 1.861–9. Similar rules are included in the 2020 FTC proposed regulations for partnership distributions described in section 733.

The Treasury Department and the IRS have determined that similar rules should apply in appropriate cases to associate a portion of foreign tax imposed on an item of foreign gross income constituting gain recognized on the sale or other disposition of stock in a corporation or a partnership interest with amounts that constitute nontaxable basis recovery for U.S. tax purposes. Such similar treatment is appropriate to minimize differences in the foreign tax credit consequences of a sale or a distribution in redemption of the taxpayer's interest. Proposed rules on the allocation of foreign income tax on such dispositions are included in the 2020 FTC proposed regulations.

Proposed § 1.861–20 addressed the assignment to statutory and residual groupings of foreign gross income arising from disregarded payments between a foreign branch (as defined in § 1.904–4(f)(3)) and its owner. If the foreign gross income item arises from a payment made by a foreign branch to its owner, proposed § 1.861–20(d)(3)(ii)(A) generally assigned the item by deeming the payment to be made ratably out of the foreign branch's accumulated after-tax income, calculated based on the tax book value of the branch's assets in each grouping. If the item of foreign gross income arises from a disregarded payment to a foreign branch from its owner, proposed § 1.861–20(d)(3)(ii)(B) generally assigned the item to the residual grouping, with the result that any taxes imposed on the disregarded payment would be allocated and apportioned to the residual grouping as well. In addition, proposed § 1.904–6(b)(2) included special rules assigning foreign gross income items arising from certain disregarded payments for purposes of applying section 904 as the operative section.

Several comments asserted that foreign tax on disregarded payments from a foreign branch owner to a foreign branch should not be allocated and apportioned to the residual grouping, which results in an effective denial of foreign tax credits in the case of a branch of a CFC, because items of foreign gross income that arise from disregarded payments of items such as interest or royalties should give rise to creditable foreign income taxes despite being nontaxable for Federal income tax purposes. Some comments recommended adopting a tracing regime similar to the rules in § 1.904–4(f) to trace foreign gross income that a taxpayer includes by reason of a disregarded payment to current year income of the payor for purposes of determining the grouping to which tax on the disregarded payment is allocated and apportioned. Comments also requested that the final regulations clarify whether the rule for remittances or contributions applies in the case of payments between two foreign branches.

The Treasury Department and the IRS generally agree with the comments that

rules similar to the rules in § 1.904–4(f) should apply under § 1.861–20 to trace foreign gross income that a taxpayer includes by reason of a disregarded payment to the current year income of the payor to which the disregarded payment would be allocable if regarded for U.S. tax purposes. However, in order to provide taxpayers additional opportunity to comment, the final regulations reserve on the allocation and apportionment of foreign tax on disregarded payments, and new proposed rules are contained in the 2020 FTC proposed regulations. See Part V.F.4 of the Explanation of Provisions in the 2020 FTC proposed regulations. Similarly, the special rules in proposed § 1.904–6(b)(2) for assigning foreign gross income items arising from certain disregarded payments for purposes of applying section 904 as the operative section are reproposed in the 2020 FTC proposed regulations. The other special rules in proposed § 1.861–20(d)(3) for allocating foreign tax in connection with a taxpayer's investment in a corporation or a disregarded entity are reorganized, and some of the definitions in proposed § 1.861–20(b) are correspondingly revised, in the final regulations to group the rules on the basis of how the entity is classified, and whether the transaction giving rise to the item of foreign gross income results in the recognition of gross income or loss, for U.S. tax purposes. The rule in proposed § 1.904–6(b)(3) relating to dispositions of property resulting in certain disregarded reallocation transactions is removed and reproposed as part of proposed § 1.861–20 as contained in the 2020 FTC proposed regulations.

Finally, one comment requested that §§ 1.904–1 and 1.904–6 clarify that the tax allocation rules apply to taxes paid to United States territories, which are generally treated as foreign countries for purposes of the foreign tax credit. The final regulations clarify this point by including a cross reference to § 1.901–2(g), which defines a foreign country to include the territories. See § 1.861–20(b)(6).

V. Foreign Tax Redeterminations Under Section 905(c) and Penalty Provisions Under Section 6689

Portions of the temporary regulations relating to sections 905(c), 986(a), and 6689 (TD 9362) (the ''2007 temporary regulations'') were reproposed in order to provide taxpayers an additional opportunity to comment on those rules in light of the changes made by the TCJA. In particular, the rules in the 2007 temporary regulations that were reproposed in the 2019 FTC proposed regulations were: (1) Proposed § 1.905–3(b)(2), which addressed foreign taxes deemed paid under section 960, (2) proposed § 1.905–4, which in general provided the procedural rules for how to notify the IRS of a foreign tax redetermination, and (3) proposed § 301.6689–1, which provided rules for the penalty for failure to notify the IRS of a foreign tax redetermination. In addition, the 2019 FTC proposed regulations contained a transition rule in proposed §§ 1.905–3(b)(2)(iv) and 1.905–5 to address foreign tax redeterminations of foreign corporations that relate to taxable years that predated the amendments made by the TCJA.

A. Adjustments to Foreign Taxes Paid by Foreign Corporations

One comment requested clarification on whether multiple payments to foreign tax authorities under a single assessment (for example, payments to stop the running of interest and penalties) each result in a foreign tax redetermination under section 905(c).

Under § 1.905–3(a) of the 2019 FTC final regulations, each payment of tax that has accrued in a later year in excess of the amount originally accrued results in a separate foreign tax redetermination. However, the 2019 FTC proposed regulations at § 1.905–4(b)(1)(iv), which is finalized without change, only required one amended return for each affected prior year to reflect all foreign tax redeterminations that occur in the same taxable year. In the case of payments that are made across multiple taxable years, § 1.905–4(b)(1)(iv) of the final regulations also provides that, if more than one foreign tax redetermination requires a redetermination of U.S. tax liability for the same affected year and those redeterminations occur within the same taxable year or within two consecutive taxable years, the taxpayer may file for the affected year one amended return and one statement under § 1.905–4(c) with respect to all of the redeterminations. Otherwise, separate amended returns for each affected year are required to reflect each foreign tax redetermination. Accordingly, no changes are made in response to this comment.

The comment also requested that the Treasury Department and the IRS clarify whether contested taxes that are paid before the contest is resolved are considered to accrue for foreign tax credit purposes when paid or whether they represent an advance payment against a future liability that does not accrue until the final liability is determined. Proposed rules addressing this issue are included in the 2020 FTC proposed regulations. See Part X.D.3 of the Explanation of Provisions in the 2020 FTC proposed regulations.

B. Deductions for Foreign Income Taxes

One comment requested clarification on whether the general rules under section 905(c) apply to taxpayers who elect to take a deduction, rather than a credit, for creditable foreign taxes in the prior year to which the adjusted taxes relate. Additionally, the comment requested that the Treasury Department and the IRS clarify whether the ten-year statute of limitations under section 6511(d)(3)(A) applies to refund claims based on such deductions.

In the case of a U.S. taxpayer that directly pays or accrues foreign income taxes, no U.S. tax redetermination is required in the case of a foreign tax redetermination of such taxes if the taxpayer did not claim a foreign tax credit in the taxable year to which such taxes relate. See § 1.905–3(b)(1) (a redetermination of U.S. tax liability is required with respect to foreign income tax claimed as a credit under section 901). However, in the case of a U.S. shareholder of a CFC that pays or accrues foreign income tax, proposed § 1.905–3(b)(2)(i) and (ii), which are finalized without substantive change, provided that a redetermination of U.S. tax liability is required to account for the effect of a foreign tax redetermination even in situations in which the foreign tax credit is not changed, such as for purposes of computing earnings and profits or applying the high-tax exception described in section 954(b)(4), including in the case of a U.S. shareholder that chooses to deduct foreign income taxes rather than to claim a foreign tax credit. Additional guidance addressing the accrual rules for creditable foreign taxes that are deducted or claimed as a credit is included in § 1.461–4(g)(6)(B)(iii) and in the 2020 FTC proposed regulations.

The question of whether section 6511(d)(3)(A) applies to refunds relating to foreign taxes that are deducted, instead of taken as a foreign tax credit, is beyond the scope of this rulemaking. See, however, *Trusted Media Brands, Inc.* v. *United States,* 899 F.3d 175 (2d. Cir. 2018) (holding that section 6511(d)(3)(A) only applies to refund claims based on foreign tax credits). In addition, the 2020 FTC proposed regulations include proposed amendments to the regulations under section 901(a), which provides that an election to claim foreign income taxes as a credit for a particular taxable year may be made or changed at any time before the expiration of the period prescribed for claiming a refund of U.S. tax for that year. See Part X.B.2 of the Explanation

of Provisions in the 2020 FTC proposed regulations.

C. Application to GILTI High-Tax Exclusion

Proposed § 1.905–3(b)(2)(ii) provided that the required adjustments to U.S. tax liability by reason of a foreign tax redetermination of a foreign corporation include not only adjustments to the amount of foreign taxes deemed paid and related section 78 dividend, but also adjustments to the foreign corporation's income and earnings and profits and the amount of the U.S. shareholder's inclusions under sections 951 and 951A in the year to which the redetermined foreign tax relates.

One comment requested that final regulations clarify whether a U.S. tax redetermination is required when the foreign tax redetermination affects whether the taxpayer is eligible for the GILTI high-tax exclusion. Specifically, the comment stated that because a redetermination of U.S. tax liability is required when the foreign tax redetermination affects whether a taxpayer is eligible for the subpart F high-tax election under section 954(b)(4), a similar result should apply for taxpayers that make (or seek to make) the GILTI high-tax exclusion election, and that taxpayers should be allowed to make the election on an annual basis. Further, the comment suggested that if taxpayers are allowed to make an annual election under the final GILTI high-tax exclusion regulations, then taxpayers should be permitted to make or revoke the election on an amended return following a foreign tax redetermination.

Proposed § 1.905–3(b)(2)(ii) provided that the required U.S. tax redetermination applies for purposes of determining amounts excluded from a CFC's gross tested income under section 951A(c)(2)(A)(i)(III), and this provision is retained in the final regulations with minor modifications. Furthermore, under final regulations issued on July 23, 2020 (TD 9902, 85 FR 44620), taxpayers may make the GILTI high-tax exclusion election on an annual basis and may do so on an amended return filed within 24 months of the unextended due date of the original income tax return. See § 1.951A–2(c)(7)(viii)(A)(*1*)(*i*).

D. Foreign Tax Redeterminations of Successor Entities

Proposed § 1.905–3(b)(3) provided that if at the time of a foreign tax redetermination the person with legal liability for the tax (the ''successor'') is a different person than the person that had legal liability for the tax in the year to which the redetermined tax relates (the ''original taxpayer''), the required redetermination of U.S. tax liability is made as if the foreign tax redetermination occurred in the hands of the original taxpayer. The proposed regulations further provided that Federal income tax principles apply to determine the tax consequences if the successor remits, or receives a refund of, a tax that in the year to which the redetermined tax relates was the legal liability of, and thus considered paid by, the original taxpayer.

One comment suggested that proposed § 1.905–3(b)(3), as drafted, did not clearly address cases where the ownership of a disregarded entity changes. The comment recommended clarifying that in the case of a disregarded entity, the owner of the disregarded entity is treated as the person with legal liability for the tax or the person with the legal right to a refund, as applicable.

The Treasury Department and the IRS have determined that no clarification is necessary. Existing regulations make clear that the owner of a disregarded entity is considered to be legally liable for the tax. See § 1.901–2(f)(4)(ii) (legal liability for income taxes imposed on a disregarded entity).

The same comment stated that the preamble to the proposed regulations incorrectly suggested that under U.S. tax principles the payment of tax by a successor entity owned by the original taxpayer (for example, by a CFC that was formerly a disregarded entity) is treated as a distribution. The comment further recommended addressing the issue of contingent liabilities in future guidance. The Treasury Department and the IRS agree that there may be multiple ways to characterize the tax consequences of tax paid by a successor in the example described in the preamble to the proposed regulations. Furthermore, the Treasury Department and the IRS have determined that the issue of contingent foreign tax liabilities in connection with foreign tax redeterminations under section 905(c) requires further study and may be considered as part of future guidance.

E. Notification to the IRS of Foreign Tax Redeterminations and Related Penalty Provisions

1. Notification Through Amended Returns

In general, proposed § 1.905–4(b)(1)(i) provided that any taxpayer for which a redetermination of U.S. tax liability is required must notify the IRS of the foreign tax redetermination by filing an amended return.

Several comments suggested that taxpayers should be allowed to report adjustments to U.S. tax liability in prior years by reason of foreign tax redeterminations on an attachment to their Federal income tax return for the taxable year in which the redetermination occurs, instead of requiring taxpayers to file amended tax returns for the taxable year in which the adjusted foreign tax was claimed as a credit and any intervening years in which the foreign tax redetermination affected U.S. tax liability. Specifically, comments suggested that taxpayers could be allowed to file a statement with their return for the taxable year in which the foreign tax redetermination occurs notifying the IRS of overpayments or underpayments of U.S. tax and applicable interest due for prior taxable years that resulted from the foreign tax redetermination. One comment suggested that taxpayers could be required to maintain books and records reflecting all the adjustments that would normally accompany an amended return, without actually being required to prepare and file such a return. Another comment suggested that the IRS could amend Schedule E on Form 5471 to include this type of information about the changes to prior year U.S. tax liabilities that result from foreign tax redeterminations. Comments noted that providing an alternative to filing amended Federal income tax returns would relieve taxpayers from having to file amended state tax returns.

The Treasury Department and the IRS have determined that, based on existing processes, the only manner in which taxpayers can properly notify the IRS of a change in U.S. tax liability for a prior taxable year that results from a foreign tax redetermination is by filing an amended return reflecting all the necessary U.S. tax adjustments. In addition, the Treasury Department and the IRS have determined that the type of statement suggested by the comments, reflecting a recomputation of Federal income tax liability for a prior year, could be viewed by state tax authorities as the functional equivalent of an amended Federal income tax return that may not necessarily operate to relieve taxpayers of their obligations to file amended state tax returns. In any event, taxpayer requests for relief from state tax filing obligations are properly directed to state tax authorities, rather than to the Treasury Department and the IRS. Therefore, the comments are not adopted. However, the Treasury Department and the IRS continue to study whether new processes or forms can be developed to streamline the

filing requirements while ensuring that the IRS receives the necessary information to verify that taxpayers have made the required adjustments to their U.S. tax liability. Under § 1.905–4(b)(3) of the final regulations, the IRS may prescribe alternative notification requirements through forms, instructions, publications, or other guidance.

Comments also suggested that the notification due date should be extended (for example, to up to three years from the due date of the original return for the taxable year in which the foreign tax redetermination occurred).

The Treasury Department and the IRS have determined that deferring the due date of the required amended returns beyond the due date (with extensions) of the return for the year in which the foreign tax redetermination occurs would not substantially reduce compliance burdens and could be more difficult for the IRS to administer, because the same filing obligations would be required, though with respect to foreign tax redeterminations that occurred three years earlier rather than in the current taxable year. In addition, taxpayers have an economic incentive to promptly file amended returns claiming a refund of U.S. tax in cases where a foreign tax redetermination reduces, rather than increases, U.S. tax liability; the Treasury Department and the IRS have determined that it is appropriate to require comparable promptness when a foreign tax redetermination increases U.S. tax due in order to permit timely verification of the required U.S. tax adjustments when the relevant documentation and personnel are more readily available. Accordingly, the comments are not adopted. However, a transition rule is added at § 1.905–4(b)(6) to give taxpayers an additional year to file required notifications with respect to foreign tax redeterminations occurring in taxable years ending on or after December 16, 2019, and before November 12, 2020.

Comments also requested that the final regulations provide that for foreign tax redeterminations below a certain de minimis threshold (for example, 10 percent of foreign taxes as originally accrued, or $5 million), taxpayers should be allowed to account for the foreign tax redeterminations by making adjustments to current year taxes and foreign tax credits claimed in the taxable year in which the foreign tax redetermination occurs, rather than by adjusting U.S. tax liability in the prior year or years in which the adjusted foreign taxes were claimed as a credit. Alternatively, some comments requested that for foreign tax redeterminations below a de minimis or materiality threshold, taxpayers should be completely relieved of adjusting U.S. tax liability and from all notification and amended return requirements.

The Treasury Department and the IRS have determined that, as amended by the TCJA, section 905(c) mandates retroactive adjustments to U.S. tax liability when foreign taxes claimed as credits are redetermined. The TCJA repealed section 902 and the regulatory authority at the end of section 905(c)(1) to prescribe alternative adjustments to multi-year pools of earnings and taxes of foreign corporations in lieu of the required adjustments to U.S. tax liability for the affected years. Recharacterizing prior year taxes as current year taxes would have substantive effects on the amounts of a taxpayer's GILTI and subpart F inclusions, the applicable carryover periods for excess credits, the applicable currency translation conventions, the amounts of interest owed by or due to the taxpayer, and the applicable statutes of limitation for refund or assessment. Therefore, the comments are not adopted.

Finally, a comment requested that § 1.905–4(b)(1)(ii) be amended to allow a taxpayer that avails itself of special procedures under Revenue Procedure 94–69 to notify the IRS of a foreign tax redetermination when the taxpayer makes a Revenue Procedure 94–69 disclosure during an audit for the taxable year for which U.S. tax liability is increased by reason of the foreign tax redetermination.

In relevant part, Revenue Procedure 94–69 provides special procedures for a taxpayer in the Large Corporate Compliance program (formerly the Coordinated Examination Program or Coordinated Industry Case program) to avoid the potential application of the accuracy-related penalty currently described in section 6662. Under Revenue Procedure 94–69, a taxpayer may file a written statement that is treated as a qualified amended return within 15 days after the IRS requests it. However, Revenue Procedure 94–69 does not provide any protection for penalties under section 6689 for failure to file a notice of a foreign tax redetermination, and it requires a statement that is less detailed than the notification statement required under § 1.905–4(b)(1)(ii). Further, section 905(c) contemplates that the burden is on the taxpayer to notify the IRS of a foreign tax redetermination, whereas Revenue Procedure 94–69 places the burden on the IRS to request information. Finally, the notification requirement under § 1.905–4(b)(1)(ii) affords a taxpayer more time to satisfy its reporting obligation as opposed to the 15-day notification requirement in Revenue Procedure 94–69. Therefore, the comment is not adopted.

2. Foreign Tax Redeterminations of Pass-Through Entities

Proposed § 1.905–4(b)(2) generally provided that a pass-through entity that reports creditable foreign income tax to its partners, shareholders, or beneficiaries is required to notify the IRS and its partners, shareholders, or beneficiaries if there is a foreign tax redetermination with respect to such foreign income tax. See proposed § 1.905–4(c) for the information required to be provided with the notification. Additionally, proposed § 1.905–4(b)(2)(ii) provided that if a redetermination of U.S. tax liability would require a partnership adjustment as defined in § 301.6241–1(a)(6), the partnership must file an administrative adjustment request (''AAR'') under section 6227 without regard to the time restrictions on filing an AAR in section 6227(c). See also § 1.6227–1(g).

One comment suggested that S corporations should be allowed to follow similar notification procedures as partnerships that are subject to sections 6221 through 6241 (enacted in § 1101 of the Bipartisan Budget Act of 2015, Pub. L. 114–74 (''BBA'') and as amended by the Protecting Americans from Tax Hikes Act of 2015, Pub. L. 114–113, div Q, and by sections 201 through 207 of the Tax Technical Corrections Act of 2018, contained in Title II of Division U of the Consolidated Appropriations Act of 2018, Pub. L. 115–141).

By their terms, the BBA rules only apply to partnerships and not S corporations, except in the limited circumstance in which an S corporation is a partner in a partnership subject to the BBA rules. See sections 6226(b)(4) and 6227(b). But in cases where the S corporation is not a partner in a BBA partnership that made the election, there is no provision under BBA or any other provision of the Code to allow the S corporation to pay the imputed underpayment on behalf of its shareholders. Because the statute does not generally allow for S corporations to pay imputed underpayments on behalf of its shareholders, the approach suggested by the comment is not viable and therefore the comment is not adopted. However, as described in Part V.E.1 of this Summary of Comments and Explanation of Revisions, the Treasury Department and the IRS continue to study whether new processes or forms can be developed to streamline the amended return requirements, including in the case of S corporations that report

foreign tax redeterminations to their shareholders.

3. Foreign Tax Redeterminations of LB&I Taxpayers

Proposed § 1.905–4(b)(4) provided a limited alternative notification requirement for U.S. taxpayers that are under the jurisdiction of the IRS's Large Business & International (''LB&I'') Division. Under proposed § 1.905–4(b)(4)(i)(B), the alternative notification requirement is available only if certain conditions are met, including that an amended return reflecting a foreign tax redetermination would otherwise be due while the return for the affected taxable year is under examination, and that the foreign tax redetermination results in a downward adjustment to the amount of foreign tax paid or accrued, or included in the computation of foreign taxes deemed paid.

Several comments suggested broadening the scope of proposed § 1.905–4(b)(4) to include upward adjustments to foreign taxes paid or accrued. The comments also recommended that the special notification rules apply when multiple foreign tax redeterminations involving different foreign jurisdictions occur in the same taxable year and result in offsetting adjustments, for example, if there is an additional payment of foreign tax in one jurisdiction and a refund of a comparable amount in another jurisdiction.

The proposed regulations limited the alternative notification requirement to cases where the foreign tax redetermination results in a downward adjustment to the amount of foreign taxes paid or accrued because failure to comply with the notification requirements exposes taxpayers to penalties under section 6689 only if the foreign tax redetermination results in an underpayment of U.S. tax. As provided in § 1.905–4(b)(1)(iii), if a foreign tax redetermination results in an overpayment of U.S. tax, in order to claim a refund of U.S. tax the taxpayer must file an amended return within the period specified in section 6511. See section 6511(d)(3)(A), providing a special 10-year period of limitations for refund claims based on foreign tax credits. However, in unusual circumstances, an increase in foreign tax liability for a prior year may result in an underpayment (rather than an overpayment) of U.S. tax (for example, if an increase in foreign income tax liability causes a CFC to have a tested loss or to qualify for the high-tax exclusion of section 954(b)(4), reducing the amount of foreign taxes deemed paid).

In addition, in some cases the complexity of the required computations may make it difficult for taxpayers to identify easily which particular foreign tax redeterminations will ultimately result in an underpayment of U.S. tax. Accordingly, the final regulations extend the alternative notification procedures to cover the case of any adjustment (whether upward or downward) of foreign taxes by reason of a foreign tax redetermination that increases U.S. tax liability, and so would otherwise require the filing of an amended return while the affected year of the LB&I taxpayer is under examination. In addition, the final regulations provide that an LB&I taxpayer that has a foreign tax redetermination that decreases U.S. tax liability for an affected year that is under examination may (but is not required to) notify the examiner of the adjustment in lieu of filing an amended return to claim a refund (within the time period provided in section 6511). However, because section 6511(d)(3) generally allows taxpayers 10 years to seek a U.S. tax refund attributable to foreign tax credits and the regulations do not preclude taxpayers from filing such an amended return before the audit of an affected year is completed, the IRS may either accept the alternative notification or require the taxpayer to file an amended return. The additional flexibility added to the final regulations will assure timely notification of, and penalty protection for taxpayers with respect to, all foreign tax redeterminations that may increase or decrease U.S. tax liability for an affected taxable year, including in the case of offsetting foreign tax redeterminations that occur in the same taxable year.

Finally, comments recommended that examiners should be granted authority to accept notifications of foreign tax redeterminations outside the periods specified in § 1.905–4(b)(4)(ii)(A) through (C) and for affected taxable years that are not currently under examination. For example, the comments suggested that the notification deadline for an LB&I taxpayer should be extended upon the taxpayer's request and at the examiner's discretion.

The Treasury Department and the IRS have determined that amended returns reflecting additional U.S. tax due should be timely filed in order to ensure examiners have sufficient time to take into account any redetermination of U.S. tax liability without prolonging the audit. In addition, the special notification rules are not extended to taxpayers that are not currently under examination. The alternative notification rules in § 1.905–4(b)(4) are predicated on the fact that the examiner is in the process of determining whether to propose adjustments to the items included on the taxpayer's return for the taxable year under examination, and it is appropriate to defer the requirement to file an amended return reflecting the effect of a foreign tax redetermination on the taxpayer's U.S. tax liability for that taxable year until the examination has concluded. These considerations do not apply to affected taxable years that are not currently under examination when an amended return would otherwise be due. Accordingly, these comments are not adopted.

F. Transition Rule Relating to the TCJA

Proposed §§ 1.905–3(b)(2)(iv) and 1.905–5 provided a transition rule providing that post-2017 redeterminations of pre-2018 foreign income taxes of foreign corporations must be accounted for by adjusting the foreign corporation's taxable income and earnings and profits, post-1986 undistributed earnings, and post-1986 foreign income taxes (or pre-1987 accumulated profits and pre-1987 foreign income taxes, as applicable) in the pre-2018 year to which the redetermined foreign taxes relate.

The preamble to the 2019 FTC proposed regulations requested comments on whether an alternative adjustment to account for post-2017 foreign tax redeterminations with respect to pre-2018 taxable years of foreign corporations, such as an adjustment to the foreign corporation's taxable income and earnings and profits, post-1986 undistributed earnings, and post-1986 foreign income taxes as of the foreign corporation's last taxable year beginning before January 1, 2018, may provide for a simplified and reasonably accurate alternative.

Several comments supported this suggestion. A comment further noted that certain taxpayers should be excluded from any alternative rule where it would be distortive. For example, the comment suggested excluding taxpayers that distributed material amounts of earnings and profits, as well as taxpayers who took advantage of the subpart F high-tax exception in the foreign corporation's final pre-TCJA taxable year. Another comment noted that taxpayers should be allowed to adjust the foreign corporation's final pre-2018 year only if the adjustments would not cause a deficit in the foreign corporation's tax pool in that final year. A comment also suggested that the alternative rule should provide that in case of foreign corporations that ceased to be subject to

the pooling regime before 2018 (for example, due to a liquidation or sale to a foreign acquiror), the required adjustments should be made in the foreign corporation's last year in which the pooling rules are relevant). Additionally, several comments suggested that foreign tax redeterminations of foreign corporations below a certain threshold should not require a redetermination or adjustment of a taxpayer's section 965(a) inclusion or the amount of foreign taxes deemed paid with respect to such section 965(a) inclusion. Instead, some comments suggested that the redetermination be taken into account in the post-2017 year of the redetermination.

In response to comments, the final regulations under § 1.905–5(e) provide an irrevocable election for a foreign corporation's controlling domestic shareholders to account for all foreign tax redeterminations that occur in taxable years ending on or after November 2, 2020, with respect to pre-2018 taxable years of foreign corporations as if they occurred in the foreign corporation's last taxable year beginning before January 1, 2018 (the ''last pooling year''). The rules in §§ 1.905–3T and 1.905–5T (as contained in 26 CFR part 1 revised as of April 1, 2019) will apply for purposes of determining whether a particular foreign tax redetermination must instead be accounted for in the year to which the redetermined foreign tax relates, instead of in the last pooling year. The election is made by the foreign corporation's controlling domestic shareholders, and is binding on all persons who are, or were in a prior year to which the election applies, U.S. shareholders of the foreign corporation with respect to which the election is made for all of its subsequent foreign tax redeterminations, as well as foreign tax redeterminations of other members of the same CFC group as the foreign corporation for which the election is made. For this purpose, the definition of a CFC group in § 1.905–5(e)(2)(iv)(B) is modeled off the definition contained in § 1.951A–2(c)(7)(viii)(E)(*2*).

No exception is provided that would allow taxpayers to avoid redetermination or adjustment of the amount of a taxpayer's section 965(a) inclusion or foreign income taxes deemed paid with respect to such section 965(a) inclusion if under section 905(c) a foreign tax redetermination with respect to a foreign corporation's pre-2018 year requires such an adjustment to the taxpayer's U.S. tax liability. As discussed in Part V.E.1 of this Summary of Comments and Explanation of Revisions, section 905(c) mandates retroactive adjustments to U.S. tax liability when foreign taxes claimed as credits are redetermined, and there is no technical or policy basis on which to exclude such adjustments when the U.S. tax liability arises as a result of section 965 as opposed to another section of the Code.

G. Protective Claims

One comment requested guidance on how to file protective refund claims to account for contested foreign taxes that may result in foreign tax redeterminations after the expiration of the applicable statute of limitations. Providing guidance on the procedures for filing protective claims is beyond the scope of this rulemaking.

VI. Foreign Income Taxes Taken Into Account Under Section 954(b)(4)

The 2019 FTC proposed regulations included a clarification relating to schemes involving jurisdictions that do not impose corporate income tax on a CFC until its earnings are distributed. The proposed regulations clarified that foreign income taxes that have not accrued because they are contingent on a future distribution are not taken into account for purposes of determining the amount of foreign income taxes paid or accrued with respect to an item of income.

No comments were received with respect to this provision, and the rules are finalized without change. In addition, proposed § 1.905–1(d)(1) in the 2020 FTC proposed regulations further clarifies that taxes contingent on a future distribution are not treated as accrued.

VII. Applicability Dates

A. Regulations Relating to Foreign Tax Credits

The 2019 FTC proposed regulations provided that the rules in proposed §§ 1.861–8, 1.861–9, 1.861–12, 1.861–14, 1.904–4(c)(7) and (8), 1.904(b)–3, 1.905–3, 1.905–4, 1.905–5, 1.954–1, 1.954–2, 1.965–5(b)(2), and 301.6689–1 are applicable to taxable years that end on or after December 16, 2019. Certain provisions, such as §§ 1.704–1(b)(4)(viii)(*d*)(*1*), 1.861–17, 1.861–20, 1.904–6, and 1.960–1, were proposed to be applicable to taxable years beginning after December 31, 2019, while proposed §§ 1.904–4(e) and 1.904(g)–3 were proposed to be applicable to taxable years ending on or after the date the final regulations are filed. Proposed § 1.1502–4 was proposed to be applicable to taxable years for which the original consolidated Federal income tax return is due (without extensions) after December 17, 2019.

Several comments requested that the applicability dates to the 2019 FTC proposed regulations generally be delayed to taxable years beginning on or after the final regulations are published to allow more time for taxpayers to adapt to the new rules, and also requested that the regulations allow taxpayers the flexibility to rely on either the 2019 FTC proposed regulations or the final regulations for any preceding taxable years.

The Treasury Department and the IRS agree that the applicability date of the expense allocation rules in §§ 1.861–8 and 1.861–14, which particularly in the case of stewardship expenses contain significant changes relative to the 2019 FTC proposed regulations, should be delayed to allow taxpayers more time to comply with the revisions made in the final regulations. Therefore, the applicability dates of §§ 1.861–8 and 1.861–14 are revised to apply to taxable years beginning after December 31, 2019 (consistent with the later applicability date provided for §§ 1.861–17, 1.861–20, 1.904–6, and 1.960–1). In addition, although the applicability date of the notification requirements for foreign tax redeterminations in § 1.905–4 is adopted as proposed to apply to foreign tax redeterminations occurring in taxable years ending on or after December 16, 2019, a transition rule is added to the final regulations to provide taxpayers an additional year to file required notifications with respect to foreign tax redeterminations occurring in taxable years ending before November 12, 2020. Also, because section 1503(a) provides that regulations under section 1502 only apply to consolidated tax returns if they are prescribed before the last day prescribed by law for the filing of such return, the applicability date of § 1.1502–4 is revised to apply to taxable years for which the original consolidated Federal income tax return is due (without extensions) after November 12, 2020. However, the other provisions in the 2019 FTC proposed regulations which were proposed to apply to taxable years ending on or after December 16, 2019 (§§ 1.861–9, 1.861–12, 1.904–4(c)(7) and (8), 1.904(b)–3, 1.905–3, 1.905–5, 1.954–1, 1.954–2, 1.965–5(b)(2), and 301.6689–1), generally received minimal or no comments and have been adopted with no or minimal changes. Therefore, the Treasury Department and the IRS have determined that taxpayers with 2019 calendar years have been sufficiently on notice of these rules and little benefit would be afforded by providing a delayed applicability date or an election

to apply either the proposed or final regulations to preceding years, given that these rules have not significantly changed between the proposed and final regulations.

The 2019 FTC proposed regulations provided that, with respect to § 1.861–17, taxpayers that use the sales method for taxable years beginning after December 31, 2017, and before January 1, 2020 (or taxpayers that use the sales method only for their last taxable year that begins before January 1, 2020), may rely on proposed § 1.861–17 if they apply it consistently with respect to such taxable year and any subsequent year. Therefore, a taxpayer using the sales method for its taxable year beginning in 2018 may rely on proposed § 1.861–17 but must also apply the sales method (relying on proposed § 1.861–17) for its taxable year beginning in 2019.

These final regulations provide that a taxpayer may choose to apply § 1.861–17 (as contained in these final regulations) to taxable years beginning before January 1, 2020, provided that it applies the final regulations in their entirety, and provided that if a taxpayer applies the final regulations to the taxable year beginning in 2018, the taxpayer must also apply the final regulations for the subsequent taxable year beginning in 2019. Alternatively, and consistent with the 2019 FTC proposed regulations, a taxpayer may rely on proposed § 1.861–17 in its entirety for taxable years beginning after December 31, 2017, and beginning before January 1, 2020. A taxpayer that applies either the proposed or final version of § 1.861–17 to a taxable year beginning on or after January 1, 2018, and beginning before January 1, 2020, must apply it with respect to all operative sections (including both section 250 and 904). See § 1.861–8(f).

B. Rules Relating to Hybrid Arrangements and Section 951A

Under the 2020 hybrids proposed regulations, the rules under section 245A(e) relating to hybrid deduction accounts were proposed to be applicable to taxable years ending on or after the date that final regulations are published in the **Federal Register**, although a taxpayer could choose to consistently apply those final regulations to earlier taxable years. See proposed § 1.245A(e)–1(h)(2). In addition, the 2020 hybrids proposed regulations provided that a taxpayer could consistently rely on the proposed rules with respect to earlier taxable years.

Further, under the 2020 hybrids proposed regulations, the rules under section 881 relating to conduit financing arrangements were proposed to be applicable to payments made on or after the date that final regulations are published in the **Federal Register**. See proposed § 1.881–3(f). Finally, the rules under section 951A relating to disqualified payments were proposed to be applicable to taxable years of foreign corporations ending on or after April 7, 2020, and to taxable years of United States shareholders in which or with which such taxable years end. See proposed § 1.951A–7(d).

As discussed in Part III.B of this Summary of Comments and Explanation of Revisions, a comment recommended modifying the applicability date for the rules under section 881 if the final regulations were to include some of the proposed rules, such as the rule that treated as a financing transaction an instrument that is equity for both U.S. and foreign tax purposes and that gives rise to notional interest deductions. The final regulations do not include those rules. In addition, no comments suggested a modification to the applicability dates for the other rules under the 2020 hybrids proposed regulations. Therefore, the final regulations adopt applicability dates consistent with the proposed applicability dates under the 2020 hybrids proposed regulations. See §§ 1.245A(e)–1(h)(2); 1.881–3(f); and 1.951A–7(d). The final regulations also clarify that for a taxpayer to apply the final rules under section 245A(e) to a taxable year ending before November 12, 2020, the taxpayer must consistently apply those rules to that taxable year and any subsequent taxable year ending before November 12, 2020. See § 1.245A(e)–1(h)(2).

Special Analyses

I. Regulatory Planning and Review

Executive Orders 13771, 13563 and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. For purposes of Executive Order 13771, this final rule is regulatory.

These final regulations have been designated as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (MOA) (April 11, 2018) between the Treasury Department and the Office of Management and Budget (OMB) regarding review of tax regulations. The Office of Information and Regulatory Affairs has designated these regulations as economically significant under section 1(c) of the MOA. Accordingly, the OMB has reviewed these regulations.

A. Background and Need for the Final Regulations

1. Regulations Relating to Foreign Tax Credits

Before the Tax Cuts and Jobs Act (TCJA), the United States taxed its citizens, residents, and domestic corporations on their worldwide income. However, to the extent that a foreign jurisdiction and the United States taxed the same income, this framework could have resulted in double taxation. The U.S. foreign tax credit (FTC) regime alleviated potential double taxation by allowing a non-refundable credit for foreign income taxes paid or accrued that could be applied to reduce the U.S. tax on foreign source income. Although TCJA eliminated the U.S. tax on some foreign source income, the United States continues to tax other foreign source income, and to provide foreign tax credits against this U.S. tax. The changes made by TCJA to international taxation necessitate certain changes in this FTC regime.

The FTC calculation operates by defining different categories of foreign source income (a ''separate category'') based on the type of income.[3] Foreign taxes paid or accrued as well as deductions for expenses borne by U.S. parents and domestic affiliates that support foreign operations are also allocated to the separate categories under similar principles. The taxpayer can then use foreign tax credits allocated to each category against the U.S. tax owed on income in that category. This approach means that taxpayers who pay foreign taxes on income in one category cannot claim a credit against U.S. taxes owed on income in a different category, an important feature of the FTC regime. For example, suppose a domestic corporate taxpayer has $100 of active foreign source income in the ''general category'' and $100 of passive foreign source income, such as interest income, in the ''passive category.'' It also has $50 of foreign taxes associated with the

[3] Prior to the TCJA, these categories were primarily the passive income and general income categories. The TCJA added new separate categories for global intangible low-taxed income (the section 951A category) and foreign branch income.

''general category'' income and $0 of foreign taxes associated with the ''passive category'' income. The allowable FTC is determined separately for the two categories. Therefore, none of the $50 of ''general category'' FTCs can be used to offset U.S. tax on the ''passive category'' income. This taxpayer has a pre-FTC U.S. tax liability of $42 (21 percent of $200) but can claim an FTC for only $21 (21 percent of $100) of this liability, which is the U.S. tax owed with respect to active foreign source income in the general category. The $21 represents what is known as the taxpayer's foreign tax credit limitation. The taxpayer may carry the remaining $29 of foreign taxes ($50 minus $21) back to the prior taxable year and then forward for up to 10 years (until used), and is allowed a credit against U.S. tax on general category foreign source income in the carryover year, subject to certain restrictions.

The final regulations are needed to address changes introduced by the TCJA and to respond to outstanding issues raised in comments to foreign tax credit regulations issued in 2018. In particular, the comments highlighted the following areas of concern: (a) Uncertainty concerning appropriate allocation of R&E expenditures across FTC categories, and (b) the need to treat loans from partnerships to partners the same as loans from partners to partnerships with respect to aligning interest income to interest expense. In addition, the final regulations are needed to expand the application of section 905(c) to cases where a foreign tax redetermination changes a taxpayer's eligibility for the high-taxed exception under subpart F and GILTI.

In addition to the 2018 FTC final regulations, the Treasury Department and the IRS also issued final regulations in 2019 (84 FR 69022) (2019 FTC final regulations) and proposed regulations (84 FR 69124) (2019 FTC proposed regulations), which are being finalized in this document, and are issuing additional proposed regulations simultaneously with these final regulations.

2. Regulations Relating to Hybrid Arrangements and to Section 951A

The TCJA introduced two new provisions, sections 245A(e) and 267A, that affect the treatment of hybrid arrangements, and a new section 951A, which imposes tax on United States shareholders with respect to certain earnings of their CFCs.[4] The Treasury Department and the IRS previously issued final regulations under sections 245A(e) and 267A (2020 hybrids final regulations) as well as proposed regulations under sections 245A(e), 881, and 951A (2020 hybrids proposed regulations). See TD 9896, 85 FR 19802; REG–106013–19, 85 FR 19858. The Treasury Department and the IRS are issuing additional final regulations relating to finalize the 2020 hybrids proposed regulations.

Section 245A(e) disallows the dividends received deduction (DRD) for any dividend received by a U.S. shareholder from a CFC if the dividend is a hybrid dividend. In addition, section 245A(e) treats hybrid dividends between CFCs with a common U.S. shareholder as subpart F income. The statute defines a hybrid dividend as an amount received from a CFC for which a deduction would be allowed under section 245A(a) and for which the CFC received a deduction or other tax benefit in a foreign country. This disallowance of the DRD for hybrid dividends and the treatment of hybrid dividends as subpart F income neutralizes the double non-taxation that might otherwise be produced by these dividends.[5] The 2020 hybrids final regulations require that taxpayers maintain ''hybrid deduction accounts'' to track a CFC's (or a person related to a CFC's) hybrid deductions allowed in foreign jurisdictions across sources and years. The 2020 hybrids final regulations then provide that a dividend received by a U.S. shareholder from the CFC is a hybrid dividend to the extent of the sum of those accounts.

These final regulations also include rules regarding conduit financing arrangements.[6] Under the regulations in § 1.881–3 (the ''conduit financing regulations''), a ''financing arrangement'' means a series of transactions by which one entity (the financing entity) advances money or other property to another entity (the financed entity) through one or more intermediaries, and there are ''financing transactions'' linking each of those parties. If the IRS determines that a principal purpose of such an arrangement is to avoid U.S. tax, the IRS may disregard the participation of intermediate entities. As a result, U.S.-source payments from the financed entity are, for U.S. withholding tax purposes, treated as being made directly to the financing entity.

For example, consider a foreign entity that is seeking to finance its U.S. subsidiary but is not entitled to U.S. tax treaty benefits; thus, U.S.-source payments made to this entity are not entitled to reduced withholding tax rates. Instead of lending money directly to the U.S. subsidiary, the foreign entity might loan money to an affiliate residing in a treaty jurisdiction and have the affiliate lend on to the U.S. subsidiary in order to access U.S. tax treaty benefits.

Under the conduit financing regulations, if the IRS determines that a principal purpose of such an arrangement is to avoid U.S. tax, the IRS may disregard the participation of the affiliate. As a result, U.S.-source interest payments from the U.S. subsidiary are, for U.S. withholding tax purposes, treated as being made directly to the foreign entity.

In general, the conduit financing regulations apply only if ''financing transactions,'' as defined under the regulations, link the financing entity, the intermediate entities, and the financed entity. Under the prior conduit financing regulations, before the finalization of these regulations, an instrument that is equity for U.S. tax purposes generally will not be treated as a ''financing transaction'' unless it provides the holder significant redemption rights or the issuer has a right to redeem that likely will be exercised. This is the case even if the instrument is treated as debt under the laws of the foreign jurisdiction (for example, perpetual debt). As a result, the prior conduit financing regulations would not apply to an equity instrument in the absence of such attributes, and the U.S.-source payment might be entitled to a lower rate of U.S. withholding tax.

These final regulations also implement items in section 951A of the TCJA. Section 951A provides for the taxation of global intangible low-taxed

[4] Hybrid arrangements are tax-avoidance tools used by certain multinational corporations (MNCs) that have operations both in the U.S. and a foreign country. These hybrid arrangements use differences in tax treatment by the U.S. and a foreign country to reduce taxes in one or both jurisdictions. Hybrid arrangements can be ''hybrid entities,'' in which a taxpayer is treated as a flow-through or disregarded entity in one country but as a corporation in another, or ''hybrid instruments,'' which are financial transactions that are treated as debt in one country and as equity in another.

[5] The tax treatment under which certain payments are deductible in one jurisdiction and not included in income in a second jurisdiction is referred to as a deduction/no-inclusion outcome (''D/NI outcome'').

[6] On December 22, 2008, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–113462–08) that proposed adding § 1.881–3(a)(2)(i)(C) to the conduit financing regulations. The preamble to the proposed regulations provides that the Treasury Department and the IRS are also studying transactions where a financing entity advances cash or other property to an intermediate entity in exchange for a hybrid instrument (that is, an instrument treated as debt under the tax laws of the foreign country in which the intermediary is resident and equity for U.S. tax purposes), and states that they may issue separate guidance to address the treatment under § 1.881–3 of certain hybrid instruments.

income (GILTI), effective beginning with the first taxable year of a CFC that begins after December 31, 2017. The existing final regulations under section 951A address the treatment of a deduction or loss attributable to basis created by certain transfers of property from one CFC to a related CFC after December 31, 2017, but before the date on which section 951A first applies to the transferring CFC's income. Those regulations state that such a deduction or loss is allocated to residual CFC gross income; that is, income that is not attributable to tested income, subpart F income, or income effectively connected with a trade or business in the United States.

B. Overview of the Final Regulations

1. Regulations Relating to Foreign Tax Credits

These final regulations address the following issues: (1) The allocation and apportionment of deductions under sections 861 through 865, including new rules on the allocation and apportionment of research and experimentation (R&E) expenditures; (2) the allocation of foreign income taxes to the foreign income to which such taxes relate; (3) the interaction of the branch loss and dual consolidated loss recapture rules with sections 904(f) and (g); (4) the effect of foreign tax redeterminations of foreign corporations on the application of the high-tax exception described in section 954(b)(4) (including for purposes of determining tested income under section 951A(c)(2)(A)(i)(III)), and required notifications under section 905(c) to the IRS of foreign tax redeterminations and related penalty provisions; (5) the definition of foreign personal holding company income under section 954; (6) the application of the foreign tax credit disallowance under section 965(g); and (7) the application of the foreign tax credit limitation to consolidated groups.

2. Regulations Relating to Hybrid Arrangements and to Section 951A

These final regulations address three main issues. First, these final regulations address adjustments to hybrid deduction accounts under section 245A(e) and the 2020 hybrids final regulations. The 2020 hybrids final regulations stipulate that hybrid deduction accounts should generally be reduced to the extent that earnings and profits of the CFC that have not been subject to foreign tax as a result of certain hybrid arrangements are included in income in the United States by some provision other than section 245A(e). These final regulations provide new rules for reducing hybrid deduction accounts by reason of income inclusions attributable to subpart F, GILTI, and sections 951(a)(1)(B) and 956. An inclusion due to subpart F or GILTI reduces a hybrid deduction account only to the extent that the inclusion is not offset by a deduction or credit, such as a foreign tax credit, that likely will be afforded to the inclusion. Because deductions and credits are not available to offset income inclusions under section 951(a)(1)(B) and 956, these inclusions reduce a hybrid deduction account dollar-for-dollar.

Second, these final regulations address conduit financing arrangements under § 1.881–3 by expanding the types of transactions classified as financing transactions. These final regulations state that if a financial instrument is debt under the tax law of the foreign jurisdiction where the issuer is a resident, or, if the issuer is not a tax resident of any country, where it is created, organized, or otherwise established, then it may now be characterized as a financing transaction even though the instrument is equity for U.S. tax purposes. Accordingly, the conduit financing regulations would apply to multiple-party financing arrangements using these types of instruments. This change is consistent with the policy of § 1.881–3 and also helps to align the conduit regulations with the policy of section 267A by discouraging the exploitation of differences in treatment of financial instruments across jurisdictions. While section 267A and the 2020 hybrids final regulations apply only if the D/NI outcome is a result of the use of a hybrid entity or instrument, the conduit financing regulations apply regardless of causation and instead look to whether there is a tax avoidance plan. Thus, this new rule, to a limited extent, will address economically similar transactions that section 267A and the 2020 hybrids final regulations do not cover.

Finally, these final regulations address certain payments made after December 31, 2017, but before the date of the start of the first fiscal year for the transferor CFC for which 951A applies (the ''disqualified period'') in which payments, such as pre-payments of royalties, create income during the disqualified period and a corresponding deduction or loss claimed in taxable years after the disqualified period. Absent these final regulations, those deductions or losses could have been used to reduce tested income or increase tested losses, among other benefits. However, under these final regulations, these deductions will no longer provide such a tax benefit, and will instead be allocated to residual CFC income, similar to deductions or losses from certain property transfers in the disqualified period under the existing final regulations under section 951A.

C. Economic Analysis

1. Baseline

In this analysis, the Treasury Department and the IRS assess the benefits and costs of these final regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these regulations.

2. Summary of Economic Effects

i. Regulations Relating to Foreign Tax Credits

The final regulations provide certainty and clarity to taxpayers regarding the allocation of income, expenses, and foreign income taxes to the separate categories. In the absence of the enhanced specificity provided by these provisions of the regulations, similarly-situated taxpayers might interpret the foreign tax credit provisions of the Code differently, potentially resulting in inefficient patterns of economic activity. For example, in the absence of the final regulations, one taxpayer might have chosen not to undertake research (that is, incur R&E expenses) in a particular location, based on that taxpayer's interpretation of the tax consequences of such expenditures, that another taxpayer, making a different interpretation of the tax treatment of R&E, might have chosen to pursue. If this difference in interpretations confers a competitive advantage on the less productive enterprise, U.S. economic performance may suffer. Thus, the guidance provided in these regulations helps to ensure that taxpayers face more uniform incentives when making economic decisions. In general, economic performance is enhanced when businesses face more uniform signals about tax treatment.

To the extent that taxpayers would generally, in the absence of this final guidance, have interpreted the foreign tax credit rules as being less favorable to the taxpayer than the final regulations provide, the final regulations may result in additional international activity by these taxpayers relative to the no-action baseline. This additional activity may include both activities that are beneficial to the U.S. economy (perhaps because they represent enhanced international opportunities for businesses with U.S. owners) and activities that are not beneficial

(perhaps because they are accompanied by reduced activity in the United States). The Treasury Department and the IRS recognize that additional foreign economic activity by U.S. taxpayers may be a complement or substitute to activity within the United States and that to the extent these regulations change this activity, relative to the no-action baseline or alternative regulatory approaches, a mix of results may occur.

The Treasury Department and the IRS have not undertaken quantitative estimates of the economic effects of the foreign tax credit provisions of the regulations. The Treasury Department and the IRS do not have readily available data or models to estimate with reasonable precision (i) the tax stances that taxpayers would likely take in the absence of the final regulations or under alternative regulatory approaches; (ii) the difference in business decisions that taxpayers might make between the final regulations and the no-action baseline or alternative regulatory approaches as a result of these tax stances; or (iii) how this difference in those business decisions would affect measures of U.S. economic performance.

In the absence of such quantitative estimates, the Treasury Department and the IRS have undertaken a qualitative analysis of the economic effects of the final regulations relative to the no-action baseline and relative to alternative regulatory approaches. This analysis is presented in Parts I.C.3.i through iii of this Special Analyses.

ii. Regulations Relating to Hybrid Arrangements and Section 951A

These provisions of the final regulations provide certainty and clarity to taxpayers regarding (i) adjustments to hybrid deduction accounts under section 245A(e) and the 2020 hybrids final regulations; (ii) the determination of withholding taxes on payments made pursuant to conduit financing arrangements under § 1.881–3; and (iii) the allocation of deductions for certain payments between related CFCs for purposes of section 951A and the final regulations under section 951A.

In the absence of this clarity, the likelihood that different taxpayers would interpret the rules regarding hybrid arrangements and certain deductible payments under the final regulations under section 951A differently would be exacerbated. In general, overall economic performance is enhanced when businesses face more uniform signals about tax treatment. Certainty and clarity over tax treatment generally also reduce compliance costs for taxpayers.

For those statutory provisions for which similar taxpayers would generally adopt similar interpretations of the statute even in the absence of guidance, the final regulations provide value by helping to ensure that those interpretations are consistent with the intent and purpose of the statute. Because the tax treatment in these final regulations advances the intent and purpose of the statute, this guidance enhances U.S. economic performance, relative to the no-action baseline or alternative regulatory approaches, within the context of Congressional intent.

These provisions of the final regulations will further enhance U.S. economic performance by helping to ensure that similar economic arrangements face similar tax treatments. Disparate tax treatment of similar economic transactions may create economic inefficiencies by leading taxpayers to undertake less productive economic activities.

The Treasury Department and the IRS have not undertaken quantitative estimates of the economic effects of these provisions of the final regulations because they do not have readily available data or models to estimate with reasonable precision (i) the types or volume of hybrid arrangements or certain disqualified payments between related CFCs that would likely be covered under these regulations, under the no-action baseline, or under alternative regulatory approaches; or (ii) the effects of those hybrid arrangements or disqualified payments on businesses' overall economic performance, including possible differences in compliance costs.

In the absence of such quantitative estimates, the Treasury Department and the IRS have undertaken a qualitative analysis of the economic effects of the final regulations relative to the no-action baseline and relative to alternative regulatory approaches. This analysis is presented in Parts I.C.3.iv through vi of this Special Analyses.

iii. Summary of Economic Effects of All Provisions

The Treasury Department and the IRS project that the final regulations will have economic effects greater than $100 million per year ($2020) relative to the no-action baseline. This determination is based on the substantial size of many of the businesses potentially affected by these regulations and the general responsiveness of business activity to effective tax rates,[7] one component of which is the creditability of foreign taxes. Based on these two magnitudes, even modest changes in the treatment of foreign taxes or the allocation of deductions between related CFCs provided by the final regulations, relative to the no-action baseline, can be expected to have annual effects greater than $100 million ($2020).

3. Economic Effects of Specific Provisions

i. Rules for Allocating R&E Expenditures Under the Sales Method

a. Background

Under long-standing foreign tax credit rules, taxpayers must allocate expenditures to income categories. In the case of research and experimentation (R&E) expenditures, taxpayers can elect between a ''sales method'' and a ''gross income method'' to allocate the R&E expenses.[8]

The TCJA created some uncertainty regarding the application of the sales method because of the introduction of the section 951A category. In particular, comments raised issues regarding whether any R&E expenditures should be allocated to the section 951A category. The fact that sales by CFCs generate tested income and tested income is generally assigned to the section 951A category might imply that R&E expenditures should be allocated to the section 951A category. But the fact that royalty payments from the CFC to the U.S. taxpayer (*e.g.,* in remuneration for IP held by the parent that is licensed to the CFC to create the products that are sold) are in the general category implies that R&E expenditures should be allocated to the general category.

The gross income method is based on a different apportionment factor (gross income) as compared to the sales method (gross receipts). However, the gross income method is subject to certain conditions that require the result to be within a certain band around the result under the sales method, because historically the Treasury Department and the IRS have considered that the gross income method could lead to anomalous results and could be more easily manipulated than the sales

[7] See E. Zwick and J. Mahon, ''Tax Policy and Heterogeneous Investment Behavior,'' at *American Economic Review* 2017, 107(1): 217–48 and articles cited therein.

[8] If the taxpayer chooses the gross income method, 25 percent of the R&E expenditures are exclusively apportioned to the source where more than 50 percent of the taxpayer's R&E activities occur (generally the United States), and the other 75 percent is apportioned ratably. If a taxpayer chooses the sales method then 50 percent of the R&E expenditures are exclusively apportioned on the same basis, and the other 50 percent is apportioned ratably.

method.[9] The uncertainty with respect to R&E expense allocation under the sales method needed resolution, and because the gross income method is tied to the sales method, any changes to the sales method required consideration of the gross income method.

b. Options Considered for the Final Regulations

The Treasury Department and the IRS considered three options with respect to the allocation of R&E expenditures to the section 951A category for purposes of calculating the FTC limitation. The first option was to confirm that R&E expenditures are allocated to the section 951A category under the sales method and to otherwise leave their treatment under the gross income method unchanged. The second option was to revise the sales method to provide that R&E expenditures are only allocated to the income that represents the taxpayer's return on intellectual property (thus, R&E expenditures could not be allocated to income from the taxpayer's CFC sales) and otherwise leave their treatment under the gross income method unchanged. The third option was to revise the sales method as considered in the second option and eliminate the gross income method for purposes of allocating R&E expenditures.

The final regulations adopt the third option. This option allows for the provision of an allocation and apportionment method for R&E expenditures that generally matches the expense reasonably with the income it generates. The matching of income and expenses generally produces a more efficient tax system contingent on the overall Code relative to the alternative options. Additionally, because this option results in no R&E expense being allocated to section 951A category income, it does not incentivize taxpayers with excess credits (which cannot be carried over to prior or future taxable years and therefore become unusable) in the section 951A category to perform R&E through foreign subsidiaries; instead, the chosen option generally incentivizes choosing the location of R&E based on economic considerations rather than tax-related reasons, contingent on the overall Code. Finally, because the final regulations adopt the principle of allocating and apportioning R&E expenditures to IP-related income of the U.S. taxpayer, the gross income method is no longer relevant, because it allocates and apportions R&E expenditures to the section 951A category, and section 951A category gross income is not IP income to the U.S. taxpayer.

c. Number of Affected Taxpayers

The Treasury Department and the IRS have determined that the population of affected taxpayers consists of any U.S. taxpayer with R&E expenditures and foreign operations. There are around 2,500 such taxpayers in currently available tax filings from tax year 2018. Based on Statistics of Income data, approximately $40 billion of R&E expenses of such taxpayers were allocated to foreign source income, out of a total of $190 billion in qualified research expenses reported by such taxpayers.[10]

ii. Application of Section 905(c) to Changes Affecting the High-Tax Exception

a. Background

Section 905(c) provides special rules for a foreign tax redetermination (FTR), which is when the amount of foreign tax paid in an earlier year (origin year) is changed in a later year (FTR year). This redetermination may be necessary, for example, because the taxpayer gets a refund or because a foreign audit determines that the taxpayer owes additional foreign tax. Since these additional taxes (or refunds) relate to the origin year, an FTR affects a taxpayer's origin year tax position (as well as FTC carryovers from that year). Before the TCJA, FTRs of foreign corporations generally resulted in prospective ''pooling adjustments'' to foreign tax credits. Under this approach, taxpayers simply added to or reduced the amount of foreign taxes in their foreign subsidiary's FTC ''pool'' going forward rather than amend the deemed paid taxes claimed on their origin year return. TCJA eliminated the pooling mechanism for taxes (because the adoption of a participation exemption system along with the elimination of deferral made it unnecessary) and replaced it with a system where taxes are deemed paid each year with an inclusion or distribution of previously taxed earnings and profits (''PTEP'').

The 2019 FTC final regulations make clear that an FTR of a United States taxpayer must always be accounted for in the origin year, and that the taxpayer must file an amended return reflecting any resulting change in the taxpayer's U.S. tax liability.

Section 905(c) provides tools to enforce this amended return requirement. It suspends the statute of limitations with respect to the assessment of any additional U.S. tax liability that results from an FTR, and imposes a civil penalty on taxpayers who fail to notify the IRS (through an amended return) of an FTR. To reflect the repeal of the pooling mechanism, the final regulations generally require taxpayers to account for FTRs of foreign subsidiaries on an amended return that reflects revised foreign taxes deemed paid under section 960 and any resulting change in the taxpayer's U.S. tax liability. However, the 2019 FTC final regulations require U.S. tax redeterminations only by reason of FTRs that affect the amount of foreign tax credit taxpayers claimed in the origin year. The rules do not apply to other tax effects, such as when the FTR changes the amount of earnings and profits the taxpayer's CFC had in the origin year, or affects whether or not the CFC's income qualifies for the high-tax exception under GILTI or subpart F.

The interaction of FTRs and the high-tax exception under GILTI and subpart F increases the importance of filing an origin year amended return. In particular, FTRs can give rise to inaccurate origin year U.S. liability calculations in the absence of an amended return precisely because they can change taxpayers' eligibility for the high-tax exception. Therefore, the final regulations provide that the section 905(c) rules cover situations in which the FTR affects not only the amount of FTCs taxpayers claimed in the origin year, but also whether or not their CFC's income qualified for the high-tax exception.

b. Options Considered for the Final Regulations

The Treasury Department and the IRS considered two options in applying section 905(c) in connection with the high-tax exception. The first option was to limit section 905(c) to changes in the amount of FTCs. The second option was to provide that section 905(c) applies in connection with the high-tax exceptions under GILTI and subpart F.

The final regulations adopt the second option. The first option would lead to frequent occurrences of inaccurate results with respect to the GILTI and subpart F high- tax exceptions because it is common for foreign audits to change the amount of tax paid in a prior

[9] The gross income method is more susceptible to manipulation because taxpayers can manage the type and amount of their foreign gross income by, for example, not paying a dividend and because presuming a factual relationship between the R&E expenditure and the related class of income based on the relative amounts of a taxpayer's gross income was more attenuated than a factual relationship based on sales.

[10] Note, however, that these taxpayers might have additional R&E expenses which are not qualified R&E expenses. The tax data do not separately identify such expenses.

year. Furthermore, taxpayers would have an incentive to overpay their CFC's foreign tax in the origin year, claim the high-tax exception to avoid subpart F or GILTI inclusions, wait for the 3 year statute of limitations to pass, and then claim a foreign tax refund with the foreign authorities. Without section 905(c) applying, taxpayers would have no obligation or threat of penalty for not amending the origin year return. Although there are FTC regulations that deny a credit if taxpayers make a noncompulsory payment of tax (*i.e.,* taxpayers paid more foreign tax than is necessary under foreign law), those rules are challenging to administer. While taxpayers have the burden to prove that they were legally required to pay the tax, the IRS may need to engage foreign tax law experts to establish that the taxpayer could have successfully fought paying it.

The second option provides a more accurate tax calculation than the first option, and it is instrumental in avoiding abuse. The increased number of amended returns relative to the alternative regulatory approach will increase compliance costs for taxpayers, but the Treasury Department and the IRS consider that, in light of the high-tax exception, accurate origin year tax liability calculations necessitate these increased costs.

c. Number of Affected Taxpayers

The Treasury Department and the IRS determined that the final regulations potentially affect those U.S. taxpayers that pay foreign taxes and have a redetermination of that tax. Although data reporting the number of taxpayers subject to an FTR in a given year are not readily available, some taxpayers currently subject to FTRs will file amended returns. The Treasury Department and the IRS estimate that there were between 8,900 and 13,500 taxpayers with foreign affiliates that filed amended returns in 2018. However, the elimination of the pooling mechanism and the expanded incidence of deemed paid taxes in connection with the GILTI regime may significantly increase the number of taxpayers filing amended returns, and the expansion of the section 905(c) requirement to file an amended return to instances where a FTR changes eligibility for the high-tax exception under GILTI or subpart F (but does not affect the taxpayer's foreign tax credit) has the potential to modestly increase that number. The Treasury Department and the IRS have determined that a high upper bound for the number of taxpayers subject to a FTR that will be required to file amended returns (that is, taxpayers affected by this provision) can be derived by estimating the number of taxpayers with a potential GILTI or subpart F inclusion. Based on currently available tax filings for taxable year 2018, there were about 16,500 C corporations with CFCs that filed at least one Form 5471 with their Form 1120 return. In addition, for the same year, there were about 41,000 individuals with CFCs that e-filed at least one Form 5471 with their Form 1040 return.

In 2018, there were about 3,250 S corporations with CFCs that filed at least one Form 5471 with their 1120S return. The identified S corporations had an estimated 23,000 shareholders. Finally, the Treasury Department and the IRS estimate that there were approximately 7,500 U.S. partnerships with CFCs that e-filed at least one Form 5471 as Category 4 or 5 filers in 2018. The identified partnerships had approximately 1.7 million partners, as indicated by the number of Schedules K–1 filed by the partnerships. This number includes both domestic and foreign partners, so it substantially overstates the number of partners that would actually be affected by the final regulations because it includes foreign partners.

iii. Extension of the Partnership Loan Rule to Loans From the Partnership to a U.S. Partner

a. Background

The 2019 FTC final regulations provide a rule that aligns interest income and expense when a U.S. partner makes a loan to the partnership. Under this matching rule, the partner's gross interest income is apportioned between U.S. and foreign sources in each separate category based on the partner's interest expense apportionment ratios. This rule minimizes the artificial increase in foreign source taxable income based solely on offsetting amounts of interest income and expense from a related party loan to a partnership. Comments in response to the 2018 FTC proposed regulations requested an equivalent rule when the partnership makes a loan to a U.S. partner.

b. Options Considered for the Final Regulations

The Treasury Department and the IRS considered two options with respect to this rule. The first option was to not provide a rule, because the abuse the Treasury Department and the IRS were concerned about was not relevant with respect to loans from the partnership to the partner. In the absence of a matching rule, the U.S. partner's U.S. source taxable income would be artificially increased but this income is not eligible to be sheltered by FTCs. The second option was to provide an identical rule for loans from the partnership to the partner as was provided in the 2019 FTC final regulations for loans from the partner to the partnership. The final regulations adopt the second option. This symmetry helps to ensure that similar economic transactions are treated similarly.

c. Number of Affected Taxpayers

The Treasury Department and the IRS consider the population of affected taxpayers to consist of any U.S. partner in a partnership which has a loan from the partnership to the partner or certain other parties related to the partner. The Treasury Department and the IRS estimate that there are approximately 450 partnerships and 5,000 partners that would be affected by this regulation.

iv. Section 245A(e)—Adjustment of Hybrid Deduction Account

a. Background

Under the 2020 hybrids final regulations, taxpayers must maintain hybrid deduction accounts to track income of a CFC that was sheltered from foreign tax due to hybrid arrangements, so that it may be included in U.S. income under section 245A(e) when paid as a dividend. The final regulations address how hybrid deduction accounts should be adjusted to account for earnings and profits of a CFC included in U.S. income due to certain provisions other than section 245A(e). The final regulations provide rules reducing a hybrid deduction account for three categories of inclusions: subpart F inclusions, GILTI inclusions, and inclusions under sections 951(a)(1)(B) and 956.

b. Options Considered for the Final Regulations

One option for addressing the treatment of earnings and profits included in U.S. income due to provisions other than section 245A(e) would be to not issue additional guidance beyond current tax rules and thus not to adjust hybrid deduction accounts to account for such inclusions. This would be the simplest approach among those considered, but under this approach, some income could be subject to double taxation in the United States. For example, if no adjustment is made, to the extent that a CFC's earnings and profits were sheltered from foreign tax as a result of certain hybrid arrangements, the section 245A DRD would be disallowed for an amount of

dividends equal to the amount of the sheltered earnings and profits, even if some of the sheltered earnings and profits were included in the income of a U.S. shareholder under the subpart F rules. The U.S. shareholder would be subject to tax on both the dividends and on the subpart F inclusion. Owing to this double taxation, the final regulations do not adopt this approach.

A second option would be to reduce hybrid deduction accounts by amounts included in gross income under the three categories; that is, without regard to deductions or credits that may offset the inclusion. While this option is also relatively simple, it could lead to double non-taxation and thus would give rise to results not intended by the statute. Subpart F and GILTI inclusions may be offset by—and thus may not be fully taxed in the United States as a result of—foreign tax credits and, in the case of GILTI, the section 250 deduction.[11] Therefore, this option for reducing hybrid deduction accounts may result in some income that was sheltered from foreign tax due to hybrid arrangements also escaping full U.S. taxation. This double non-taxation is economically inefficient because otherwise similar activities are taxed differently, potentially leading to inefficient business decisions.

A third option, which is the option finalized by the Treasury Department and the IRS, is to reduce hybrid deduction accounts by the amount of the inclusions from the three categories, but only to the extent that the inclusions are likely not offset by foreign tax credits or, in the case of GILTI, the section 250 deduction. For subpart F and GILTI inclusions, the final regulations stipulate adjustments to be made to account for the foreign tax credits and the section 250 deduction available for GILTI inclusions. These adjustments are intended to provide a precise, administrable manner for measuring the extent to which a subpart F or GILTI inclusion is included in U.S. income and not shielded by foreign tax credits or deductions. This option results in an outcome aligned with statutory intent, as it generally ensures that the section 245A DRD is disallowed (and thus a dividend is included in U.S. income without any regard for foreign tax credits) only for amounts that were sheltered from foreign tax by reason of a hybrid arrangement but that have not yet been subject to U.S. tax.

[11] Deductions or credits are not available to offset income inclusions under sections 951(a)(1)(B) and 956, the third category of income inclusions that reduce hybrid deduction accounts addressed by these final regulations.

Relative to a no-action baseline, these final regulations provide taxpayers with new instructions regarding how to adjust hybrid deduction accounts to account for earnings and profits that are included in U.S. income by reason of certain provisions other than section 245A(e). This new instruction avoids possible double taxation. Double taxation is inconsistent with the intent and purpose of the statute and is economically inefficient because it may result in otherwise similar income streams facing different tax treatment, incentivizing taxpayers to finance operations with specific income streams and activities that may not be the most economically productive.

The Treasury Department and the IRS have not estimated the difference in compliance costs under each of the three options for the treatment of earnings and profits included in U.S. income due to provisions other than section 245A(e) because they do not have readily available data or models that can provide such estimates.

c. Number of Affected Taxpayers

The Treasury Department and IRS estimate that this provision will impact an upper bound of approximately 2,000 taxpayers. This estimate is based on the top 10 percent of taxpayers (by gross receipts) that filed a domestic corporate income tax return for tax year 2017 with a Form 5471 attached, because only domestic corporations that are U.S. shareholders of CFCs are potentially affected by section 245A(e).[12]

This estimate is an upper bound on the number of large corporations affected because it is based on all transactions, even though only a portion of such transactions involve hybrid arrangements. The tax data do not report whether these reported dividends were part of a hybrid arrangement because such information was not relevant for calculating tax before the TCJA. In addition, this estimate is an upper bound because the Treasury Department and the IRS anticipate that fewer taxpayers would engage in hybrid arrangements going forward as the statute and § 1.245A(e)–1 would make such arrangements less beneficial to taxpayers. Further, it is anticipated that the final regulations will result in only a small increase in compliance costs for those taxpayers who do engage in hybrid arrangements (relative to the baseline) because a reduction to hybrid deduction accounts under these final regulations generally uses information required to be computed under other provisions of the Code.

[12] Because of the complexities involved, primarily only large taxpayers engage in hybrid arrangements. The estimate that the top 10 percent of otherwise-relevant taxpayers (by gross receipts) are likely to engage in hybrid arrangements is based on the judgment of the Treasury Department and IRS.

v. Conduit Financing Regulations To Address Hybrid Instruments

a. Background

The conduit financing regulations allow the IRS to disregard intermediate entities in a multiple-party financing arrangement for the purposes of determining withholding tax rates if the instruments used in the arrangement are considered ''financing transactions.'' Financing transactions generally exclude instruments that are treated as equity for U.S. tax purposes unless they have significant redemption-type features. Thus, in the absence of further guidance, the conduit financing regulations would not apply to an equity instrument in the absence of such features. This would allow payments made under these arrangements to continue to be eligible for reduced withholding tax rates through a conduit structure.

b. Options Considered for the Final Regulations

One option for addressing the current disparate treatment would be to not change the conduit financing regulations, which currently treat equity as a financing transaction only if it has specific redemption-type features; this is the no-action baseline. This option is not adopted by the Treasury Department and the IRS, since it is inconsistent with the Treasury Department's and the IRS's ongoing efforts to address financing transactions that use hybrid instruments, as discussed in the 2008 proposed regulations.

A second option, which is adopted in the final regulations, is to treat as a financing transaction an instrument that is equity for U.S. tax purposes but debt under the tax law of the issuer's jurisdiction of residence or, if the issuer is not a tax resident of any country, the tax law of the country in which the issuer is created, organized or otherwise established. This approach will prevent taxpayers from using this type of hybrid instrument to engage in treaty shopping through a conduit jurisdiction. However, this approach does not cover certain cases, such as if a jurisdiction offers a tax benefit to non-debt instruments (for example, a notional interest deduction with respect to equity). The Treasury Department and the IRS adopt this second option in these final regulations because it will, in a manner that is clear and

administrable, prevent a basic form of inappropriate avoidance of the conduit financing regulations.

A third option considered, which was proposed in the 2020 hybrids proposed regulations, would be to treat as a financing transaction any instrument that is equity for U.S. tax purposes and which entitles its issuer or its shareholder a deduction or similar tax benefit in the issuer's resident jurisdiction or in the jurisdiction where the resident has a permanent establishment. This rule would be broader than the second option. It would cover all instruments that give rise to deductions or similar tax benefits, such as credits, rather than only those instruments that are treated as debt under foreign law. This rule would also cover instruments where a financing payment is attributable to a permanent establishment of the issuer, and the tax law of the permanent establishment's jurisdiction allows a deduction or similar treatment for the instrument. This approach would prevent issuers from routing transactions through their permanent establishments to avoid the anti-conduit rules. The Treasury Department and the IRS did not adopt this third option in these final regulations. As discussed in Part III.B of the Summary of Comments and Explanation of Revisions, the Treasury Department and the IRS plan to finalize this rule separately to allow additional time to consider the comments received.

Relative to a no-action baseline, the final regulations are likely to incentivize some taxpayers to shift away from conduit financing arrangements and hybrid arrangements, a shift that is likely to result in little to no overall economic loss, or even an economic gain, because conduit arrangements are generally not economically productive arrangements and are typically pursued only for tax-related reasons. The Treasury Department and the IRS recognize, however, that as a result of these provisions, some taxpayers may face a higher effective tax rate, which may lower their economic activity.

The Treasury Department and the IRS have not undertaken more precise quantitative estimates of either of these economic effects because they do not have readily available data or models to estimate with reasonable precision: (i) The types or volume of conduit arrangements that taxpayers would likely use under the final regulations or under the no-action baseline; or (ii) the effects of those arrangements on businesses' overall economic performance, including possible differences in compliance costs.

c. Number of Affected Taxpayers

The Treasury Department and the IRS estimate that the number of taxpayers potentially affected by the final conduit financing regulations will be an upper bound of approximately 7,000 taxpayers. This estimate is based on the top 10 percent of taxpayers (by gross receipts) that filed a domestic corporate income tax return with a Form 5472, ''Information Return of a 25% Foreign-Owned U.S. Corporation or a Foreign Corporation Engaged in a U.S. Trade or Business,'' attached because primarily foreign entities that advance money or other property to a related U.S. entity through one or more foreign intermediaries are potentially affected by the conduit financing regulations.[13]

This estimate is an upper bound on the number of large corporations affected because it is based on all domestic corporate arrangements involving foreign related parties, even though only a portion of such arrangements are conduit financing arrangements that use hybrid instruments. The tax data do not report whether these arrangements were part of a conduit financing arrangement because such information is not provided on tax forms. In addition, this estimate is an upper bound because the Treasury Department and the IRS anticipate that fewer taxpayers would engage in conduit financing arrangements that use hybrid instruments going forward as the proposed conduit financing regulations would make such arrangements less beneficial to taxpayers.

vi. Rules Under Section 951A To Address Certain Disqualified Payments Made During the Disqualified Period

a. Background

The final section 951A regulations include a rule that addresses certain transactions involving disqualified transfers of property between related CFCs during the disqualified period that may have the effect of reducing GILTI inclusions due to timing differences between when income is included and when resulting deductions, such as depreciation expenses, are claimed. The disqualified period of a CFC is the period between December 31, 2017, which is the last earnings and profits measurement date under section 965, and the beginning of the CFC's first taxable year that begins after December 31, 2017, which is the first taxable year with respect to which section 951A is effective. The final regulations refine this rule to extend its applicability to other transactions for which similar timing differences can arise.

b. Options Considered for the Final Regulations

The Treasury Department and the IRS considered two options with respect to providing a rule that would apply to certain transactions during the disqualified period in addition to disqualified transfers. The first option was to not provide a rule that would apply to additional transactions. This option was not adopted in the final regulations, since it would result in certain transactions involving payments during the disqualified period giving rise to reduced GILTI inclusions simply due to timing differences. In addition, this option would not provide a similar tax treatment for transactions involving payments as for disqualified transfers of property occurring during the disqualified period.

The second option, which is the option adopted in the final regulations, is to provide an identical rule for disqualified payments between related CFCs as was provided in the section 951A final regulations for disqualified transfers of property between related CFCs during the disqualified period. This symmetry helps to ensure that similar economic transactions are treated similarly.

In the absence of such a rule, certain payments between related CFCs made during the disqualified period may give rise to lower income inclusions for their U.S. shareholders. For example, suppose that a CFC licensed property to a related CFC for ten years and received pre-payments of royalties during the disqualified period from the related CFC. Since these prepayments were received by the licensor CFC during the disqualified period, they would not have affected amounts included under section 965 nor given rise to GILTI tested income. However, the licensee CFC that made the payments would not have claimed the total of the corresponding deductions during the disqualified period, since the timing of deductions are generally tied to economic performance over the period of use. The licensee CFC would claim deductions over the ten years of the contract, and since these deductions would be claimed during taxable years when section 951A is in effect, these deductions would reduce GILTI tested income or increase GILTI tested loss. Thus, this type of transaction could

[13] Because of the complexities involved, primarily only large taxpayers engage in conduit financing arrangements. The estimate that the top 10 percent of otherwise-relevant taxpayers (by gross receipts) are likely to engage in conduit financing arrangements is based on the judgment of the Treasury Department and IRS.

lower overall income inclusions for the U.S. shareholder of these CFCs in a manner that does not accurately reflect the earnings of the CFCs over time.

Under the final regulations, all deductions attributable to disqualified payments to a related CFC during the disqualified period are allocated and apportioned to residual CFC gross income. These deductions will not thereby reduce tested, subpart F or effectively connected income. This rule provides similar treatment to transactions involving payments as the rule in the section 951A final regulations provides to property transfers between related CFCs during the disqualified period.

Relative to a no-action baseline, the final regulations harmonize the treatment of similar transactions. Since this rule applies to deductions resulting from transactions that occurred during the disqualified period and not to any new transactions, the Treasury Department and the IRS do not expect changes in taxpayer behavior under the final regulations, relative to the no-action baseline.

c. Number of Affected Taxpayers

The Treasury Department and the IRS estimate that the number of taxpayers potentially affected by this rule will be an upper bound of approximately 25,000 to 35,000 taxpayers. This estimate is based on filers of income tax returns with a Form 5471 attached because only filers that are U.S. shareholders of CFCs or that have at least a 10 percent ownership in a foreign corporation would be subject to section 951A. This estimate is an upper bound because it is based on all filers subject to section 951A, even though only a portion of such taxpayers may have engaged in the pre-payment transactions during the disqualified period described in the proposed regulations. Therefore, the Treasury Department and the IRS estimate that the number of taxpayers potentially affected by this rule will be substantially less than 25,000 to 35,000 taxpayers.

II. Paperwork Reduction Act

A. Regulations Relating to Foreign Tax Credits

For purposes of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) (''PRA''), there is a collection of information in §§ 1.905–4 and 1.905–5(b) and (e). When a redetermination of U.S. tax liability is required by reason of a foreign tax redetermination (FTR), the final regulations generally require the taxpayer to notify the IRS of the FTR and provide certain information necessary to redetermine the U.S. tax due for the year or years affected by the FTR. If there is no change in the U.S. tax liability as a result of the FTR or if the FTR is caused by certain de minimis fluctuations in foreign currency rates, the taxpayer may simply attach the notification to their next filed tax return and make any appropriate adjustments in that year. However, taxpayers are generally required to file an amended return (or an administrative adjustment request in the case of certain partnerships) for the year or years affected by the FTR along with an updated Form 1116 Foreign Tax Credit (Individual, Estate, or Trust) (covered under OMB Control Number 1545–0074 individual, or 1545–0121 and 1545–0092 estate and trust) or Form 1118 Foreign Tax Credit-Corporations (OMB Control Number 1545–0123), and a written statement providing specific information relating to the FTR (covered under OMB Control Number 1545–1056). Since the burden for filing amended income tax returns and the Forms 1116 and 1118 is covered under the OMB Control Numbers listed in the prior sentence, the burden estimates for OMB Control Number 1545–1056 only cover the burden for the written statements. Sections 1.905–5(b) and 1.905–5(e) only apply to foreign tax redeterminations of foreign corporations that relate to a taxable year of the foreign corporation beginning before January 1, 2018. Section 1.905–4 applies to all other foreign tax redeterminations. Section 1.905–5(b) and (e) reference the same notification and information requirements as § 1.905–4, subject to certain modifications.

For purposes of the PRA, the reporting burden associated with §§ 1.905–4 and 1.905–5(b) and (e) will be reflected in the PRA submission associated with OMB control number 1545–1056, which is set to expire on December 31, 2020. The number of respondents to this collection was estimated to be in a range from 8,900 to 13,500 and the total estimated burden time was estimated to be 56,000 hours and total estimated monetized costs of $2,583,840 ($2017). The IRS will be requesting a revision of the paperwork burden under OMB control number 1545–1056 prior to its expiration date.

For taxpayers who are required to file an amended return (along with related Form 1116 or Form 1118) in order to report an FTR, and for purposes of the PRA, the reporting burden for filing the amended return will be reflected in OMB control numbers 1545–0123 (relating to business filers, which represents a total estimated burden time, including all related forms and schedules, of 3.344 billion hours and total estimated monetized costs of $61.558 billion ($2019)), 1545–0074 (relating to individual filers, which represents a total estimated burden time, including all related forms and schedules, of 1.717 billion hours and total estimated monetized costs of $33.267 billion ($2019)), 1545–0092 (relating to estate and trust filers with respect to all related forms and schedules except Form 1116, which represents a total estimated burden time, including all related forms and schedules except Form 1116, of 307,844,800 hours and total estimated monetized costs of $14.077 billion ($2018)), and 1545–0121 (relating to estate and trust filers but solely with respect to Form 1116, which represents a total estimated burden time related solely to Form 1116 of 25,066,693 hours and total estimated monetized costs of $1.744 billion ($2018)). In general, burden estimates for OMB control numbers 1545–0123 and 1545–0074 include, and therefore do not isolate, the estimated burden of the foreign tax credit-related forms. These reported burdens are therefore insufficient for future calculations of the burden imposed by the final regulations. However, with respect to estate and trust filers (OMB control numbers 1545–0121 and 1545–0092) the burdens with respect to foreign tax credit-related forms are isolated in OMB control number 1545–0121 which relates solely to Form 1116, and, therefore may be sufficient to determine future burdens imposed by the final regulations. These particular burden estimates, except OMB control number 1545–0121, have also been reported for other regulations related to the taxation of cross-border income and the Treasury Department and the IRS urge readers to recognize that these numbers are duplicates and to guard against overcounting the burden that international tax provisions imposed prior to the TCJA.

As a result of the changes made in the TCJA to the foreign tax credit rules generally, and to section 905(c) specifically, the Treasury Department and the IRS anticipate that the number of respondents may increase among taxpayers who file Form 1120 series returns. The possible increase in the number of respondents is due to the increase in foreign tax credits claimed by taxpayers in connection with the new GILTI regime and the elimination of adjustments to pools of post-1986 earnings and profits and post-1986 foreign income taxes as an alternative to filing an amended return following the changes made in the TCJA. These

changes to the burden estimate will be reflected in the PRA submission for the renewal of OMB control number 1545–1056 as well as in the OMB control numbers 1545–0074 (for individuals) and 1545–0123 (for business taxpayers).

The estimates for the number of impacted filers with respect to the collections of information described in this Part II of the Special Analyses are based on filers of income tax returns that file a Form 1065, Form 1040, or Form 1120 series for years 2015 through 2017 because only filers of these forms are generally subject to the collection of information requirement. The IRS estimates the number of impacted filers to be the following:

TAX FORMS IMPACTED

Collection of information	Number of respondents (estimated)	Forms to which the information may be attached
§ 1.905–4	8,900—13,500	Form 1065 series, Form 1040 series, and Form 1120 series.
§ 1.905–5(b)	8,900—13,500	Form 1065 series, Form 1040 series, and Form 1120 series.
§ 1.905–5(e)	8,900—13,500	Form 1065 series, Form 1040 series, and Form 1120 series.

Source: IRS data (MeF, DCS, and Compliance Data Warehouse).

No burden estimates specific to the final regulations are currently available. The Treasury Department and the IRS have not estimated the burden, including that of any new information collections, related to the requirements under the final regulations. Those estimates would capture both changes made by the TCJA and those that arise out of discretionary authority exercised in the final regulations.

The Treasury Department and the IRS request comments on all aspects of the forms that reflect the information collection burdens related to the final regulations, including estimates for how much time it would take to comply with the paperwork burdens related to the forms described and ways for the IRS to minimize the paperwork burden. Proposed revisions (if any) to these forms that reflect the information collections related to the final regulations will be made available for public comment at *https://apps.irs.gov/app/picklist/list/draftTaxForms.html* and will not be finalized until after these forms have been approved by OMB under the PRA.

B. Regulations Relating to Hybrid Arrangements and Section 951A

Pursuant to § 1.6038–2(f)(14), certain U.S. shareholders of a CFC must provide information relating to the CFC and the rules of section 245A(e) on Form 5471, ''Information Return of U.S. Persons With Respect to Certain Foreign Corporations,'' (OMB control number 1545–0123), as the form or other guidance may prescribe. The final regulations do not impose any additional information collection requirements relating to section 245A(e). However, the final regulations provide guidance regarding certain computations required under section 245A(e), and such could affect the information required to be reported on Form 5471. For purposes of the PRA, the reporting burden associated with § 1.6038–2(f)(14) is reflected in the PRA submission for Form 5471. See the chart at the end of this Part II.B of this Special Analyses section for the status of the PRA submission for Form 5471. As described in the Special Analyses section in the 2020 hybrids final regulations, and as set forth in the chart below, the Treasury Department and the IRS estimate the number of affected filers to be 2,000.

Pursuant to § 1.6038–5, certain U.S. shareholders of a CFC must provide information relating to the CFC and the U.S. shareholder's GILTI inclusion under section 951A on new Form 8992, ''U.S. Shareholder Calculation of Global Intangible Low-Taxed Income (GILTI),'' (OMB control number 1545–0123), as the form or other guidance may prescribe. The final regulations do not impose any additional information collection requirements relating to section 951A. However, the final regulations provide guidance regarding computations required under section 951A for taxpayers who engaged in certain transactions during the disqualified period, and such guidance could affect the information required to be reported by these taxpayers on Form 8992. For purposes of the PRA, the reporting burden associated with the collection of information under § 1.6038–5 is reflected in the PRA submission for Form 8992. See the chart at the end of this Part II.B of the Special Analyses for the status of the PRA submission for Form 8992. As discussed in the Special Analyses of the preamble to the proposed regulations under section 951A (REG–104390–18, 83 FR 51072), and as set forth in the chart below, the Treasury Department and the IRS estimate the number of filers subject to § 1.6038–5 to be 25,000 to 35,000. Since the final regulations only apply to taxpayers who engaged in certain transactions during the disqualified period, the Treasury Department and the IRS estimate that the number of filers affected by the final regulations and subject to the collection of information in § 1.6038–5 will be significantly less than 25,000 to 35,000.

There is no existing collection of information relating to conduit financing arrangements, and the final regulations do not impose any new information collection requirements relating to conduit financing arrangements. Therefore, a PRA analysis is not required with respect to the final regulations relating to conduit financing arrangements. As a result, the Treasury Department and the IRS estimate the number of filers affected by the final regulations for hybrid arrangements and section 951A to be the following.

TAX FORMS IMPACTED

Collection of information	Number of respondents (estimated, rounded to nearest 1,000)	Forms in which information may be collected
§ 1.6038–2(f)(14)	2,000	Form 5471 (Schedule I).
§ 1.6038–5	25,000—35,000	Form 8992.

Source: IRS data (MeF, DCS, and Compliance Data Warehouse).

The current status of the PRA submissions related to the tax forms associated with the information collections in §§ 1.6038–2(f)(14) and 1.6038–5 is provided in the accompanying table. The reporting burdens associated with the information collections in §§ 1.6038–2(f)(14) and 1.6038–5 are included in the aggregated burden estimates for OMB control number 1545–0123, which represents a total estimated burden time for all forms and schedules for corporations of 3.157 billion hours and total estimated monetized costs of $58.148 billion ($2017). The overall burden estimates provided in 1545–0123 are aggregate amounts that relate to the entire package of forms associated with the OMB control number, and are therefore not suitable for future calculations needed to assess the burden specific to certain regulations, such as the information collections under § 1.6038–2(f)(14) or § 1.6038–5.

No burden estimates specific to the final regulations are currently available. The Treasury Department and the IRS have not identified any burden estimates, including those for new information collections, related to the requirements under the final regulations. The Treasury Department and the IRS estimate PRA burdens on a taxpayer-type basis rather than a provision-specific basis. Changes in those estimates from the estimates reported here will capture both changes made by the TCJA and those that arise out of discretionary authority exercised in the final regulations.

The Treasury Department and the IRS request comments on the forms that reflect the information collection burdens related to the final regulations, including estimates for how much time it would take to comply with the paperwork burdens related to the forms described and ways for the IRS to minimize the paperwork burden. Proposed revisions (if any) to these forms that reflect the information collections related to the final regulations will be made available for public comment at *https://apps.irs.gov/app/picklist/list/draftTaxForms.html* and will not be finalized until after these forms have been approved by OMB under the PRA.

Form	Type of filer	OMB No.(s)	Status
Form 5471	Business (NEW Model)	1545–0123	Approved by OIRA 1/30/2020 until 1/31/2021.
	Link: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201907-1545-001*		
	Individual (NEW Model)	1545–0074	Approved by OIRA 1/30/2020 until 1/31/2021.
	Link: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201909-1545-021*		
Form 8992	Business (NEW Model)	1545–0123	Approved by OIRA 1/30/2020 until 1/31/2021.
	Link: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201907-1545-001*		

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these final regulations will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act.

A. Regulations Relating to Foreign Tax Credits

These final regulations provide guidance needed to comply with statutory changes and affect individuals and corporations claiming foreign tax credits. The domestic small business entities that are subject to the foreign tax credit rules in the Code and in these final regulations are generally those domestic small business entities that are at least 10 percent corporate shareholders of foreign corporations, and so are eligible to claim dividends-received deductions or compute foreign taxes deemed paid under section 960 with respect to inclusions under subpart F and section 951A from CFCs. Other aspects of these final regulations also affect domestic small business entities that operate in foreign jurisdictions or that have income from sources outside of the United States. Based on 2017 Statistics of Income data, the Treasury Department and the IRS computed the fraction of taxpayers owning a CFC by gross receipts size class. The smaller size classes have a relatively small fraction of taxpayers that own CFCs, which suggests that many domestic small business entities would be unaffected by these regulations.

Many of the important aspects of these final regulations, including all of the rules in §§ 1.861–8(d)(2)(ii)(B), 1.904–4(c)(7), 1.904–6(f), 1.905–3(b)(2), 1.905–5, 1.954–1, 1.954–2, and 1.965–5(b)(2) apply only to U.S. persons that operate a foreign business in corporate form, and, in most cases, only if the foreign corporation is a CFC. Other provisions in these final regulations, including the rules in §§ 1.861–8(d)(2)(v) and (e)(16), 1.861–14, 1.1502–4, and 1.1502–21, generally apply only to members of a consolidated group and insurance companies or other members of the financial services industry earning income from sources outside of the United States. It is infrequent for domestic small entities to operate as part of an affiliated group, to be taxed as an insurance company, or to constitute a financial services entity, and also earn income from sources outside of the United States. Consequently, the Treasury Department and the IRS expect that these final regulations are unlikely to affect a substantial number of domestic small business entities; however, adequate data are not available at this time to certify that a substantial number of small entities would be unaffected.

The Treasury Department and the IRS have determined that these final regulations will not have a significant economic impact on domestic small business entities. Based on published information from 2017, foreign tax credits as a percentage of three different tax-related measures of annual receipts (see Table for variables) by corporations are substantially less than the 3 to 5 percent threshold for significant economic impact for businesses in all categories of business receipts. The amount of foreign tax credits in 2017 is an upper bound on the change in foreign tax credits resulting from these final regulations.

Size (by business receipts)	Under $500,000	$500,000 under $1,000,000	$1,000,000 under $5,000,000	$5,000,000 under $10,000,000	$10,000,000 under $50,000,000	$50,000,000 under $100,000,000	$100,000,000 under $250,000,000	$250,000,000 or more
FTC/Total Receipts	0.12%	0.00%	0.00%	0.01%	0.01%	0.01%	0.02%	0.28%
FTC/(Total Receipts-Total Deductions)	0.61%	0.03%	0.09%	0.05%	0.35%	0.71%	1.38%	9.89%
FTC/Business Receipts	0.84%	0.00%	0.00%	0.00%	0.01%	0.01%	0.02%	0.05%

Source: RAAS: KDA: (Tax Year 2017 SOI Data).

Although § 1.905–4 contains a collection of information requirement, the small businesses that are subject to the requirements of § 1.905–4 are domestic small entities with significant foreign operations. The data to assess precise counts of small entities affected by § 1.905–4 are not readily available. However, as demonstrated in the accompanying Table in this Part III, foreign tax credits do not have a significant economic impact for any gross-receipts class of business entities. Accordingly, it is hereby certified that the requirements of § 1.905–4 will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 7805(f), the proposed regulations preceding these final regulations (REG–105495–19) were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses and no comments were received.

B. Regulations Relating to Hybrid Arrangements and Section 951A

The final regulations amend certain computations required under section 245A(e) or section 951A. As discussed in the Special Analyses accompanying the preambles to the 2020 hybrids final regulations and the proposed regulations under section 951A (REG–104390–18, 83 FR 51072), as well as in Part II.B of the Special Analyses, the Treasury Department and the IRS project that a substantial number of domestic small business entities will not be subject to sections 245A(e) and 951A, and therefore, the existing requirements in §§ 1.6038–2(f)(14) and 1.6038–5 will not have a significant economic impact on a substantial number of small entities.

The small entities that are subject to section 245A(e) and § 1.6038–2(f)(14) are controlling U.S. shareholders of a CFC that engage in a hybrid arrangement, and the small entities that are subject to section 951A and § 1.6038–5 are U.S. shareholders of a CFC. A CFC is a foreign corporation in which more than 50 percent of its stock is owned by U.S. shareholders, measured either by value or voting power. A U.S. shareholder is any U.S. person that owns 10 percent or more of a foreign corporation's stock, measured either by value or voting power, and a controlling U.S. shareholder of a CFC is a U.S. person that owns more than 50 percent of the CFC's stock.

The Treasury Department and the IRS estimate that there are only a small number of taxpayers having gross receipts below either $25 million (or $41.5 million for financial entities) who would potentially be affected by these regulations.[14] The Treasury Department and the IRS's estimate of those entities who could potentially be affected is based on their review of those taxpayers who filed a domestic corporate income tax return in 2016 with gross receipts below either $25 million (or $41.5 million for financial institutions) who also reported dividends on a Form 5471. The Treasury Department and the IRS estimate that this number is between 1 and 6 percent of all affected entities regardless of size.

The Treasury Department and the IRS cannot readily identify from these data amounts that are received pursuant to hybrid arrangements because those amounts are not separately reported on tax forms. Thus, dividends received as reported on Form 5471 are an upper bound on the amount of hybrid arrangements by these taxpayers.

The Treasury Department and the IRS estimated the upper bound of the relative cost of the statutory and regulatory hybrids provisions, as a percentage of revenue, for these taxpayers as (i) the statutory tax rate of 21 percent multiplied by dividends received as reported on Form 5471, divided by (ii) the taxpayer's gross receipts. Based on this calculation, the Treasury Department and the IRS estimate that the upper bound of the relative cost of these statutory and regulatory provisions is above 3 percent for more than half of the small entities described in the preceding paragraph. Because this estimate is an upper bound, a smaller subset of these taxpayers (including potentially zero taxpayers) is likely to have a cost above three percent of gross receipts.

[14] This estimate is limited to those taxpayers who report gross receipts above $0.

Pursuant to section 7805(f), the proposed regulations preceding these final regulations (REG–106013–19) were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses and no comments were received.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. This rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

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

VI. Congressional Review Act

The Administrator of the Office of Information and Regulatory Affairs of the OMB has determined that this Treasury decision is a major rule for purposes of the Congressional Review Act (5 U.S.C. 801 *et seq.*) (''CRA''). Under section 801(3) of the CRA, a major rule takes effect 60 days after the rule is published in the **Federal Register**. Accordingly, the Treasury Department and IRS are adopting these final regulations with the delayed

effective date generally prescribed under the Congressional Review Act.

Drafting Information

The principal authors of the final regulations are Corina Braun, Karen J. Cate, Jeffrey P. Cowan, Jorge M. Oben, Richard F. Owens, Jeffrey L. Parry, Tracy M. Villecco, Suzanne M. Walsh, and Andrew L. Wigmore of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Income taxes, Penalties, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by revising the entry for § 1.861–14 and adding an entry for § 1.905–4 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805.

* * * * *

Section 1.861–14 also issued under 26 U.S.C. 864(e)(7).

* * * * *

Section 1.905–4 also issued under 26 U.S.C. 989(c)(4), 26 U.S.C. 6227(d), 26 U.S.C. 6241(11), and 26 U.S.C. 6689(a).

* * * * *

■ **Par. 2.** Section 1.245A(e)–1 is amended by:

■ 1. Adding paragraphs (d)(4)(i)(B) and (d)(4)(ii).

■ 2. Adding a sentence at the end of the introductory text of paragraph (g).

■ 3. Adding paragraphs (g)(1)(v) and (h)(2).

The additions read as follows:

§ 1.245A(e)–1 Special rules for hybrid dividends.

* * * * *

(d) * * *

(4) * * *

(i) * * *

(B) Second, the account is decreased (but not below zero) pursuant to the rules of paragraphs (d)(4)(i)(B)(*1*) through (*3*) of this section, in the order set forth in this paragraph (d)(4)(i)(B).

(*1*) *Adjusted subpart F inclusions*—(*i*) *In general.* Subject to the limitation in paragraph (d)(4)(i)(B)(*1*)(*ii*) of this section, the account is reduced by an adjusted subpart F inclusion with respect to the share for the taxable year, as determined pursuant to the rules of paragraph (d)(4)(ii) of this section.

(*ii*) *Limitation.* The reduction pursuant to paragraph (d)(4)(i)(B)(*1*)(*i*) of this section cannot exceed the hybrid deductions of the CFC allocated to the share for the taxable year multiplied by a fraction, the numerator of which is the sum of the items of gross income of the CFC that give rise to subpart F income (determined without regard to an amount treated as subpart F income by reason of section 964(e)(4)(A)(i), to the extent that a deduction under section 245A(a) is allowed for a portion of the amount included under section 964(e)(4)(A)(ii) in the gross income of a domestic corporation) of the CFC for the taxable year and the denominator of which is the sum of all the items of gross income of the CFC for the taxable year.

(*iii*) *Special rule allocating otherwise unused adjusted subpart F inclusions across accounts in certain cases.* This paragraph (d)(4)(i)(B)(*1*)(*iii*) applies after each of the specified owner's hybrid deduction accounts with respect to its shares of stock of the CFC are adjusted pursuant to paragraph (d)(4)(i)(B)(*1*)(*i*) of this section but before the accounts are adjusted pursuant to paragraph (d)(4)(i)(B)(*2*) of this section, to the extent that one or more of the hybrid deduction accounts would have been reduced by an amount pursuant to paragraph (d)(4)(i)(B)(*1*)(*i*) of this section but for the limitation in paragraph (d)(4)(i)(B)(*1*)(*ii*) of this section (the aggregate of the amounts that would have been reduced but for the limitation, the *unused reduction amount,* and the accounts that would have been reduced by the unused reduction amount, the *unused reduction amount accounts*). When this paragraph (d)(4)(i)(B)(*1*)(*iii*) applies, the specified owner's hybrid deduction accounts other than the unused reduction amount accounts (if any) are ratably reduced by the lesser of the unused reduction amount and the difference of the following two amounts: The hybrid deductions of the CFC allocated to the specified owner's shares of stock of the CFC for the taxable year multiplied by the fraction described in paragraph (d)(4)(i)(B)(*1*)(*ii*) of this section; and the reductions pursuant to paragraph (d)(4)(i)(B)(*1*)(*i*) of this section with respect to the specified owner's shares of stock of the CFC.

(*2*) *Adjusted GILTI inclusions*—(*i*) *In general.* Subject to the limitation in paragraph (d)(4)(i)(B)(*2*)(*ii*) of this section, the account is reduced by an adjusted GILTI inclusion with respect to the share for the taxable year, as determined pursuant to the rules of paragraph (d)(4)(ii) of this section.

(*ii*) *Limitation.* The reduction pursuant to paragraph (d)(4)(i)(B)(*2*)(*i*) of this section cannot exceed the hybrid deductions of the CFC allocated to the share for the taxable year multiplied by a fraction, the numerator of which is the sum of the items of gross tested income of the CFC for the taxable year and the denominator of which is the sum of all the items of gross income of the CFC for the taxable year.

(*iii*) *Special rule allocating otherwise unused adjusted GILTI inclusions across accounts in certain cases.* This paragraph (d)(4)(i)(B)(*2*)(*iii*) applies after each of the specified owner's hybrid deduction accounts with respect to its shares of stock of the CFC are adjusted pursuant to paragraph (d)(4)(i)(B)(*2*)(*i*) of this section but before the accounts are adjusted pursuant to paragraph (d)(4)(i)(B)(*3*) of this section, to the extent that one or more of the hybrid deduction accounts would have been reduced by an amount pursuant to paragraph (d)(4)(i)(B)(*2*)(*i*) of this section but for the limitation in paragraph (d)(4)(i)(B)(*2*)(*ii*) of this section (the aggregate of the amounts that would have been reduced but for the limitation, the *unused reduction amount,* and the accounts that would have been reduced by the unused reduction amount, the *unused reduction amount accounts*). When this paragraph (d)(4)(i)(B)(*2*)(*iii*) applies, the specified owner's hybrid deduction accounts other than the unused reduction amount accounts (if any) are ratably reduced by the lesser of the unused reduction amount and the difference of the following two amounts: The hybrid deductions of the CFC allocated to the specified owner's shares of stock of the CFC for the taxable year multiplied by the fraction described in paragraph (d)(4)(i)(B)(*2*)(*ii*) of this section; and the reductions pursuant to paragraph (d)(4)(i)(B)(*2*)(*i*) of this section with respect to the specified owner's shares of stock of the CFC. *See* paragraph (g)(1)(v)(C) of this section for an illustration of the application of this paragraph (d)(4)(i)(B)(*2*)(*iii*).

(*3*) *Certain section 956 inclusions.* The account is reduced by an amount included in the gross income of a domestic corporation under sections 951(a)(1)(B) and 956 with respect to the share for the taxable year of the domestic corporation in which or with which the CFC's taxable year ends, to the extent so included by reason of the application of section 245A(e) and this

section to the hypothetical distribution described in § 1.956–1(a)(2).

* * * * *

(ii) *Rules regarding adjusted subpart F and GILTI inclusions.* (A) The term *adjusted subpart F inclusion* means, with respect to a share of stock of a CFC for a taxable year of the CFC, a domestic corporation's pro rata share of the CFC's subpart F income included in gross income under section 951(a)(1)(A) (determined without regard to an amount included in gross income by the domestic corporation by reason of section 964(e)(4)(A)(ii), to the extent a deduction under section 245A(a) is allowed for the amount) for the taxable year of the domestic corporation in which or with which the CFC's taxable year ends, to the extent attributable to the share (as determined under the principles of section 951(a)(2) and § 1.951–1(b) and (e)), adjusted (but not below zero) by—

(*1*) Adding to the amount the associated foreign income taxes with respect to the amount; and

(*2*) Subtracting from such sum the quotient of the associated foreign income taxes divided by the percentage described in section 11(b).

(B) The term *adjusted GILTI inclusion* means, with respect to a share of stock of a CFC for a taxable year of the CFC, a domestic corporation's GILTI inclusion amount (within the meaning of § 1.951A–1(c)(1)) for the U.S. shareholder inclusion year (within the meaning of § 1.951A–1(f)(7)), to the extent attributable to the share (as determined under paragraph (d)(4)(ii)(C) of this section), adjusted (but not below zero) by—

(*1*) Adding to the amount the associated foreign income taxes with respect to the amount;

(*2*) Multiplying such sum by the difference of 100 percent and the section 250(a)(1)(B)(i) deduction percentage; and

(*3*) Subtracting from such product the quotient of 80 percent of the associated foreign income taxes divided by the percentage described in section 11(b).

(C) A domestic corporation's GILTI inclusion amount for a U.S. shareholder inclusion year is attributable to a share of stock of the CFC based on a fraction—

(*1*) The numerator of which is the domestic corporation's pro rata share of the tested income of the CFC for the U.S. shareholder inclusion year, to the extent attributable to the share (as determined under the principles of § 1.951A–1(d)(2)); and

(*2*) The denominator of which is the aggregate of the domestic corporation's pro rata share of the tested income of each tested income CFC (as defined in § 1.951A–2(b)(1)) for the U.S. shareholder inclusion year.

(D) The term *associated foreign income taxes* means—

(*1*) With respect to a domestic corporation's pro rata share of the subpart F income of the CFC included in gross income under section 951(a)(1)(A) and attributable to a share of stock of a CFC for a taxable year of the CFC, current year tax (as described in § 1.960–1(b)(4)) allocated and apportioned under § 1.960–1(d)(3)(ii) to the subpart F income groups (as described in § 1.960–1(b)(30)) of the CFC for the taxable year, to the extent allocated to the share under paragraph (d)(4)(ii)(E) of this section; and

(*2*) With respect to a domestic corporation's GILTI inclusion amount under section 951A attributable to a share of stock of a CFC for a taxable year of the CFC, the product of—

(*i*) Current year tax (as described in § 1.960–1(b)(4)) allocated and apportioned under § 1.960–1(d)(3)(ii) to the tested income groups (as described in § 1.960–1(b)(33)) of the CFC for the taxable year, to the extent allocated to the share under paragraph (d)(4)(ii)(F) of this section;

(*ii*) The domestic corporation's inclusion percentage (as described in § 1.960–2(c)(2)); and

(*iii*) The section 904 limitation fraction with respect to the domestic corporation for the U.S. shareholder inclusion year.

(E) Current year tax allocated and apportioned to a subpart F income group of a CFC for a taxable year is allocated to a share of stock of the CFC by multiplying the foreign income tax by a fraction—

(*1*) The numerator of which is the domestic corporation's pro rata share of the subpart F income of the CFC for the taxable year, to the extent attributable to the share (as determined under the principles of section 951(a)(2) and § 1.951–1(b) and (e)); and

(*2*) The denominator of which is the subpart F income of the CFC for the taxable year.

(F) Current year tax allocated and apportioned to a tested income group of a CFC for a taxable year is allocated to a share of stock of the CFC by multiplying the foreign income tax by a fraction—

(*1*) The numerator of which is the domestic corporation's pro rata share of tested income of the CFC for the taxable year, to the extent attributable to the share (as determined under the principles § 1.951A–1(d)(2)); and

(*2*) The denominator of which is the tested income of the CFC for the taxable year.

(G) The term *section 904 limitation fraction* means, with respect to a domestic corporation for a U.S. shareholder inclusion year, a fraction—

(*1*) The numerator of which is the amount of foreign tax credits for the U.S. shareholder inclusion year that, by reason of sections 901 and 960(d) and taking into account section 904, the domestic corporation is allowed for the separate category set forth in section 904(d)(1)(A) (amounts includible in gross income under section 951A); and

(*2*) The denominator of which is the amount of foreign tax credits for the U.S. shareholder inclusion year that, by reason of sections 901 and 960(d) and without regard to section 904, the domestic corporation would be allowed for the separate category set forth in section 904(d)(1)(A) (amounts includible in gross income under section 951A).

(H) The term *section 250(a)(1)(B)(i) deduction percentage* means, with respect to a domestic corporation for a U.S. shareholder inclusion year, a fraction—

(*1*) The numerator of which is the amount of the deduction under section 250 allowed to the domestic corporation for the U.S. shareholder inclusion year by reason of section 250(a)(1)(B)(i) (taking into account section 250(a)(2)(B)); and

(*2*) The denominator of which is the domestic corporation's GILTI inclusion amount for the U.S. shareholder inclusion year.

* * * * *

(g) * * * No amounts are included in the gross income of US1 under section 951(a)(1)(A), 951A(a), or 951(a)(1)(B) and section 956.

(1) * * *

(v) *Alternative facts—account reduced by adjusted GILTI inclusion.* The facts are the same as in paragraph (g)(1)(i) of this section, except that for taxable year 1 FX has $130x of gross tested income and $10.5x of current year tax (as described in § 1.960–1(b)(4)) that is allocated and apportioned under § 1.960–1(d)(3)(ii) to the tested income groups of FX. US1's ability to credit the $10.5x of current year tax is not limited under section 904(a). In addition, FX has $119.5x of tested income ($130x of gross tested income, less the $10.5x of current year tax deductions properly allocable to the gross tested income). Further, of US1's pro rata share of the tested income ($119.5x), $80x is attributable to Share A and $39.5x is attributable to Share B (as determined under the principles of § 1.951A–1(d)(2)). Moreover, US1's net deemed tangible income return (as defined in § 1.951A–1(c)(3)) for taxable year 1 is $71.7x, and US1 does not own any stock of a CFC

other than its stock of FX. Thus, US1's GILTI inclusion amount (within the meaning of § 1.951A–1(c)(1)) for taxable year 1, the U.S. shareholder inclusion year, is $47.8x (net CFC tested income of $119.5x, less net deemed tangible income return of $71.7x) and US1's inclusion percentage (as described in § 1.960–2(c)(2)) is 40 ($47.8x/$119.5x). The deduction allowed to US1 under section 250 by reason of section 250(a)(1)(B)(i) is not limited as a result of section 250(a)(2)(B). At the end of year 1, US1's hybrid deduction account with respect to Share A is: First, increased by $80x (the amount of hybrid deductions allocated to Share A); and second, decreased by $10x (the sum of the adjusted GILTI inclusion with respect to Share A, and the adjusted GILTI inclusion with respect to Share B that is allocated to the hybrid deduction account with respect to Share A) to $70x. *See* paragraphs (d)(4)(i)(A) and (B) of this section. In year 2, the entire $30x of each dividend received by US1 from FX during year 2 is a hybrid dividend, because the sum of US1's hybrid deduction accounts with respect to each of its shares of FX stock at the end of year 2 ($70x) is at least equal to the amount of the dividends ($60x). *See* paragraph (b)(2) of this section. At the end of year 2, US1's hybrid deduction account with respect to Share A is decreased by $60x (the amount of the hybrid deductions in the account that give rise to a hybrid dividend or tiered hybrid dividend during year 2) to $10x. *See* paragraph (d)(4)(i)(C) of this section. Paragraphs (g)(1)(v)(A) through (C) of this section describe the computations pursuant to paragraph (d)(4)(i)(B)(*2*) of this section.

(A) To determine the adjusted GILTI inclusion with respect to Share A for taxable year 1, it must be determined to what extent US1's $47.8x GILTI inclusion amount is attributable to Share A. *See* paragraph (d)(4)(ii)(B) of this section. Here, $32x of the inclusion is attributable to Share A, calculated as $47.8x multiplied by a fraction, the numerator of which is $80x (US1's pro rata share of the tested income of FX attributable to Share A) and denominator of which is $119.5x (US1's pro rata share of the tested income of FX, its only CFC). *See* paragraph (d)(4)(ii)(C) of this section. Next, the associated foreign income taxes with respect to the $32x GILTI inclusion amount attributable to Share A must be determined. *See* paragraphs (d)(4)(ii)(B) and (D) of this section. Such associated foreign income taxes are $2.8x, calculated as $10.5x (the current year tax allocated and apportioned to the tested income groups of FX) multiplied by a fraction, the numerator of which is $80x (US1's pro rata share of the tested income of FX attributable to Share A) and the denominator of which is $119.5x (the tested income of FX), multiplied by 40% (US1's inclusion percentage), multiplied by 1 (the section 904 limitation fraction with respect to US1's GILTI inclusion amount). *See* paragraphs (d)(4)(ii)(D), (F), and (G) of this section. Thus, pursuant to paragraph (d)(4)(ii)(B) of this section, the adjusted GILTI inclusion with respect to Share A is $6.7x, computed by—

(*1*) Adding $2.8x (the associated foreign income taxes with respect to the $32x GILTI inclusion attributable to Share A) to $32x, which is $34.8x;

(*2*) Multiplying $34.8x (the sum of the amounts in paragraph (g)(1)(v)(A)(*1*) of this section) by 50% (the difference of 100 percent and the section 250(a)(1)(B)(i) deduction percentage), which is $17.4x; and

(*3*) Subtracting $10.7x (calculated as $2.24x (80% of the $2.8x of associated foreign income taxes) divided by .21 (the percentage described in section 11(b)) from $17.4x (the product of the amounts in paragraph (g)(1)(v)(A)(*2*) of this section), which is $6.7x.

(B) Pursuant to computations similar to those discussed in paragraph (g)(1)(v)(A) of this section, the adjusted GILTI inclusion with respect to Share B is $3.3x. However, the hybrid deduction account with respect to Share B is not reduced by such $3.3x, because of the limitation in paragraph (d)(4)(i)(B)(*2*)(*ii*) of this section, which, with respect to Share B, limits the reduction pursuant to paragraph (d)(4)(i)(B)(*2*)(*i*) of this section to $0 (calculated as $0, the hybrid deductions allocated to the share for the taxable year, multiplied by 1, the fraction described in paragraph (d)(4)(i)(B)(*2*)(*ii*) of this section (computed as $130x, the sole item of gross tested income, divided by $130x, the sole item of gross income)). *See* paragraphs (d)(4)(i)(B)(*2*)(*i*) and (*ii*) of this section.

(C) US1's hybrid deduction account with respect to Share A is reduced by the entire $6.7x adjusted GILTI inclusion with respect to the share, as such $6.7x does not exceed the limit in paragraph (d)(4)(i)(B)(*2*)(*ii*) of this section ($80x, calculated as $80x, the hybrid deductions allocated to the share for the taxable year, multiplied by 1, the fraction described in paragraph (d)(4)(i)(B)(*2*)(*ii*) of this section). *See* paragraphs (d)(4)(i)(B)(*2*)(*i*) and (*ii*) of this section. In addition, the hybrid deduction account is reduced by another $3.3x, the amount of the adjusted GILTI inclusion with respect to Share B that is allocated to the hybrid deduction account with respect to Share A. *See* paragraph (d)(4)(i)(B)(*2*)(*iii*) of this section. As a result, pursuant to paragraph (d)(4)(i)(B)(*2*) of this section, US1's hybrid deduction account with respect to Share A is reduced by $10x ($6.7x plus $3.3x).

* * * * *

(h) * * *

(2) *Special rules.* Paragraphs (d)(4)(i)(B) and (d)(4)(ii) of this section (decrease of hybrid deduction accounts; rules regarding adjusted subpart F and GILTI inclusions) apply to taxable years ending on or after November 12, 2020. However, a taxpayer may choose to apply paragraphs (d)(4)(i)(B) and (d)(4)(ii) of this section to a taxable year ending before November 12, 2020, so long as the taxpayer consistently applies paragraphs (d)(4)(i)(B) and (d)(4)(ii) of this section to that taxable year and any subsequent taxable year ending before November 12, 2020.

■ **Par. 3.** Section 1.704–1 is amended by:

■ 1. In paragraph (b)(1)(ii)(*b*)(*1*), revising the fourth sentence and adding a new fifth sentence.

■ 2. Revising paragraph (b)(4)(viii)(*d*)(*1*).

The revisions and addition read as follows:

§ 1.704–1 Partner's distributive share.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(*b*) * * *

(*1*) * * * Except as provided in the next sentence, the provisions of paragraphs (b)(4)(viii)(*a*)(*1*), (b)(4)(viii)(*c*)(*1*), (b)(4)(viii)(*c*)(*2*)(*ii*) and (*iii*), (b)(4)(viii)(*c*)(*3*) and (*4*), and (b)(4)(viii)(*d*)(*1*) (as in effect on July 24, 2019) and in paragraphs (b)(6)(i), (ii), and (iii) of this section (*Examples 1, 2,* and *3*) apply for partnership taxable years that both begin on or after January 1, 2016, and end after February 4, 2016. For partnership taxable years beginning after December 31, 2019, paragraph (b)(4)(viii)(*d*)(*1*) of this section applies.

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(4) * * *

(viii) * * *

(*d*) * * * (*1*) *In general.* CFTEs are allocated and apportioned to CFTE categories in accordance with § 1.861–20 by treating each CFTE category as a statutory grouping (with no residual grouping). See paragraphs (b)(6)(ii) and (iii) of this section (*Examples 2* and *3*), which illustrate the application of this paragraph (b)(4)(viii)(*d*)(*1*) in the case of serial disregarded payments subject to withholding tax. In addition, if as described in § 1.861–20(e), foreign law does not provide for the direct allocation or apportionment of expenses, losses or other deductions allowed under foreign law to a CFTE category of income, then such expenses, losses or other deductions must be allocated and apportioned to gross income as determined under foreign law in a manner that is consistent with the allocation and apportionment of such items for purposes of determining the net income in the CFTE categories for Federal income tax purposes pursuant to paragraph (b)(4)(viii)(*c*)(*3*) of this section.

* * * * *

■ **Par. 4.** Section 1.861–8 is amended by:

■ 1. Adding a sentence to the end of paragraph (a)(1).

■ 2. In paragraph (d)(1), removing the language ''§ 1.1502–4(d)(1) and the last sentence of'' in the fifth sentence and removing the last sentence.

■ 3. Revising paragraph (d)(2)(ii)(B).

■ 4. Adding paragraph (d)(2)(v).
■ 5. Revising paragraph (e)(4)(ii).
■ 6. Redesignating paragraph (e)(5) as paragraph (e)(5)(i).
■ 7. Adding a heading for paragraph (e)(5) and paragraphs (e)(5)(ii) and (iii).
■ 8. Revising the first sentence of paragraph (e)(6)(i) and paragraphs (e)(7) and (8).
■ 9. Adding paragraphs (e)(16) and (g)(15) through (18).
■ 10. Revising paragraph (h).

The additions and revisions read as follows:

§ 1.861–8 Computation of taxable income from sources within the United States and from other sources and activities.

(a) * * *

(1) * * * The term *section 861 regulations* means this section and §§ 1.861–8T, 1.861–9, 1.861–9T, 1.861–10, 1.861–10T, 1.861–11, 1.861–11T, 1.861–12, 1.861–12T, 1.861–13, 1.861–14, 1.861–14T, 1.861–17, and 1.861–20.

* * * * *

(d) * * *

(2) * * *

(ii) * * *

(B) *Certain stock and dividends.* The term *exempt income* includes the portion of the dividends that are deductible under section 243(a)(1) or (2) (relating to the dividends received deduction) or section 245(a) (relating to the dividends received deduction for dividends from certain foreign corporations). Thus, for purposes of apportioning deductions using a gross income method, gross income does not include a dividend to the extent that it gives rise to a dividends-received deduction under either section 243(a)(1), section 243(a)(2), or section 245(a). In addition, for purposes of apportioning deductions using an asset method, assets do not include that portion of the value of the stock (determined in accordance with § 1.861–9(g), and, as relevant, §§ 1.861–12 and 1.861–13) equal to the portion of dividends that would be offset by a deduction under either section 243(a)(1), section 243(a)(2), or section 245(a), to the extent the stock generates, has generated, or can reasonably be expected to generate such dividends. For example, in the case of stock for which all dividends would be allowed a deduction of 50 percent under section 243(a)(1), 50 percent of the value of the stock is treated as an exempt asset. In the case of stock which generates, has generated, or can reasonably be expected to generate qualifying dividends deductible under section 243(a)(3), such stock does not constitute an exempt asset. However, such stock and the qualifying dividends thereon are eliminated from consideration in the apportionment of interest expense under the affiliated group rule set forth in § 1.861–11T(c), and in the apportionment of other expenses under the affiliated group rules set forth in § 1.861–14T.

* * * * *

(v) *Dividends-received deduction and tax-exempt interest of insurance companies*—(A) *In general.* For purposes of characterizing gross income or assets as exempt or not exempt under this section, the following rules apply on a company wide basis pursuant to the rules in paragraphs (d)(2)(v)(A)(*1*) and (*2*) of this section.

(*1*) In the case of an insurance company taxable under section 801, the term *exempt income* includes the portion of dividends received that satisfy the requirements of deductibility under sections 243(a)(1) and (2) and 245(a) but without regard to any disallowance under section 805(a)(4)(A)(ii) of the policyholder's share of the dividends or any similar disallowance under section 805(a)(4)(D), and also includes tax-exempt interest but without reduction for the policyholder's share of tax-exempt interest that reduces the closing balance of items described in section 807(c), as provided under section 807(a)(2)(B) and 807(b)(1)(B). The term *exempt assets* includes the corresponding portion of assets that generates, has generated, or can reasonably be expected to generate exempt income described in the preceding sentence. See § 1.861–8(e)(16) for a special rule concerning the allocation of reserve expenses to dividends received by a life insurance company.

(*2*) In the case of an insurance company taxable under section 831, the term *exempt income* includes the portion of interest and dividends deductible under sections 832(c)(7) and (12) or sections 834(c)(1) and (7). Exempt income also includes the amounts reducing the losses incurred under section 832(b)(5) to the extent such amounts are not already taken into account in the preceding sentence. The term *exempt assets* includes the corresponding portion of assets that give rise to exempt income described in the preceding two sentences.

(B) *Examples.* The following examples illustrate the application of paragraph (d)(2)(v)(A) of this section.

(*1*) *Example 1*—(*i*) *Facts.* U.S.C. is a domestic life insurance company that has $300x; of gross income, consisting of $100x of foreign source general category income and $200x of U.S. source passive category interest income, $100x; of the latter of which is tax-exempt interest income from municipal bonds under section 103. U.S.C.'s opening balance of its section 807(c) reserves is $50,000x; and USP's closing balance of its section 807(c) reserves is $50,130x. Under section 807(b)(1)(B), USP's closing balance of its section 807(c) reserves, $50,130x, is reduced by the amount of the policyholder's share of tax-exempt interest. The policyholder's share of tax-exempt interest under section 812(b) is equal to 30 percent of the $100x of tax-exempt interest ($30x). Therefore, under sections 803(a)(2) and 807(b), USP's reserve deduction is $100x ($50,130x of reserve deduction minus $30x (30 percent of $100x of tax-exempt interest), minus $50,000x). U.S.C. has no other income or deductions.

(*ii*) *Analysis—allocation.* Under section 818(f)(1), U.S.C.'s reserve deduction is treated as an item that cannot be definitely allocated to an item or class of gross income. Accordingly, under paragraph (b)(5) of this section, U.S.C.'s reserve deduction is allocable to all of U.S.C.'s gross income as a class.

(*iii*) *Analysis—apportionment.* Under paragraph (c)(3) of this section, the reserve deduction is ratably apportioned between the statutory grouping (foreign source general category income) and the residual grouping (U.S. source income) on the basis of the relative amounts of gross income in each grouping. For purposes of apportioning deductions under § 1.861–8T(d)(2)(i)(B), exempt income is not taken into account. Under paragraph (d)(2)(v)(A)(*1*) of this section, in the case of an insurance company taxable under section 801, exempt income includes tax-exempt interest without regard to any reduction for the policyholder's share. U.S.C. has U.S. source income of $200x of which $100x is tax-exempt without regard to the reduction for the policyholder's share of tax-exempt interest that reduces the closing balance of items described in section 807(c). Thus, the gross income taken into account in apportioning U.S.C.'s reserve deduction is $100x of foreign source general category gross income and $100x of U.S. source gross income. Of U.S.C.'s $100x reserve deduction, $50x ($100 × $100x;/$200x) is apportioned to foreign source general category gross income and $50x ($100x × $100x/$200x) is apportioned to U.S. source gross income.

(*2*) *Example 2*—(*i*) *Facts.* U.S.C. is a domestic life insurance company that has $300x of gross income consisting of $10x of foreign source general category income and $200x of U.S. source general category dividend income eligible for the 50% dividends received

deduction (DRD) under section 243(a)(1). Under section 805(a)(4)(A)(ii), U.S.C. is allowed a 50% DRD on the company's share of the dividend received. Under section 812(a), the company's share of the dividend is equal to 70% of the dividend income eligible for the DRD under section 243(a)(1), which results in a DRD of $70x (50% × 70% × $200), and under section 812(b), the policyholder's share of the dividend is equal to 30% of the dividend income eligible for the DRD under section 243(a)(1), which would result in a DRD of $30x (50% × 30% × $200x). U.S.C. is entitled to a $130x deduction for an increase in its life insurance reserves under sections 803(a)(2) and 807(b). Unlike for tax-exempt interest income, there is no adjustment under section 807(b)(1)(B) to the reserve deduction for the policyholder's share of dividends that would be offset by the DRD under section 243(a)(1). U.S.C. has no other income or deductions.

(*ii*) *Analysis—allocation.* Under section 818(f)(1), U.S.C.'s reserve deduction is treated as an item that cannot be definitely allocated to an item or class of gross income except that, under § 1.861–8(e)(16), an amount of reserve expenses of a life insurance company equal to the DRD that is disallowed because it is attributable to the policyholder's share of dividends is treated as definitely related to such dividends. Thus, U.S.C. has a life insurance reserve deduction of $130x, of which $30 (equal to the policyholder's share of the DRD that would have been allowed under section 243(a)(1)) is directly allocated and apportioned to U.S. source dividend income. Under paragraph (b)(5) of this section, the remaining portion of U.S.C.'s reserve deduction ($100x) is allocable to all of U.S.C.'s gross income as a class.

(*iii*) *Analysis—apportionment.* Under paragraph (c)(3) of this section, the deduction is ratably apportioned between the statutory grouping (foreign source general category income) and the residual grouping (U.S. source income) on the basis of the relative amounts of gross income in each grouping. For purposes of apportioning deductions under § 1.861–8T(d)(2)(i)(B), exempt income is not taken into account. Under paragraph (d)(2)(v)(A)(*1*) of this section, in the case of an insurance company taxable under section 801, exempt income includes dividends deductible under section 805(a)(4) without regard to any reduction to the DRD for the policyholder's share in section 804(a)(4)(A)(ii). Thus, the gross income taken into account in apportioning $100x of U.S.C.'s remaining reserve deduction is $100x of foreign source general category gross income and $100x of U.S. source gross income. Of U.S.C.'s $100x remaining reserve deduction, $50x ($100x × $100x /$200x) is apportioned to foreign source general category gross income and $50x ($100x × $100x/$200x) is apportioned to U.S. source gross income.

* * * * *

(e) * * *

(4) * * *

(ii) *Stewardship expenses*—(A) *In general.* Stewardship expenses are those expenses resulting from ''duplicative activities'' (as defined in § 1.482–9(l)(3)(iii)) or ''shareholder activities'' (as defined in § 1.482–9(l)(3)(iv)) that are undertaken for a person's own benefit as an investor in a related entity, which for purposes of this paragraph (e)(4)(ii) includes a business entity as described in § 301.7701–2(a) of this chapter that is classified for Federal income tax purposes as either a corporation or a partnership, or is disregarded as an entity separate from its owner (''disregarded entity''). Thus, for example, stewardship expenses include expenses of an activity the sole effect of which is to protect the investor's capital investment in the entity or to facilitate compliance by the investor with reporting, legal, or regulatory requirements applicable specifically to the investor. If an investor has a foreign or international department which exercises oversight functions with respect to related entities and, in addition, the department performs other functions that generate other foreign-source income (such as fees for services rendered outside of the United States for the benefit of foreign related corporations or foreign-source royalties), some part of the deductions with respect to that department are considered definitely related to the other foreign-source income. In some instances, the operations of a foreign or international department will also generate U.S. source income (such as fees for services performed in the United States). Stewardship expenses are allocated and apportioned on a separate entity basis without regard to the affiliated group rules in § 1.861–14. See § 1.861–14(e)(1)(i).

(B) *Allocation.* In the case of stewardship expenses incurred to oversee a corporation, the expenses are considered definitely related and allocable to dividends received or amounts included, or to be received or included, under sections 78, 301, 951, 951A, 1291, 1293, and 1296, from the corporation. In the case of stewardship expenses incurred to oversee a partnership, the expenses are considered definitely related and allocable to a partner's distributive share of partnership income. In the case of stewardship expenses incurred to oversee a disregarded entity, the expenses are considered definitely related and allocable to all gross income attributable to the disregarded entity. Stewardship expenses are allocated to income from a particular entity (or entities) related to the taxpayer if the expense is definitely related to the oversight of that entity or entities as provided in § 1.861–8(b)(1) under all the facts and circumstances.

(C) *Apportionment.* Stewardship expenses must be apportioned between the statutory and residual groupings based on the relative values of the entity or entities in each grouping that are owned by the investor taxpayer, and without regard to the relative amounts of gross income in the statutory and residual groupings to which the stewardship expense is allocated. In the case of stewardship expenses incurred to oversee a lower-tier entity owned indirectly by the taxpayer, the stewardship expenses must be apportioned based on the relative values of the owner or owners of the lower-tier entity that are owned directly by the taxpayer. In the case of stewardship expenses incurred to oversee a corporation, the corporation's value is the value of its stock as determined and characterized under the asset method in § 1.861–9 (and, as relevant, §§ 1.861–12 and 1.861–13) for purposes of allocating and apportioning the taxpayer's interest expense. For purposes of the preceding sentence, if the corporation is a member of the same affiliated group as the investor, the value of the corporation's stock is determined under the asset method in § 1.861–9 and is characterized by the investor in proportion to how the corporation's assets are characterized for purposes of apportioning the group's interest expense. In the case of stewardship expenses incurred to oversee a partnership, the partnership's value is determined and characterized under the asset method in § 1.861–9 (taking into account any adjustments under sections 734(b) and 743(b)). In the case of stewardship expenses incurred to oversee a disregarded entity, the disregarded entity's character and value is determined using the principles of the asset method in § 1.861–9 as if the disregarded entity were treated as a corporation for Federal income tax purposes. For purposes of determining the tax book value of assets under this

paragraph (e)(4)(ii)(C), section 864(e)(3) and § 1.861–8(d)(2) do not apply.

(5) *Legal and accounting fees and expenses; damages awards, prejudgment interest, and settlement payments*— * * *

(ii) *Product liability and other claims for damages.* Except as otherwise provided in this paragraph (e)(5), awards for litigation or arbitral damages, prejudgment interest, and payments in settlement of or in anticipation of claims for damages, including punitive damages, arising from claims relating to sales, licenses, or leases of products or the provision of services, are definitely related and allocable to the class of gross income of the type produced by the specific sales or leases of the products or provision of services that gave rise to the claims for damage or injury. Such damages and payments may include, but are not limited to, product liability or patent infringement claims. The deductions are apportioned among the statutory and residual groupings on the basis of the relative amounts of gross income in the relevant class in each grouping in the year in which the deductions are allowed. If the claims arise from an event incident to the production or sale of products or provision of services (such as an industrial accident), the payments are definitely related and allocable to the class of gross income ordinarily produced by the assets that are involved in the event. The deductions are apportioned among the statutory and residual groupings on the basis of the relative values (as determined under the asset method in § 1.861–9 for purposes of allocating and apportioning the taxpayer's interest expense) of the assets that were involved in the event or that were used to produce or sell products or services in the relevant class in each grouping; such values are determined in the year the deductions are allowed.

(iii) *Investor lawsuits.* If the claims are made by investors in a corporation and arise from negligence, fraud, or other malfeasance of the corporation (or its representatives), then the damages, prejudgment interest, and settlement payments paid by the corporation are definitely related and allocable to all income of the corporation and are apportioned among the statutory and residual groupings based on the relative value of the corporation's assets in each grouping (as determined under the asset method in § 1.861–9 for purposes of allocating and apportioning the taxpayer's interest expense) in the year the deductions are allowed.

(6) * * *

(i) * * * The deduction for foreign income, war profits, and excess profits taxes allowed by section 164 is allocated and apportioned among the applicable statutory and residual groupings under § 1.861–20. * * *

* * * * *

(7) *Losses on the sale, exchange, or other disposition of property.* See §§ 1.865–1 and 1.865–2 for rules regarding the allocation and apportionment of certain losses.

(8) *Net operating loss deduction*—(i) *Components of net operating loss.* A net operating loss is separated into components that are assigned to statutory or residual groupings by reference to the losses in each such statutory or residual grouping that are not allocated to reduce income in other groupings in the taxable year of the loss. For example, for purposes of applying this paragraph (e)(8)(i) with respect to section 904 as the operative section, the source and separate category components of a net operating loss are determined by reference to the amounts of separate limitation loss and U.S. source loss (determined without regard to adjustments required under section 904(b)) that are not allocated to reduce U.S. source income or income in other separate categories under the rules of sections 904(f) and 904(g) for the taxable year in which the net operating loss arose. See § 1.904(g)–3(d)(2). See § 1.1502–4 for rules applicable in computing the foreign tax credit limitation and determining the source and separate category of a net operating loss of a consolidated group. Similarly, for purposes of applying this paragraph (e)(8)(i) with respect to another operative section (as described in § 1.861–8(f)(1)), a net operating loss is divided into component parts based on the amounts of the deductions that are assigned to the relevant statutory and residual groupings and that are not absorbed in the taxable year in which the loss is incurred under the rules of that operative section. Deductions that are considered absorbed for purposes of an operative section may differ from the deductions that are considered absorbed for purposes of another provision of the Code that requires determining the components of a net operating loss.

(ii) *Allocation and apportionment of section 172 deduction.* A net operating loss deduction allowed under section 172 is allocated and apportioned to statutory and residual groupings by reference to the statutory and residual groupings of the components of the net operating loss (as determined under paragraph (e)(8)(i) of this section) that is deducted in the taxable year. Except as provided under the rules for an operative section, a partial net operating loss deduction is treated as ratably comprising the components of a net operating loss. See, for example, § 1.904(g)–3, which is an exception to the general rule described in the previous sentence and provides rules for determining the source and separate category of a partial net operating loss deduction for purposes of section 904 as the operative section.

* * * * *

(16) *Special rule for the allocation and apportionment of reserve expenses of a life insurance company.* An amount of reserve expenses of a life insurance company equal to the dividends received deduction that is disallowed because it is attributable to the policyholders' share of dividends received is treated as definitely related to such dividends. See paragraph (d)(2)(v)(B)(*2*) of this section (*Example 2*).

* * * * *

(g) * * *

(15) *Example 15: Payment in settlement of claim for damages allocated to specific class of gross income*—(i) *Facts.* USP, a domestic corporation, sells Product A in the United States. USP also owns and operates a disregarded entity (FDE) in Country X. FDE, which constitutes a foreign branch of USP within the meaning of § 1.904–4(f)(3)(vii), sells Product A inventory in Country X. FDE's functional currency is the U.S. dollar. In each of its taxable years from 2018 through 2020, USP earns $2,000x of U.S. source gross income from sales of Product A to customers in the United States. USP also sells Product A to FDE for an arm's length price and FDE sells Product A to customers in Country X. After the application of section 862(a)(6), § 1.861–7(c), and the disregarded payment rules of § 1.904–4(f)(2)(vi), the sales of Product A in Country X result in $1,500x of general category foreign source gross income and $500x of foreign branch category foreign source gross income in each of 2018 and 2019 and $2,500x of general category foreign source gross income and $500x of foreign branch category foreign source gross income in 2020. FDE is sued for damages in 2019 after Product A harms a customer in Country X in 2018. In 2020, FDE makes a deductible payment of $60x to the Country X customer in settlement of the legal claims for damages.

(ii) *Analysis.* Under paragraph (e)(5)(ii) of this section, the deductible settlement payment is definitely related and allocable to the class of gross income of the type produced by the specific sales of property that gave rise

to the damages claims, that is USP's gross income from sales of Product A in Country X. Claims that might arise from damages caused by Product A to customers in the United States are irrelevant in allocating the deduction for the settlement payments made to the customer in Country X. For purposes of determining USP's foreign tax credit limitation under section 904(d), because in 2020 that class of gross income consists of both foreign source foreign branch category income and foreign source general category income, the settlement payment of $60x is apportioned between gross income in the two categories in proportion to the relative amounts of gross income in each category in 2020, the year the deduction is allowed. Therefore, $10x ($60x × $500x/$3,000x) is apportioned to foreign source foreign branch category income, and the remaining $50x ($60x × $2,500x/$3,000x) is apportioned to foreign source general category income.

(16) *Example 16: Legal damages payment arising from event incident to production and sale*—(i) *Facts*—The facts are the same as in paragraph (g)(15) of this section (the facts in *Example 15*) except that instead of a product liability lawsuit relating to a 2018 event, in 2019 there is a disaster at a warehouse owned by USP in the United States arising from the negligence of an employee. The warehouse is used to store Product A inventory intended for sale both by USP in the United States and by FDE in Country X. In 2020, the warehouse asset is characterized under § 1.861–9T(g)(3)(ii) as a multiple category asset that is assigned 10% to the foreign source foreign branch category, 50% to the foreign source general category, and 40% to the residual grouping of U.S. source income. The inventory of Product A in the warehouse is destroyed and USP employees as well as residents in the vicinity of the warehouse are injured. USP's reputation in the United States suffers such that USP expects to subsequently lose market share in the United States. In 2020, USP makes deductible damages payments totaling $50x to injured employees and the nearby residents, all of whom are in the United States.

(ii) *Analysis.* USP's warehouse in the United States is used in connection with sales of Product A to customers in both the United States and Country X. Thus, under paragraph (e)(5)(ii) of this section, the $50x damages payment arises from an event incident to the sales of Product A and is therefore definitely related and allocable to the class of gross income ordinarily produced by the asset (the warehouse) that is involved in the event—that is, the gross income from sales of Product A by USP in the United States and by FDE in Country X. Under paragraph (e)(5)(ii) of this section, the $50x deduction for the damages payment is apportioned for purposes of applying section 904(d) on the basis of the relative value in each grouping (as determined under § 1.861–9(g) for purposes of allocating and apportioning USP's interest expense) of USP's warehouse, the asset involved in the event, in 2020, the year the deduction is allowed. USP's warehouse is a multiple category asset as described in § 1.861–9T(g)(3)(ii) and 10% of the value of USP's warehouse is properly characterized as an asset generating foreign source foreign branch category in 2020. Accordingly, $5x (10% × $50x) of the deduction is apportioned to foreign source foreign branch category income. Additionally, 50% of the value of USP's warehouse is properly characterized as an asset generating foreign source general category income in 2020 and, accordingly, $25x (50% × $50x) is apportioned to such grouping. The remaining $20x (40% × $50x) is apportioned to U.S. source income.

(17) *Example 17: Payment following a change in law*—(i) *Facts.* The facts are the same as in paragraph (g)(16) of this section (the facts in *Example 16*), except that the disaster at USP's warehouse occurred not in 2019 but in 2016 and thus before the enactment of the section 904(d) separate category for foreign branch category income. The deductible damages payments are made in 2020.

(ii) *Analysis.* USP's U.S. warehouse was used in connection with making sales of Product A in both the United States and Country X. Under paragraph (e)(5)(ii) of this section, the 2020 damages payment arises from an event incident to the sales of Product A and is therefore definitely related and allocable to the class of gross income ordinarily produced by the asset (the warehouse) that is involved in the event, that is the gross income from sales of Product A by USP in the United States and by FDE in Country X. Under the law in effect in 2016, the income earned from the Product A sales in Country X was solely general category income. Under paragraph (e)(5)(ii) of this section, the damages payment is definitely related and allocable to the class of gross income consisting of sales of Product A by USP in the United States and by FDE in Country X, and apportioned to the statutory and residual groupings based on the relative value in each grouping (as determined under § 1.861–9(g) for purposes of allocating and apportioning USP's interest expense) of USP's warehouse, the asset involved in the event, in 2020, the year in which the deduction is allowed. Accordingly, for purposes of determining USP's foreign tax credit limitation under section 904(d), the 2020 deductible damages payment of $50x is allocated and apportioned in the same manner as in paragraph (g)(16)(ii) of this section (the analysis in *Example 16*).

(18) *Example 18: Stewardship and supportive expenses*—(i) *Facts*—(A) *Overview.* USP, a domestic corporation, manufactures and sells Product A in the United States. USP directly owns 100% of the stock of USSub, a domestic corporation, and each of CFC1, CFC2, and CFC3, which are all controlled foreign corporations. USP and USSub file separate returns for U.S. Federal income tax purposes but are members of the same affiliated group as defined in section 243(b)(2). USSub, CFC1, CFC2, and CFC3 perform similar functions in the United States and in the foreign countries T, U, and V, respectively. USP's tax book value in the stock of USSub is $15,000x. USP's tax book value in the stock of each of CFC1, CFC2, and CFC3 is, respectively, $5,000x, $10,000x, and $15,000x.

(B) *USP Department expenses.* USP's supervision department (the Department) incurs expenses of $1,500x. The Department is responsible for the supervision of its four subsidiaries and for rendering certain services to the subsidiaries, and the Department provides all the supportive functions necessary for USP's foreign activities. The Department performs three types of activities. First, the Department performs services that cost $900x outside the United States for the direct benefit of CFC2 for which a marked-up fee is paid by CFC2 to USP. Second, the Department provides services at a cost of $60x related to license agreements that USP maintains with subsidiaries CFC1 and CFC2 and which give rise to foreign source general category income to USP. Third, the Department performs activities described in § 1.482–9(l)(3)(iii) that are in the nature of shareholder oversight, that duplicate functions performed by all four of the subsidiaries' own employees, and that do not provide an additional benefit to the subsidiaries. For example, a team of auditors from USP's accounting department periodically audits the subsidiaries' books and prepares internal reports for use by USP's management. Similarly, USP's treasurer periodically reviews the subsidiaries' financial policies for the board of directors of USP. These activities do not provide an additional benefit to the related corporations. The Department's

oversight activities are related to all the subsidiaries. The cost of the duplicative activities is $540x.

(C) *USP's income.* USP earns the following items of income: First, under section 951(a), USP has $2,000x of subpart F income that is passive category income. Second, USP has a GILTI inclusion amount of $2,000x. Third, USP earns $1,000x of royalties, paid by CFC1 and CFC2, that are foreign source general category income. Finally, USP receives a fee of $1,000x from CFC2 that is foreign source general category income.

(ii) *Analysis*—(A) *Character of USP Department services.* The first and second activities (the services rendered for the benefit of CFC2, and the provision of services related to license agreements with CFC1 and CFC2) are not properly characterized as stewardship expenses because they are not incurred solely to protect the corporation's capital investment in the related corporation or to facilitate compliance by the corporation with reporting, legal, or regulatory requirements applicable specifically to the corporation. The third activity described is in the nature of shareholder oversight and is characterized as stewardship as described in paragraph (e)(4)(ii)(A) of this section because the expense is related to duplicative activities.

(B) *Allocation.* First, the deduction of $900x for expenses related to services rendered for the benefit of CFC2 is definitely related (and therefore allocable) to the fees for services that USP receives from CFC2. Second, the $60x of deductions attributable to USP's license agreements with CFC1 and CFC2 are definitely related (and therefore allocable) solely to royalties received from CFC1 and CFC2. Third, based on the relevant facts and circumstances and the Department's oversight activities, the stewardship deduction of $540x is related to the oversight of all of USP's subsidiaries and therefore is definitely related (and therefore allocable) to dividends and inclusions received or included from all the subsidiaries.

(C) *Apportionment.* (*1*) No apportionment of USP's deduction of $900x for expenses related to the services performed for CFC2 is necessary because the class of gross income to which the deduction is allocated consists entirely of a single statutory grouping, foreign source general category income.

(*2*) No apportionment of USP's deduction of $60x attributable to the services related to license agreements is necessary because the class of gross income to which the deduction is allocated consists entirely of a single statutory grouping, foreign source general category income.

(*3*) For purposes of apportioning USP's $540x stewardship expenses in determining the foreign tax credit limitation, the statutory groupings are foreign source general category income, foreign source passive category income, and foreign source section 951A category income. The residual grouping is U.S. source income.

(*4*) USP's deduction of $540x for the Department's stewardship expenses which are allocable to dividends and amounts included from the subsidiaries are apportioned using the same value of USP's stock in USSub, CFC1, CFC2, and CFC3 that is used for purposes of allocating and apportioning USP's interest expense. Pursuant to paragraph (e)(4)(ii)(A) of this section and § 1.861–14(e)(1)(i), the value of USP's stock in USSub is included for purposes of apportioning USP's stewardship expense. The value of USSub's stock is $15,000x, and USSub only owns assets that generate income in the residual grouping of gross income from U.S. sources. Therefore, for purposes of apportioning USP's stewardship expense, all of the $15,000x value of the USSub stock is characterized as an asset generating U.S. source income. Although USSub stock would be eliminated from consideration as an asset under paragraph (d)(2)(ii)(B) of this section, for purposes of apportioning USP's stewardship expense section 864(e)(3) and paragraph (d)(2) of this section do not apply. USP uses the asset method described in § 1.861–12T(c)(3)(ii) to characterize the stock in its CFCs. After application of § 1.861–13(a), USP determines that with respect to its three CFCs in the aggregate it has $15,000x of section 951A category stock in the non-section 245A subgroup, $6,000x of general category stock in the section 245A subgroup, and $9,000x of passive category stock in the non-section 245A subgroup. Although under paragraph (d)(2)(ii)(C)(*2*) of this section $7,500x of the stock that is section 951A category stock is an exempt asset, for purposes of apportioning USP's stewardship expense section 864(e)(3) and paragraph (d)(2) of this section do not apply. Finally, even though USP may be allowed a section 245A deduction with respect to dividends from the CFCs, no portion of the value of the stock of the CFCs is eliminated, because the section 245A deduction does not create exempt income or result in the stock being treated as an exempt asset. See section 864(e)(3) and paragraph (d)(2)(iii)(C) of this section.

(*5*) Taking into account the characterization of USP's stock in USSub, CFC1, CFC2, and CFC3 with a total value of $45,000x ($15,000x + $6,000x + $9,000x + $15,000x), the $540x of Department expenses is apportioned as follows: $180x ($540x × $15,000x/$45,000x) to section 951A category income, $72x ($540x × $6,000x/$45,000x) to general category income, $108x ($540x × $9,000x/$45,000x) to passive category income, and $180x ($540x × $15,000x/$45,000x) to the residual grouping of U.S. source income. Section 904(b)(4)(B)(i) and § 1.904(b)–3 apply to $72x of the stewardship expense apportioned to the CFCs' stock that is characterized as being in the section 245A subgroup in the general category.

* * * * *

(h) *Applicability date.* (1) Except as provided in this paragraph (h), this section applies to taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

(2) Paragraphs (d)(2)(ii)(B), (d)(2)(v), (e)(4) and (5), (e)(6)(i), (e)(8) and (16), and (g)(15) through (18) of this section apply to taxable years that begin after December 31, 2019. For taxable years that both begin after December 31, 2017, and end on or after December 4, 2018, and also begin on or before December 31, 2019, see § 1.861–8(d)(2)(ii)(B), (e)(4) and (5), (e)(6)(i), and (e)(8) as in effect on December 17, 2019.

(3) The last sentence of paragraph (d)(2)(ii)(C)(*1*) of this section and paragraph (f)(1)(vi)(N) of this section apply to taxable years beginning on or after January 1, 2021.

■ **Par. 5.** Section 1.861–8T is amended by revising paragraph (d)(2)(ii)(B) to read as follows:

§ 1.861–8T Computation of taxable income from sources within the United States and from other sources and activities (temporary).

* * * * *

(d) * * *

(2) * * *

(ii) * * *

(B) *Certain stock and dividends.* For further guidance, see § 1.861–8(d)(2)(ii)(B).

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■ **Par. 6.** Section 1.861–9 is amended by:

■ 1. Revising paragraph (a).

■ 2. Adding paragraph (b).

■ 3. Revising paragraphs (e)(8)(vi)(C) and (D).

■ 4. Adding paragraph (e)(9).

■ 5. Revising paragraph (k).

The revisions and additions read as follows:

§ 1.861–9 Allocation and apportionment of interest expense and rules for asset-based apportionment.

(a) *In general.* For further guidance, see § 1.861–9T(a).

(b) *Interest equivalent*—(1) *Certain expenses and losses*—(i) *General rule.* Any expense or loss (to the extent deductible) incurred in a transaction or series of integrated or related transactions in which the taxpayer secures the use of funds for a period of time is subject to allocation and apportionment under the rules of this section and § 1.861–9T(b) if such expense or loss is substantially incurred in consideration of the time value of money. However, the allocation and apportionment of a loss under this paragraph (b) and § 1.861–9T(b) does not affect the characterization of such loss as capital or ordinary for any purpose other than for purposes of the section 861 regulations (as defined in § 1.861–8(a)(1)).

(ii) *Examples.* For further guidance, see § 1.861–9T(b)(1)(ii).

(2) *Certain foreign currency borrowings.* For further guidance, see § 1.861–9T(b)(2) through (7).

(3) through (7) [Reserved]

(8) *Guaranteed payments.* Any deductions for guaranteed payments for the use of capital under section 707(c) are allocated and apportioned in the same manner as interest expense.

* * * * *

(e) * * *

(8) * * *

(vi) * * *

(C) *Downstream partnership loan.* The term *downstream partnership loan* means a loan to a partnership for which the loan receivable is held, directly or indirectly through one or more other partnerships or other pass-through entities (as defined in § 1.904–5(a)(4)), by a person (or any person in the same affiliated group as such person) that owns an interest, directly or indirectly through one or more other partnerships or other pass-through entities, in the partnership.

(D) *Downstream partnership loan interest expense (DPL interest expense).* The term *downstream partnership loan interest expense,* or *DPL interest expense,* means an item of interest expense paid or accrued with respect to a downstream partnership loan, without regard to whether the expense was currently deductible (for example, by reason of section 163(j) or the election to waive deductions pursuant to § 1.59A–3(c)(6)).

* * * * *

(9) *Special rule for upstream partnership loans*—(i) *In general.* For purposes of apportioning interest expense that is not directly allocable under paragraph (e)(4) of this section or § 1.861–10T, an upstream partnership loan debtor's (UPL debtor) pro rata share of the value of the upstream partnership loan (as determined under paragraph (h)(4)(i) of this section) is not considered an asset of the UPL debtor taken into account as described in paragraphs (e)(2) and (3) of this section.

(ii) *Treatment of interest expense and interest income attributable to an upstream partnership loan.* If a UPL debtor (or any other person in the same affiliated group as the UPL debtor) takes into account a distributive share of upstream partnership loan interest income (UPL interest income), the UPL debtor (or any other person in the same affiliated group as the UPL debtor) assigns an amount of its distributive share of the UPL interest income equal to the matching expense amount for the taxable year that is attributable to the same loan to the same statutory and residual groupings using the same ratios as the statutory and residual groupings of gross income from which the upstream partnership loan interest expense (UPL interest expense) is deducted by the UPL debtor (or any other person in the same affiliated group as the UPL debtor). Therefore, the amount of the distributive share of UPL interest income that is assigned to each statutory and residual grouping is the amount that bears the same proportion to the matching expense amount as the UPL interest expense in that statutory or residual grouping bears to the total UPL interest expense of the UPL debtor (or any other person in the same affiliated group as the UPL debtor).

(iii) *Anti-avoidance rule for third party back-to-back loans.* If, with a principal purpose of avoiding the rules in this paragraph (e)(9), a partnership makes a loan to a person that is not related (within the meaning of section 267(b) or 707) to the lender, the unrelated person makes a loan to a direct or indirect partner in the partnership (or any person in the same affiliated group as a direct or indirect partner), and the first loan would constitute an upstream partnership loan if made directly to the direct or indirect partner (or person in the same affiliated group as a direct or indirect partner), then the rules of this paragraph (e)(9) apply as if the first loan was made directly by the partnership to the partner (or affiliate of the partner), and the interest expense paid by the partner is treated as made with respect to the first loan. Such a series of loans will be subject to the recharacterization rule in this paragraph (e)(9)(iii) without regard to whether there was a principal purpose of avoiding the rules in this paragraph (e)(9) if the loan to the unrelated person would not have been made or maintained on substantially the same terms but for the loan of funds by the unrelated person to the direct or indirect partner (or affiliate of the partner). The principles of this paragraph (e)(9)(iii) also apply to similar transactions that involve more than two loans and regardless of the order in which the loans are made.

(iv) *Interest equivalents.* The principles of this paragraph (e)(9) apply in the case of a partner, or any person in the same affiliated group as the partner, that takes into account a distributive share of income and has a matching expense amount (treating any interest equivalent described in paragraph (b) of this section and § 1.861–9T(b) as interest income or expense for purposes of paragraph (e)(9)(v)(B) of this section) that is allocated and apportioned in the same manner as interest expense under paragraph (b) of this section and § 1.861–9T(b).

(v) *Definitions.* For purposes of this paragraph (e)(9), the following definitions apply.

(A) *Affiliated group.* The term *affiliated group* has the meaning provided in § 1.861–11(d)(1).

(B) *Matching expense amount.* The term *matching expense amount* means the lesser of the total amount of the UPL interest expense taken into account directly or indirectly by the UPL debtor for the taxable year with respect to an upstream partnership loan or the total amount of the distributive shares of the UPL interest income of the UPL debtor (or any other person in the same affiliated group as the UPL debtor) with respect to the loan.

(C) *Upstream partnership loan.* The term *upstream partnership loan* means a loan by a partnership to a person (or any person in the same affiliated group as such person) that owns an interest, directly or indirectly through one or more other partnerships or other pass-through entities (as defined in § 1.904–5(a)(4)(iv)), in the partnership.

(D) *Upstream partnership loan debtor (UPL debtor).* The term *upstream partnership loan debtor,* or *UPL debtor,* means the person that has the payable with respect to an upstream partnership loan. If a partnership has the payable, then any partner in the partnership (other than a partner described in paragraph (e)(4)(i) of this section) is also considered a UPL debtor.

(E) *Upstream partnership loan interest expense (UPL interest expense).* The term *upstream partnership loan*

interest expense, or *UPL interest expense,* means an item of interest expense paid or accrued with respect to an upstream partnership loan, without regard to whether the expense was currently deductible (for example, by reason of section 163(j) or the election to waive deductions pursuant to § 1.59A–3(c)(6)).

(F) *Upstream partnership loan interest income (UPL interest income).* The term *upstream partnership loan interest income,* or *UPL interest income,* means an item of gross interest income received or accrued with respect to an upstream partnership loan.

(vi) *Examples.* The following examples illustrate the application of this paragraph (e)(9).

(A) *Example 1*—(*1*) *Facts.* US1, a domestic corporation, directly owns 60% of PRS, a foreign partnership that is not engaged in a U.S. trade or business. The remaining 40% of PRS is directly owned by US2, a domestic corporation that is unrelated to US1. US1, US2, and PRS all use the calendar year as their taxable year. In Year 1, PRS loans $1,000x to US1. For Year 1, US1 has $100x of interest expense with respect to the loan and PRS has $100x of interest income with respect to the loan. US1's distributive share of the interest income is $60x. Under paragraph (e)(2) of this section, $75x of US1's interest expense with respect to the loan is allocated and apportioned to U.S. source income and $25x is allocated and apportioned to foreign source foreign branch category income. Under paragraph (h)(4)(i) of this section, US1's share of the total value of the loan between US1 and PRS is $600x.

(*2*) *Analysis.* The loan by PRS to US1 is an upstream partnership loan and US1 is an UPL debtor. Under paragraph (e)(9)(iv)(B) of this section, the matching expense amount is $60x, the lesser of the UPL interest expense taken into account by US1 with respect to the loan for the taxable year ($100x) and US1's distributive share of the UPL interest income ($60x). Under paragraph (e)(9)(ii) of this section, US1 assigns $45x of the UPL interest income to U.S. source income ($60x × $75x/$100x) and $15x of the UPL interest income to foreign source foreign branch category income ($60x × $25x/$100x). Under paragraph (e)(9)(i) of this section, the disregarded portion of the upstream partnership loan is $600x, and is not taken into account as described in paragraphs (e)(2) and (3) of this section.

(B) *Example 2*—(*1*) *Facts.* The facts are the same as in paragraph (e)(9)(vi)(A)(*1*) of this section (the facts in *Example 1*), except that US1 and US2 are part of the same affiliated group with the same ratio of U.S. and foreign assets that US1 had in paragraph (e)(9)(vi)(A)(*1*), US2's distributive share of the interest income is $40x, and under paragraph (h)(4)(i) of this section US2's share of the total value of the loan between US1 and PRS is $400x.

(*2*) *Analysis.* The loan by PRS to US1 is an upstream partnership loan and US1 is an UPL debtor. Under paragraph (e)(9)(iv)(B) of this section, the matching expense amount is $100x, the lesser of the UPL interest expense taken into account by US1 with respect to the loan for the taxable year ($100x) and the total amount of US1 and US2's distributive shares of the UPL interest income ($100x). Under paragraph (e)(9)(ii) of this section, US1 and US2 assign $75x of their total UPL interest income to U.S. source income ($100x × $75x/$100x) and $25x of their total UPL interest income to foreign source foreign branch category income ($100x × $25x/$100x). Under paragraph (e)(9)(i) of this section, the disregarded portion of the upstream partnership loan is $1,000x, the total amount of US1 and US2's share of the loan between US1 and PRS, and is not taken into account as described in paragraphs (e)(2) and (3) of this section.

* * * * *

(k) *Applicability date.* (1) Except as provided in paragraph (k)(2) of this section, this section applies to taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

(2) Paragraphs (b)(1)(i), (b)(8), and (e)(9) of this section apply to taxable years that end on or after December 16, 2019. For taxable years that both begin after December 31, 2017, and end on or after December 4, 2018, and also end before December 16, 2019, see § 1.861–9T(b)(1)(i) as contained in 26 CFR part 1 revised as of April 1, 2019.

■ **Par. 7.** Section 1.861–9T is amended by revising paragraph (b)(1)(i) and adding paragraph (b)(8) to read as follows:

§ 1.861–9T Allocation and apportionment of interest expense (temporary).

* * * * *

(b) * * *

(1) * * *

(i) *General rule.* For further guidance, see § 1.861–9(b)(1)(i).

* * * * *

(8) *Guaranteed payments.* For further guidance, see § 1.861–9(b)(8).

* * * * *

■ **Par. 8.** Section 1.861–12 is amended by revising paragraph (e), adding paragraphs (f) and (g), and revising paragraph (k) to read as follows:

§ 1.861–12 Characterization rules and adjustments for certain assets.

* * * * *

(e) *Portfolio securities that constitute inventory or generate primarily gains.* For further guidance, see § 1.861–12T(e).

(f) *Assets connected with capitalized, deferred, or disallowed interest*—(1) *In general.* In the case of any asset in connection with which interest expense accruing during a taxable year is capitalized, deferred, or disallowed under any provision of the Code, the value of the asset for allocation and apportionment purposes is reduced by the principal amount of indebtedness the interest on which is so capitalized, deferred, or disallowed. Assets are connected with debt (the interest on which is capitalized, deferred, or disallowed) only if using the debt proceeds to acquire or produce the asset causes the interest to be capitalized, deferred, or disallowed.

(2) *Examples.* The following examples illustrate the application of paragraph (f)(1) of this section.

(i) *Example 1: Capitalized interest under section 263A*—(A) *Facts.* X is a domestic corporation that uses the tax book value method of apportionment. X has $1,000x of indebtedness and incurs $100x of interest expense. Using $800x of the $1,000x debt proceeds to produce tangible property, X capitalizes $80x of interest expense under the rules of section 263A. X deducts the remaining $20x of interest expense.

(B) *Analysis.* Because interest on $800x of debt is capitalized under section 263A by reason of the use of debt proceeds to produce the tangible property, $800x of the principal amount of X's debt is connected to the tangible property under paragraph (f)(1) of this section. Therefore, for purposes of apportioning the remaining $20x of X's interest expense, the adjusted basis of the tangible property is reduced by $800x.

(ii) *Example 2: Disallowed interest under section 163(l)*—(A) *Facts.* X, a domestic corporation, owns 100% of the stock of Y, a domestic corporation. X and Y file a consolidated return and use the tax book value method of apportionment. In Year 1, X makes a loan of $1,000x to Y (Loan A) and Y then uses the Loan A proceeds to acquire in a cash purchase all the stock of a foreign corporation, Z. Interest on Loan A is payable in U.S. dollars or, at the option of Y, in stock of Z.

(B) *Analysis.* Under section 163(l), Loan A is a disqualified debt instrument because interest on Loan A is payable at the option of Y in stock of a related party to Y. Because Loan A is a

disqualified debt instrument, section 163(l)(1) disallows Y's interest deduction for interest payable on Loan A. However, the value of the Z stock is not reduced under paragraph (f)(1) of this section because the use of the Loan A proceeds to acquire the stock of Z is not the cause of Y's interest deduction being disallowed. Rather, the Loan A terms allowing interest to be paid in stock of Z is the cause of Y's interest deduction being disallowed under section 163(l). Therefore, no adjustment is made to Y's adjusted basis in the stock of Z for purposes of allocating the interest expense of X and Y.

(g) *Special rules for FSCs.* For further guidance, see § 1.861–12T(g) through (j).

* * * * *

(k) *Applicability date.* (1) Except as provided in paragraph (k)(2) of this section, this section applies to taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

(2) Paragraph (f) of this section applies to taxable years that end on or after December 16, 2019. For taxable years that both begin after December 31, 2017, and end on or after December 4, 2018, and before December 16, 2019, see § 1.861–12T(f) as contained in 26 CFR part 1 revised as of April 1, 2019.

■ **Par. 9.** Section 1.861–12T is amended by revising paragraph (f) to read as follows:

§ 1.861–12T Characterization rules and adjustments or certain assets (temporary).

* * * * *

(f) *Assets connected with capitalized, deferred, or disallowed interest.* For further guidance, see § 1.861–12(f).

* * * * *

§ 1.861–13T [REMOVED]

■ **Par. 10.** Section 1.861–13T is removed.

■ **Par. 11.** Section 1.861–14 is amended by:

■ 1. Removing the last sentence in paragraph (d)(1) and paragraphs (d)(3) through (e)(5).

■ 2. Adding paragraph (d)(3), reserved paragraph (d)(4), paragraph (e) heading, and paragraphs (e)(1) through (5).

■ 3. Removing the heading for paragraph (e)(6).

■ 4. Redesignating paragraph (e)(6)(i) as paragraph (e)(6).

■ 5. Revising the heading for newly redesignated paragraph (e)(6).

■ 6. Removing paragraphs (e)(6)(ii) and (f) through (j).

■ 7. Adding paragraph (f), reserved paragraph (g), paragraph (h), reserved paragraphs (i) and (j), and paragraph (k).

The additions and revisions read as follows:

§ 1.861–14 Special rules for allocating and apportioning certain expenses (other than interest expense) of an affiliated group of corporations.

* * * * *

(d) * * *

(3) *Inclusion of financial corporations.* For further guidance, see § 1.861–14T(d)(3) through (4).

(4) [Reserved]

(e) *Expenses to be allocated and apportioned under this section*—(1) *Expenses not directly allocable to specific income-producing activities or property.* (i) The expenses that are required to be allocated and apportioned under the rules of this section are expenses that are not directly allocable to specific income-producing activities or property solely of the member of the affiliated group that incurred the expense, including (but not limited to) certain expenses related to research and experimental expenses, supportive functions, deductions under section 250, legal and accounting expenses, and litigation damages awards, prejudgment interest, and settlement payments. Interest expense of members of an affiliated group of corporations is allocated and apportioned under § 1.861–11T and not under the rules of this section. Expenses that are included in inventory costs or that are capitalized are not subject to allocation and apportionment under the rules of this section. In addition, stewardship expenses are not subject to allocation and apportionment under the rules of this section; instead, stewardship expenses of a taxpayer are allocated and apportioned on a separate entity basis without treating members of the affiliated group as a single taxpayer. See § 1.861–8(e)(4)(ii)(A).

(ii) For further guidance, see § 1.861–14T(e)(1)(ii).

(2) *Research and experimental expenditures.* R&E expenditures (as defined in § 1.861–17(a)) in the case of an affiliated group are allocated and apportioned under the rules of § 1.861–17 as if all members of the affiliated group were a single taxpayer. Thus, R&E expenditures are allocated to all gross intangible income of all members of the affiliated group reasonably connected with the relevant broad SIC code category. If fewer than all members of the affiliated group derive gross intangible income reasonably connected with that relevant broad SIC code category, then such expenditures are apportioned under the rules of this paragraph (e)(2) only among those members, as if those members were a single taxpayer.

(3) *Expenses related to supportive functions.* For further guidance, see § 1.861–14T(e)(3).

(4) *Section 250 deduction.* Except as provided in this paragraph (e)(4), the deduction allowed under section 250(a) (the section 250 deduction) to a member of an affiliated group is allocated and apportioned on a separate entity basis under the rules of § 1.861–8(e)(13) and (14). However, the section 250 deduction of a member of a consolidated group is not directly allocable to specific income-producing activities or property solely of the member of the affiliated group that is allowed the deduction. See § 1.1502–50 for rules on applying section 250 and §§ 1.250–1 through 1.250(b)–6 to a member of a consolidated group. In such case, the section 250 deduction is allocated and apportioned as if all members of the consolidated group are treated as a single corporation.

(5) *Legal and accounting fees and expenses; damages awards, prejudgment interest, and settlement payments.* Legal and accounting fees and expenses, as well as litigation or arbitral damages awards, prejudgment interest, and settlement payments, are allocated and apportioned under the rules of § 1.861–8(e)(5). To the extent that under § 1.861–14T(c)(2) and (e)(1)(ii) such expenses are not directly allocable to specific income-producing activities or property of one or more members of the affiliated group, such expenses must be allocated and apportioned as if all members of the affiliated group were a single corporation. Specifically, such expenses must be allocated to a class of gross income that takes into account the gross income which is generated, has been generated, or is reasonably expected to be generated by the other members of the affiliated group. If the expenses relate to the gross income of fewer than all members of the affiliated group as determined under § 1.861–14T(c)(2), then those expenses must be apportioned under the rules of § 1.861–14T(c)(2), as if those fewer members were a single corporation. Such expenses must be apportioned taking into account the apportionment factors contributed by the members of the group that are treated as a single corporation.

(6) *Charitable contribution expenses.*

* * *

(f) *Computation of FSC or DISC combined taxable income.* For further guidance, see § 1.861–14T(f) and (g).

(g) [Reserved]

(h) *Special rule for the allocation and apportionment of reserve expenses of a life insurance company.* Section 1.861–

8(e)(16) applies for purposes of allocating and apportioning reserve expenses with respect to dividends received by a life insurance company. The remaining reserve expenses of such company are allocated and apportioned under the rules of § 1.861–8 and this section.

(i) through (j) [Reserved]

(k) *Applicability date.* This section applies to taxable years beginning after December 31, 2019.

■ **Par. 12.** Section 1.861–14T is amended by:

■ 1. Revising paragraphs (e)(1)(i) and (e)(2)(i).

■ 2. Removing and reserving paragraph (e)(2)(ii).

■ 3. Revising paragraphs (e)(4) and (5) and (h).

■ 4. Adding footnote 1 at the end of paragraph (j) introductory text.

The revisions and additions read as follows:

§ 1.861–14T Special rules for allocating and apportioning certain expenses (other than interest expense) of an affiliated group of corporations (temporary).

* * * * *

(e) * * *

(1) * * *

(i) For further guidance, see § 1.861–14(e)(1)(i).

* * * * *

(2) * * *

(i) For further guidance, see § 1.861–14(e)(2)(i) and (ii).

* * * * *

(4) *Section 250 deduction.* For further guidance, see § 1.861–14(e)(4).

(5) *Legal and accounting fees and expenses; damages awards, prejudgment interest, and settlement payments.* For further guidance, see § 1.861–14(e)(5).

* * * * *

(h) *Special rule for allocation of reserve expenses of life insurance companies.* For further guidance, see § 1.861–14(h).

* * * * *

(j) * * *

[1] Examples 1 and 4 of this paragraph (j) apply to taxable years beginning before January 1, 2018.

* * * * *

■ **Par. 13.** Section 1.861–17 is revised to read as follows:

§ 1.861–17 Allocation and apportionment of research and experimental expenditures.

(a) *Scope.* This section provides rules for the allocation and apportionment of research and experimental expenditures that a taxpayer deducts, or amortizes and deducts, in a taxable year under section 174 or section 59(e) (applicable to expenditures that are allowable as a deduction under section 174(a)) (*R&E expenditures*). R&E expenditures do not include any expenditures that are not deductible expenses by reason of the second sentence under § 1.482–7(j)(3)(i) (relating to CST Payments (as defined in § 1.482–7(b)(1)) owed to a controlled participant in a cost sharing arrangement).

(b) *Allocation*—(1) *In general.* The method of allocation and apportionment of R&E expenditures set forth in this section recognizes that research and experimentation is an inherently speculative activity, that findings may contribute unexpected benefits, and that the gross income derived from successful research and experimentation must bear the cost of unsuccessful research and experimentation. In addition, the method set forth in this section recognizes that successful R&E expenditures ultimately result in the creation of intangible property that will be used to generate income. Therefore, R&E expenditures ordinarily are considered deductions that are definitely related to gross intangible income (as defined in paragraph (b)(2) of this section) reasonably connected with the relevant SIC code category (or categories) of the taxpayer and therefore allocable to gross intangible income as a class related to the SIC code category (or categories) and apportioned under the rules in this section. For purposes of the allocation under this paragraph (b)(1), a taxpayer's SIC code category (or categories) are determined in accordance with the provisions of paragraph (b)(3) of this section. For purposes of this section, the term *intangible property* means intangible property (as defined in section 367(d)(4)), including intangible property either created or acquired by the taxpayer, that is derived from R&E expenditures.

(2) *Definition of gross intangible income.* The term *gross intangible income* means all gross income earned by a taxpayer that is attributable to a sale or license of intangible property (including income from platform contribution transactions described in § 1.482–7(b)(1)(ii), royalty income from the licensing of intangible property, or amounts taken into account under section 367(d) by reason of a transfer of intangible property), and the full amount of gross income from sales or leases of products or services if the income is derived directly or indirectly (in whole or in part) from intangible property. Gross intangible income also includes a distributive share of any amounts described in the previous sentence, but does not include dividends or any amounts included in income under section 951, 951A, or 1293. See § 1.904–4(f)(2)(vi) for rules addressing the assignment of gross income, including gross intangible income, to a separate category by reason of certain disregarded payments to or from a taxpayer's foreign branch.

(3) *SIC code categories*—(i) *Allocation based on SIC code categories.* Ordinarily, a taxpayer's R&E expenditures are incurred to produce gross intangible income that is reasonably connected with one or more relevant SIC code categories. Except as provided in paragraph (b)(3)(iv) of this section, where research and experimentation is conducted with respect to more than one SIC code category, the taxpayer may aggregate the categories for purposes of allocation and apportionment, provided the categories are in the same Major Group. However, the taxpayer may not subdivide any categories. Where research and experimentation is not clearly related to any SIC code category (or categories), it will be considered conducted with respect to all of the taxpayer's SIC code categories.

(ii) *Use of three digit standard industrial classification codes.* A taxpayer determines the relevant Major Groups and SIC code categories by reference to the two digit and three digit classification, respectively, of the Standard Industrial Classification Manual (SIC code). The SIC Manual is available at *https://www.osha.gov/pls/imis/sic_manual.html.*

(iii) *Consistency.* Once a taxpayer selects a SIC code category or Major Group for the first taxable year for which this section applies to the taxpayer, it must continue to use that category in following years unless the taxpayer establishes to the satisfaction of the Commissioner that, due to changes in the relevant facts, a change in the category is appropriate. Therefore, once a taxpayer elects a permissible aggregation of three digit SIC code categories into a two digit Major Group, it must continue to use that two digit category in following years unless the taxpayer establishes to the satisfaction of the Commissioner that, due to changes in the relevant facts, a change is appropriate.

(iv) *Wholesale trade and retail trade categories.* A taxpayer must use a SIC code category within the divisions of ''wholesale trade'' or ''retail trade'' if it is engaged solely in sales-related activities with respect to a particular category of products. In the case of a taxpayer that conducts material non-sales-related activities with respect to a particular category of products, all R&E

expenditures related to sales of the products must be allocated and apportioned as if the expenditures were reasonably connected to the most closely related three digit SIC code category other than those within the wholesale and retail trade divisions. For example, if a taxpayer engages in both the manufacturing and assembling of cars and trucks (SIC code 371) and in a wholesaling activity related to motor vehicles and motor vehicle parts and supplies (SIC code 501), the taxpayer must allocate and apportion all R&E expenditures related to both activities as if they relate solely to the manufacturing SIC code 371. By contrast, if the taxpayer engages only in the wholesaling activity related to motor vehicles and motor vehicle parts and supplies, the taxpayer must allocate and apportion all R&E expenditures to the wholesaling SIC code 501.

(c) *Exclusive apportionment.* Solely for purposes of applying this section to section 904 as the operative section, an amount equal to fifty percent of a taxpayer's R&E expenditures in a SIC code category (or categories) is apportioned exclusively to the residual grouping of U.S. source gross intangible income if research and experimentation that accounts for at least fifty percent of such R&E expenditures was performed in the United States. Similarly, an amount equal to fifty percent of a taxpayer's R&E expenditures in a SIC code category (or categories) is apportioned exclusively to the statutory grouping (or groupings) of foreign source gross intangible income in that SIC code category if research and experimentation that accounts for more than fifty percent of such R&E expenditures was performed outside the United States. If there are multiple separate categories with foreign source gross intangible income in the SIC code category, the fifty percent of R&E expenditures apportioned under the previous sentence is apportioned ratably to foreign source gross intangible income based on the relative amounts of gross receipts from gross intangible income in the SIC code category in each separate category, as determined under paragraph (d) of this section. Solely for purposes of determining whether fifty percent or more of R&E expenditures in a year are performed within or without the United States under this paragraph (c), a taxpayer's R&E expenditures with respect to a taxable year are determined by taking into account only the R&E expenditures incurred in such taxable year (without regard to whether such expenditures are capitalized under section 59(e) or any other provision in the Code), and do not include amounts that were capitalized in a prior taxable year and are deducted in such taxable year.

(d) *Apportionment based on gross receipts from sales of products or services*—(1) *In general.* A taxpayer's R&E expenditures not apportioned under paragraph (c) of this section are apportioned between the statutory grouping (or among the statutory groupings) within the class of gross intangible income and the residual grouping within such class according to the rules in paragraphs (d)(1)(i) through (iv) of this section. See paragraph (b) of this section for defining the class of gross intangible income in relation to SIC code categories.

(i) A taxpayer's R&E expenditures not apportioned under paragraph (c) of this section are apportioned in the same proportions that:

(A) The amounts of the taxpayer's gross receipts from sales and leases of products (as measured by gross receipts without regard to cost of goods sold) or services that are related to gross intangible income within the statutory grouping (or statutory groupings) and in the residual grouping bear, respectively; to

(B) The total amount of such gross receipts in the class.

(ii) For purposes of this paragraph (d), gross receipts from sales and leases of products are related to gross intangible income if intangible property is embedded or used in connection with the manufacture or sale of such products, and gross income from services is related to gross intangible income if intangible property is incorporated in or directly or indirectly benefits such services. See paragraph (g)(7) of this section (*Example 7*). The amount of the gross receipts used to apportion R&E expenditures also includes gross receipts from sales and leases of products or services of any controlled or uncontrolled party to the extent described in paragraphs (d)(3) and (4) of this section. A royalty or other amount paid to the taxpayer for intangible property constitutes gross intangible income, but is not considered part of gross receipts arising from the sale or lease of a product or service, and so is not taken into account in apportioning the taxpayer's R&E expenditures to its gross intangible income.

(iii) The statutory grouping (or groupings) or residual grouping to which the gross receipts are assigned is the grouping to which the gross intangible income related to the sale, lease, or service is assigned. In cases where the gross intangible income of the taxpayer is income not described in paragraph (d)(3) or (4) of this section, the grouping to which the taxpayer's gross receipts and the gross intangible income are assigned is the same. In cases where the taxpayer's gross intangible income is related to sales, leases, or services described in paragraph (d)(3) or (4) of this section, the gross receipts that will be used for purposes of this paragraph (d) are the gross receipts of the controlled and uncontrolled parties that are taken into account under paragraphs (d)(3) and (4) of this section. The grouping to which the controlled or uncontrolled parties' gross receipts are assigned is determined based on the grouping of the taxpayer's gross intangible income attributable to the license, sale, or other transfer of intangible property to such controlled or uncontrolled party as described in paragraph (d)(3)(i) or (d)(4)(i) of this section, and not the grouping to which the gross receipts would be assigned if the assignment were based on the income earned by the controlled or uncontrolled party. See paragraph (g)(1) of this section (*Example 1*). For purposes of applying this paragraph (d)(1)(iii) to section 250 or section 904 as the operative section, the assignment of gross receipts to the general and foreign branch categories is made after taking into account the assignment of gross intangible income to those categories as adjusted by reason of disregarded payments under the rules of § 1.904–4(f)(2)(vi), and by making similar adjustments to gross receipts under the principles of § 1.904–4(f)(2)(vi).

(iv) For purposes of applying this section to section 904 as the operative section, because a United States person's gross intangible income cannot include income assigned to the section 951A category, no R&E expenditures of a United States person are apportioned to foreign source income in the section 951A category.

(2) *Apportionment in excess of gross income.* Amounts apportioned under this section may exceed the amount of gross income related to the SIC code category within the statutory or residual grouping. In such case, the excess is applied against other gross income within the statutory or residual grouping. See § 1.861–8(d)(1) for applicable rules where the apportionment results in an excess of deductions over gross income within the statutory or residual grouping.

(3) *Sales or services of uncontrolled parties*—(i) *In general.* For purposes of the apportionment within a class under paragraph (d)(1) of this section, if a taxpayer reasonably expects an

uncontrolled party to (through a license, purchase, or transfer): Acquire intangible property that would arise from the taxpayer's current R&E expenditures; acquire products in which such intangible property is embedded or used in connection with the manufacture or sale of such products; or receive services that incorporate or directly or indirectly benefit from such intangible property, then the gross receipts of the uncontrolled party from sales, licenses, leases, or services of the particular products or services in which the taxpayer's intangible property is embedded or incorporated or which the taxpayer's intangible property directly or indirectly benefitted are taken into account. If the taxpayer has previously licensed, sold, or transferred intangible property related to a SIC code category to an uncontrolled party, the taxpayer is presumed to expect to license, sell, or transfer to that uncontrolled party all future intangible property related to the same SIC code category. The presumption described in the preceding sentence may be rebutted by the taxpayer with facts that demonstrate that the taxpayer reasonably expects not to license, sell, or transfer future intangible property to the uncontrolled party.

(ii) *Definition of uncontrolled party.* For purposes of this paragraph (d)(3), the term *uncontrolled party* means a person that is not a controlled party as defined in paragraph (d)(4)(ii) of this section.

(iii) *Sales of components.* In the case of a sale or lease of a product by an uncontrolled party that is derived from the taxpayer's intangible property but is incorporated as a component of a larger product (for example, where the product incorporating the intangible property is a component of a large machine), only the portion of the gross receipts from the larger product that are attributable to the component derived from the intangible property is included. For purposes of the preceding sentence, a reasonable estimate based on the principles of section 482 must be made. See paragraph (g)(4)(ii)(B)(*3*) of this section (*Example 4*).

(iv) *Reasonable estimates of gross receipts.* If the amount of gross receipts of an uncontrolled party is unknown, a reasonable estimate of gross receipts must be made annually. Appropriate economic analyses, based on the principles of section 482, must be used to estimate gross receipts. See paragraph (g)(5)(ii)(B)(*3*)(*ii*) of this section (*Example 5*).

(4) *Sales or services of controlled parties*—(i) *In general.* For purposes of the apportionment within a class under paragraph (d)(1) of this section, if the controlled party is reasonably expected to (through a license, sale, or transfer): Acquire intangible property that would arise from the taxpayer's current R&E expenditures; acquire products in which such intangible property is embedded or used in connection with the manufacture or sale of such products; or receive services that incorporate or directly or indirectly benefit from such intangible property, then the gross receipts of the controlled party from all of its sales, licenses, leases, or services are taken into account. Except to the extent provided in paragraph (d)(4)(iv) of this section, if the taxpayer has previously licensed, sold, or transferred intangible property related to a SIC code category to a controlled party, the taxpayer is presumed to expect to license, sell, or transfer to that controlled party all future intangible property related to the same SIC code category. The presumption described in the preceding sentence may be rebutted by the taxpayer with facts that demonstrate that the taxpayer will not license, sell, or transfer future intangible property to the controlled party.

(ii) *Definition of a controlled party.* For purposes of this paragraph (d)(4), the term *controlled party* means any person that has a relationship to the taxpayer specified in section 267(b) or 707(b), or is a member of a controlled group of corporations (within the meaning of section 267(f)) to which the taxpayer belongs. Because an affiliated group is treated as a single taxpayer, a member of an affiliated group is not a controlled party. See paragraph (e) of this section.

(iii) *Gross receipts not to be taken into account more than once.* Sales, licenses, leases, or services among the taxpayer, controlled parties, and uncontrolled parties are not taken into account more than once; in such a situation, the amount of gross receipts of the selling person must be subtracted from the gross receipts of the buying person. Therefore, the gross receipts taken into account under paragraph (d)(4)(i) of this section generally reflect the gross receipts from sales made to end users.

(iv) *Effect of cost sharing arrangements.* If the controlled party has entered into a cost sharing arrangement, in accordance with the provisions of § 1.482–7, with the taxpayer for the purpose of developing intangible property, then the taxpayer is not reasonably expected to license, sell, or transfer to that controlled party, directly or indirectly, intangible property that would arise from the taxpayer's share of the R&E expenditures with respect to the cost shared intangibles as defined in § 1.482–7(j)(1)(i). Therefore, solely for purposes of apportioning a taxpayer's R&E expenditures (which do not include the amount of CST Payments received by the taxpayer; see paragraph (a) of this section) that are intangible development costs (as defined in § 1.482–7(d)) with respect to a cost sharing arrangement, the controlled party's gross receipts are not taken into account for purposes of paragraphs (d)(1) and (d)(4)(i) of this section.

(5) *Application of section 864(e)(3).* Section 864(e)(3) and § 1.861–8(d)(2) do not apply for purposes of this section.

(e) *Affiliated groups.* See § 1.861–14(e)(2) for rules on allocating and apportioning R&E expenditures of an affiliated group (as defined in § 1.861–14(d)).

(f) *Special rules for partnerships*—(1) *R&E expenditures.* For purposes of applying this section, if R&E expenditures are incurred by a partnership in which the taxpayer is a partner, the taxpayer's R&E expenditures include the taxpayer's distributive share of the partnership's R&E expenditures.

(2) *Purpose and location of expenditures.* In applying exclusive apportionment under paragraph (c) of this section, a partner's distributive share of R&E expenditures incurred by a partnership is treated as incurred by the partner for the same purpose and in the same location as incurred by the partnership.

(3) *Apportionment based on gross receipts.* In applying the remaining apportionment under paragraph (d) of this section, if a taxpayer is a partner in a partnership that incurs R&E expenditures described in paragraph (f)(1) of this section and the taxpayer is not reasonably expected to license, sell, or transfer to the partnership (directly or indirectly) intangible property that would arise from the taxpayer's current R&E expenditures, in the manner described in paragraph (d)(3)(i) or (d)(4)(i) of this section, then the taxpayer's gross receipts in a SIC code category include only the taxpayer's share of any gross receipts in the SIC code category of the partnership. For purposes of the preceding sentence, the taxpayer's share of gross receipts is proportionate to the taxpayer's distributive share of the partnership's gross income in the product category. However, if the taxpayer is reasonably expected to license, sell, or transfer to the partnership (directly or indirectly) intangible property that would arise from the taxpayer current R&E expenditures, in the manner described in paragraph (d)(3)(i) or (d)(4)(i) of this

section, then the taxpayer's gross receipts in a SIC code category include the full amount of any gross receipts in the SIC code category of the partnership as provided in paragraph (d)(3)(i) or (d)(4)(i) of this section.

(g) *Examples.* The following examples illustrate the application of the rules in this section.

(1) *Example 1: Controlled party and single product*—(i) *Facts.* X, a domestic corporation, is a manufacturer and distributor of small gasoline engines for lawnmowers. Gasoline engines are a product within the category, Engines and Turbines (SIC Industry Group 351). Y, a wholly owned foreign subsidiary of X, also manufactures and sells these engines abroad. X owns no other foreign subsidiaries. During Year 1, X incurred R&E expenditures of $60,000x, which it deducts under section 174 as a current expense, to invent and patent a new and improved gasoline engine. All of the research and experimentation was performed in the United States. Also in Year 1, the domestic gross receipts of X from sales of gasoline engines total $500,000x and foreign gross receipts of Y from sales of gasoline engines total $300,000x. X provides technology for the manufacture of engines to Y through a license that requires the payment of an arm's length royalty. Because X has licensed its intangible property to Y related to the SIC code, it is presumed to reasonably expect to license the intangible property that would be developed from the current research and experimentation. In Year 1, X's gross income is $210,000x, of which $140,000x is U.S. source income from domestic sales of gasoline engines, $40,000x is income included under section 951A, all of which relates to Y's foreign source income from sales of gasoline engines, $20,000x is foreign source royalties from Y, and $10,000x is U.S. source interest income. None of the foreign source royalties are allocable to passive category income of Y, and therefore, under §§ 1.904–4(d) and 1.904–5(c)(3), the foreign source royalties are general category income to X.

(ii) *Analysis*—(A) *Allocation.* The R&E expenditures were incurred in connection with developing intangible property related to small gasoline engines and they are definitely related to X's items of gross intangible income related to the SIC code category 351, namely gross income from the sale of small gasoline engines in the United States and royalties received from subsidiary Y, a foreign manufacturer of gasoline engines. Accordingly, under paragraph (b) of this section, the R&E expenditures are allocable to the class of gross intangible income related to SIC code category 351, all of which is general category income of X. X's U.S. source interest income and income included under section 951A are not within this class of gross intangible income and, therefore, no portion of the R&E expenditures are allocated to the U.S. source interest income or foreign source income in the section 951A category.

(B) *Apportionment*—(*1*) *In general.* For purposes of applying this section to section 904 as the operative section, the statutory grouping of gross intangible income is foreign source general category income and the residual grouping of gross intangible income is U.S. source income.

(*2*) *Exclusive apportionment.* Under paragraph (c) of this section, because at least 50% of X's research and experimental activity was performed in the United States, 50% of the R&E expenditures, or $30,000x ($60,000x × 50%), is apportioned exclusively to the residual grouping of U.S. source gross intangible income. The remaining 50% of the R&E expenditures is then apportioned between the statutory and residual groupings on the basis of the relative amounts of gross receipts from sales of small gasoline engines by X and Y that are related to the U.S. source sales income and foreign source royalty income, respectively.

(*3*) *Apportionment based on gross receipts.* After taking into account exclusive apportionment, X has $30,000x ($60,000x − $30,000x) of R&E expenditures that must be apportioned between the statutory and residual groupings. Under paragraph (d)(4) of this section, Y's gross receipts within the SIC code are taken into account in apportioning X's R&E expenditures. Although X has gross intangible income of $140,000x from domestic sales and $20,000x in royalties from Y, X's R&E expenditures are apportioned to that gross intangible income on the basis of the relative amounts of gross receipts arising from the sale of products by X and Y (and not the relative amounts of X's gross intangible income) in the statutory and residual groupings. Therefore, under paragraphs (d)(1) and (4) of this section $11,250x ($30,000x × $300,000x/($500,000x + $300,000x)) is apportioned to the statutory grouping of X's gross intangible income attributable to its license of intangible property to Y, or foreign source general category income. No portion of the gross receipts by X or Y are disregarded under section 864(e)(3), regardless of whether the income related to those sales is eligible for a deduction under section 250(a)(1)(A). The remaining $18,750x ($30,000x × $500,000x/($500,000x + $300,000x)) is apportioned to the residual grouping of gross intangible income, or U.S. source income.

(*4*) *Summary.* Accordingly, for purposes of the foreign tax credit limitation, $11,250x of X's R&E expenditures are apportioned to foreign source general category income, and $48,750x ($30,000x + $18,750x) of X's R&E expenditures are apportioned to U.S. source income.

(2) *Example 2: Controlled party and two products in same SIC code category*—(i) *Facts.* The facts are the same as in paragraph (g)(1)(i) of this section (the facts in *Example 1*), except that X also spends $30,000x in Year 1 for research on steam turbines, all of which is performed in the United States, and X has steam turbine gross receipts in the United States of $400,000x. X's foreign subsidiary Y neither manufactures nor sells steam turbines. The steam turbine research is in addition to the $60,000x in R&E expenditures incurred by X on gasoline engines for lawnmowers. X thus has $90,000x of R&E expenditures. X's gross income is $260,000x, of which $140,000x is U.S. source income from domestic sales of gasoline engines, $50,000x is U.S. source income from domestic sales of steam turbines, $40,000x is income included under section 951A all of which relates to foreign source income derived from Y's sales of gasoline engines, $20,000x is foreign source royalties from Y, and $10,000x is U.S. source interest income.

(ii) *Analysis*—(A) *Allocation.* X's R&E expenditures generate gross intangible income from sales of small gasoline engines and steam turbines. Both of these products are in the same three digit SIC code category, Engines and Turbines (SIC Industry Group 351). Therefore, under paragraph (a) of this section, X's R&E expenditures are definitely related to all items of gross intangible income attributable to SIC code category 351. These items of X's gross intangible income are gross income from the sale of small gasoline engines and steam turbines in the United States and royalties from foreign subsidiary Y, a foreign manufacturer and seller of small gasoline engines. X's U.S. source interest income and income included under section 951A is not within this class of gross intangible income and, therefore, no portion of X's R&E expenditures are allocated to the U.S. source interest income or income in the section 951A category.

(B) *Apportionment*—(*1*) *In general.* For purposes of applying this section to section 904 as the operative section, the statutory grouping of gross intangible

income is foreign source general category income and the residual grouping of gross intangible income is U.S. source income.

(*2*) *Exclusive apportionment.* Under paragraph (c) of this section, because at least 50% of X's research and experimental activity was performed in the United States, 50% of the R&E expenditures, or $45,000x ($90,000x × 50%), are apportioned exclusively to the residual grouping of U.S. source gross intangible income. The remaining 50% of the R&E expenditures is then apportioned between the statutory and residual groupings on the basis of the relative amounts of gross receipts of small gasoline engines and steam turbines by X and Y with respect to which gross intangible income is foreign source general category income and U.S. source income.

(*3*) *Apportionment based on gross receipts.* After taking into account exclusive apportionment, X has $45,000x ($90,000x − $45,000x) of R&E expenditures that must be apportioned between the statutory and residual groupings. Although X has gross intangible income of $190,000x from domestic sales and $20,000x in royalties from Y, X's R&E expenditures are apportioned to that gross intangible income on the basis of the relative amounts of gross receipts arising from the sale of products by X and Y (and not the relative amounts of X's gross intangible income) in the statutory and residual groupings. Even though a portion of the R&E expenditures that must be apportioned are attributable to research performed with respect to steam turbines, and Y does not sell steam turbines, because Y is reasonably expected to license all intangible property related to SIC code category 351 from X, including intangible property related to steam turbines, under paragraphs (d)(1) and (4) of this section $11,250x ($45,000x × $300,000x/($500,000x + $400,000x + $300,000x)) is apportioned to the statutory grouping of gross intangible income, or foreign source general category income attributable to the royalty income to which the gross receipts of Y are related. The remaining $33,750x ($45,000x × ($500,000x + $400,000x)/($500,000x + $400,000x + $300,000x)) is apportioned to the residual grouping of gross intangible income, or U.S. source gross income.

(*4*) *Summary.* Accordingly, for purposes of the foreign tax credit limitation, $11,250x of X's R&E expenditures are apportioned to foreign source general category income and $78,750x ($45,000x + $33,750x) of X's R&E expenditures are apportioned to U.S. source income.

(3) *Example 3: Cost sharing arrangement*—(i) *Facts*—(A) *Acquisitions and transfers by X.* The facts are the same as in paragraph (g)(1)(i) of this section (the facts in *Example 1*) except that, in Year 2, X and Y terminate the license for the manufacture of engines that was in place in Year 1 and enter into a cost sharing arrangement, in accordance with the provisions of § 1.482–7, to share the costs and risks of developing the intangible property related to the engines. Pursuant to the cost sharing arrangement, X has the exclusive rights to exploit the cost shared intangibles within the United States, and Y has the exclusive rights to exploit the cost shared intangibles outside the United States. X's and Y's shares of the reasonably anticipated benefits from the cost shared intangibles are 70% and 30%, respectively. In Year 2, Y makes a PCT Payment (as defined in § 1.482–7(b)(1)(ii)) of $50,000x that is characterized and sourced as a royalty for a license of small gasoline engine technology.

(B) *Gross receipts and R&E expenditures.* In Year 2, X and Y continue to sell gasoline engines, with gross receipts of $600,000x in the United States by X and $400,000x abroad by Y. X incurs intangible development costs associated with the cost shared intangibles of $100,000x in Year 2, which consist exclusively of research activities conducted in the United States. Y also makes a $30,000x CST Payment (as defined in § 1.482–7(b)(1)(i)) under the cost sharing arrangement. X is entitled to deduct $70,000x of its intangible development costs ($100,000x less the $30,000x CST Payment by Y) by reason of the second sentence under § 1.482–7(j)(3)(i) (relating to CST Payments).

(C) *Gross income of X.* In Year 2, X's gross income is $360,000x, of which $200,000x is U.S. source income from domestic sales of small gasoline engines, $50,000x is foreign source general category income attributable to the PCT Payment, $100,000x is income included under section 951A (all of which relates to foreign source income derived from engine sales by Y), and $10,000x is U.S. source interest income.

(ii) *Analysis*—(A) *Allocation.* The $70,000x of R&E expenditures incurred in Year 2 by X in connection with small gasoline engines are definitely related to the items of gross intangible income related to the SIC code category, namely gross income from the sale of small gasoline engines in the United States and PCT Payments from Y. Accordingly, under paragraph (a) of this section, the R&E expenditures are allocable to this class of gross intangible income. X's U.S. source interest income and income included under section 951A are not within this class of gross intangible income and, therefore, no portion of X's R&E expenditures is allocated to X's U.S. source interest income or section 951A category income.

(B) *Apportionment*—(*1*) *In general.* For purposes of applying this section to section 904 as the operative section, the statutory grouping of gross intangible income is foreign source general category income, and the residual grouping of gross intangible income is U.S. source income.

(*2*) *Exclusive apportionment.* Under paragraph (c) of this section, because at least 50% of X's research and experimentation in Year 2 was performed in the United States, 50% of the R&E expenditures, or $35,000x ($70,000x × 50%), is apportioned exclusively to the residual grouping of gross intangible income, U.S. source income.

(*3*) *Apportionment based on gross receipts.* Although X has gross intangible income of $200,000x from domestic sales and $50,000x as a PCT Payment from Y, X's R&E expenditures are apportioned to its gross intangible income on the basis of the relative amounts of gross receipts arising from the sale of products by X (and not the relative amounts of X's gross intangible income) in the statutory and residual groupings. Under paragraph (d)(4)(iv) of this section, because of the cost sharing arrangement, Y's gross receipts from sales are not taken into account in apportioning X's R&E expenditures that are intangible development costs with respect to the cost sharing arrangement. Because all of the gross receipts from sales that are taken into account under paragraph (d)(1) of this section relate to gross intangible income that is included in the residual grouping, $35,000x is apportioned to the residual grouping of gross intangible income, or U.S. source income.

(*4*) *Summary.* Accordingly, for purposes of the foreign tax credit limitation, $70,000x of X's R&E expenditures are apportioned to U.S. source income.

(4) *Example 4: Uncontrolled party*—(i) *Facts*—(A) *X's R&E expenditures.* X, a domestic corporation, is engaged in continuous research and experimentation to improve the quality of the products that it manufactures and sells, which are floodlights, flashlights, fuse boxes, and solderless connectors. All of these products are in the same three digit SIC code category, Electric

Lighting and Wiring Equipment (SIC Industry Group 364). X incurs $100,000x of R&E expenditures in Year 1 that is performed exclusively in the United States. As a result of this research activity, X acquires patents that it uses in its own manufacturing activity.

(B) *License to Y and Z.* In Year 1, X licenses its floodlight patent to Y and Z, uncontrolled parties, for use in their own territories, Countries Y and Z, respectively. Y pays X a royalty of $3,000x plus $0.20x for each unit sold. Gross receipts from sales of floodlights by Y for the taxable year are $135,000x (30,000 units at $4.50x per unit), and the royalty is $9,000x ($3,000x + $0.20x/unit × 30,000 units). Y has sales of other products of $500,000x. Z pays X a royalty of $3,000x plus $0.30x for each unit sold. Z manufactures 30,000 floodlights in the taxable year, and the royalty is $12,000x ($3,000x + $0.30x/unit × 30,000 units). The dollar value of Z's gross receipts from floodlight sales is not known to X because, in this case, the floodlights are not sold separately by Z but are instead used as a component in Z's manufacture of lighting equipment for theaters. However, a reasonable estimate of Z's gross receipts attributable to the floodlights, based on the principles of section 482, is $120,000x. The gross receipts from sales of all Z's products, including the lighting equipment for theaters, are $1,000,000x. Because X has licensed its intangible property to Y and Z related to the SIC code, it is presumed to reasonably expect to license the intangible property that would be developed from the current research and experimentation.

(C) *X's gross receipts and gross income.* X's gross receipts from sales of floodlights for the taxable year are $500,000x and its sales of its other products (flashlights, fuse boxes, and solderless connectors) are $400,000x. X has gross income of $500,000x, consisting of U.S. source gross income from domestic sales of floodlights, flashlights, fuse boxes, and solderless connectors of $479,000x, and foreign source gross income from royalties of $9,000x and $12,000x from foreign corporations Y and Z, respectively. The royalty income is general category income to X under § 1.904–4(b)(2)(ii).

(ii) *Analysis*—(A) *Allocation.* X's R&E expenditures are definitely related to all of the gross intangible income from the products that it produces, which are floodlights, flashlights, fuse boxes, and solderless connectors. All of these products are in SIC code category 364. Therefore, under paragraph (b) of this section, X's R&E expenditures are definitely related to the class of gross intangible income related to SIC code category 364 and to all items of gross intangible income attributable to the class. These items of X's gross intangible income are gross income from the sale of floodlights, flashlights, fuse boxes, and solderless connectors in the United States and royalties from Corporations Y and Z.

(B) *Apportionment*—(*1*) *In general.* For purposes of applying this section to section 904 as the operative section, the statutory grouping of gross intangible income is foreign source general category income, and the residual grouping of gross intangible income is U.S. source income.

(*2*) *Exclusive apportionment.* Under paragraph (c) of this section, because at least 50% of X's research and experimentation was performed in the United States, 50% of the R&E expenditures, or $50,000x ($100,000x × 50%), is apportioned exclusively to the residual grouping of U.S. source gross intangible income.

(*3*) *Apportionment based on gross receipts.* After taking into account exclusive apportionment, X has $50,000x ($100,000x − $50,000x) of R&E expenditures that must be apportioned between the statutory and residual groupings. Under paragraph (d)(3)(i) of this section, gross receipts from sales of Y and Z are taken into account in apportioning X's R&E expenditures. Although X has gross intangible income of $479,000x from domestic sales and $21,000x in royalties from Y and Z, X's R&E expenditures are apportioned to its gross intangible income on the basis of the relative amounts of gross receipts arising from the sale of products by X, Y and Z (and not the relative amounts of X's gross intangible income) in the statutory and residual groupings. In addition, under paragraph (d)(3)(iii) of this section only the portion of Z's gross receipts that are attributable to the floodlights that incorporate the intangible property licensed from X, rather than Z's total gross receipts, are used for purposes of apportionment. All of X's gross receipts from sales in the entire SIC code category are included for purposes of apportionment on the basis of gross intangible income attributable to those sales. Under paragraph (d)(1) of this section, $11,039x ($50,000x × ($135,000x + $120,000x)/($900,000x + $135,000x + $120,000x)) is apportioned to the statutory grouping of gross intangible income, or foreign source general category income. The remaining $38,961x ($50,000x × $900,000x/($900,000x + $135,000x + $120,000x)) is apportioned to the residual grouping of gross intangible income, or U.S. source income.

(*4*) *Summary.* Accordingly, for purposes of the foreign tax credit limitation, $11,039x of X's R&E expenditures are apportioned to foreign source general category income and $88,961x ($50,000x + $38,961x) of X's R&E expenditures are apportioned to U.S. source income.

(5) *Example 5: Uncontrolled party and sublicense*—(i) *Facts.* X, a domestic corporation, is a cloud storage service provider. Cloud storage services are a service within the category, Computer Programming, Data Processing, and other Computer Related Services (SIC Industry Group 737). During Year 1, X incurs R&E expenditures of $50,000x to invent and copyright new storage monitoring and management software. All of the research and experimentation is performed in the United States. X uses this software in its own business to provide services to customers. X also licenses a version of the software that can be used by other businesses that provide cloud storage services. X licenses the software to uncontrolled party U, which sub-licenses the software to other businesses that provide cloud storage services to customers. U does not use the software except to sublicense it. As a part of the licensing agreement with U, U and its sub-licensees are only permitted to use the software in certain countries outside of the United States. Under the contract with U, U pays X a royalty of 50% on the amount it receives from its sub-licensees that use the software to provide services to customers. Because X has licensed its intangible property to U related to the SIC code and U has sublicensed it to other businesses, it is presumed that X is reasonably expected to license the intangible property that would be developed from its current research and experimentation to U and that U would sublicense it to other businesses. In Year 1, X earns $300,000x of gross receipts from providing cloud storage services within the United States. Further, in Year 1 U receives $10,000x of royalty income from its sub-licensees and pays a royalty of $5,000x to X. Thus, X earns $300,000x of U.S. source general category gross income and also earns $5,000x of foreign source general category royalty income from licensing its software to U for use outside of the United States.

(ii) *Analysis*—(A) *Allocation.* The R&E expenditures were incurred in connection with the development of cloud computing software and they are definitely related to the items of gross intangible income related to the SIC Code category, namely gross income

from the storage monitoring and management software in the United States and royalties received from U. Accordingly, under paragraph (b) of this section, the R&E expenditures are allocable to this class of gross intangible income.

(B) *Apportionment*—(*1*) *In general.* For purposes of applying this section to section 904 as the operative section, the statutory grouping of gross intangible income is foreign source general category income, and the residual grouping of gross intangible income is U.S. source income.

(*2*) *Exclusive apportionment.* Under paragraph (c) of this section, because at least 50% of X's research and experimental activity was performed in the United States, 50% of the R&E expenditures, or $25,000x ($50,000x × 50%), is apportioned exclusively to the residual grouping of U.S. source gross intangible income.

(*3*) *Apportionment based on gross receipts*—(*i*) *In general.* After taking into account exclusive apportionment, X has $25,000x ($50,000x − $25,000x) of R&E expenditures that must be apportioned between the statutory and residual groupings. Because X has licensed its intangible property related to the SIC code to U and U has licensed it to the sub-licensees, under paragraph (d)(3)(i) of this section, gross receipts from sales of U's sublicensees are taken into account in apportioning X's R&E expenditures. Although X has gross intangible income of $300,000x from domestic sales of services and $5,000x in royalties from U, X's R&E expenditures are apportioned to its gross intangible income on the basis of the relative amounts of gross receipts arising from the sale of services by X and U's sub-licensees (and not the relative amounts of X's gross intangible income) in the statutory and residual groupings.

(*ii*) *Determination of U's sub-licensee's gross receipts.* Under paragraph (d)(3)(iv) of this section, X can make a reasonable estimate of the gross receipts of U's sub-licensees from services incorporating the intangible property licensed by X by estimating, after an appropriate economic analysis, that U would charge a royalty of 5% of the sub-licensee's sales. U received a royalty of $10,000x from the sub-licensees. X then determines U's sub-licensees' foreign sales by dividing the total royalty payments received by U by the royalty estimated rate ($10,000x/.05 = $200,000x).

(*iii*) *Results of apportionment based on gross receipts.* Therefore, under paragraphs (d)(1) and (3) of this section, $10,000x ($25,000x × $200,000x/($300,000x + $200,000x)) is apportioned to the statutory grouping of gross intangible income, or foreign source general category income. The remaining $15,000x ($25,000x × $300,000x/($300,000x + $200,000x)) is apportioned to the residual grouping of gross intangible income, or U.S. source income.

(*4*) *Summary.* Accordingly, for purposes of the foreign tax credit limitation, $10,000x of X's R&E expenditures are apportioned to foreign source general category income and $40,000x ($25,000x + $15,000x) of X's R&E expenditures are apportioned to U.S. source income.

(6) *Example 6: Foreign branch*—(i) *Facts*—(A) *Overview for X.* X, a domestic corporation, owns FDE, a disregarded entity that is a foreign branch within the meaning of § 1.904–4(f)(3)(vii). FDE conducts activities solely in Country Y. FDE's functional currency is the U.S. dollar. X is a manufacturer and distributor of small gasoline engines for lawnmowers in the United States. Gasoline engines are a product within the category, Engines and Turbines (SIC Industry Group 351). FDE also manufactures and distributes small gasoline engines but only in Country Y. During Year 1, X incurred R&E expenditures of $60,000x, which it deducts under section 174 as a current expense, to invent and patent a new and improved gasoline engine. All of the research and experimentation was performed in the United States. Also in Year 1, the domestic gross receipts of X from gasoline engines total $500,000x. X provides technology for the manufacture of engines to FDE through a license. FDE compensates X for the technology with an arm's length royalty payment of $10,000x, which is disregarded for Federal income tax purposes.

(B) *Overview for FDE.* FDE accrues and records on its books and records $100,000x of gross income from sales of gasoline engines to unrelated persons. FDE's gross income is non-passive category income and is foreign source income. In Year 1, the foreign gross receipts of FDE from sales of gasoline engines total $300,000x. The disregarded royalty payment from FDE to X is not recorded on FDE's separate books and records (as adjusted to conform to Federal income tax principles) within the meaning of paragraph § 1.904–4(f)(2)(i) because it is disregarded for Federal income tax purposes. However, the $10,000x disregarded royalty payment would be allocable to foreign source gross income attributable to FDE under § 1.904–4(f)(2)(vi)(B)(*1*)(*ii*). Therefore, under § 1.904–4(f)(2)(vi)(A) the amount of foreign source gross income attributable to FDE is adjusted downwards and the amount of foreign source gross income attributable to X is adjusted upward to take the $10,000x disregarded royalty payment into account.

(C) *Assignment of X's gross income to separate categories.* In Year 1, X has U.S. source general category gross income of $140,000x from domestic sales of gasoline engines. After application of § 1.904–4(f)(2)(vi)(A) to the disregarded payment made by FDE, X has $10,000x of foreign source general category gross income and X also has $90,000x of foreign source foreign branch category gross income.

(ii) *Analysis*—(A) *Allocation.* The R&E expenditures were incurred in connection with developing intangible property related to small gasoline engines and are definitely related to the items of gross intangible income related to the SIC code category 351, namely gross income from the sale of small gasoline engines in both the United States and Country Y.

(B) *Apportionment*—(*1*) *In general.* For purposes of applying this section to section 904 as the operative section, the statutory groupings of gross intangible income are foreign source general category income and foreign source foreign branch category income, and the residual grouping of gross intangible income is U.S. source income.

(*2*) *Exclusive apportionment.* Under paragraph (c) of this section, because at least 50% of X's research and experimental activity was performed in the United States, 50% of the R&E expenditures, or $30,000 ($60,000x × 50%), is apportioned exclusively to the residual grouping of U.S. source gross intangible income. The remaining 50% of the R&E expenditures is then apportioned between the statutory and residual groupings on the basis of the relative amounts of gross receipts from sales of small gasoline engines that are related to U.S. source income, foreign source general category income, and foreign source foreign branch category income.

(*3*) *Apportionment based on gross receipts.* After taking into account exclusive apportionment, X has $30,000x ($60,000x − $30,000x) of R&E expenditures that must be apportioned between the statutory and residual groupings. Because X's gross intangible income is not described in paragraph (d)(3) or (4) of this section (that is, there is no gross intangible income related to sales, leases or services from controlled or uncontrolled parties that are incorporating intangible property that was licensed, sold, or transferred to controlled or uncontrolled parties), the

groupings to which the taxpayer's gross receipts and gross intangible income are assigned is the same. However, because the assignment of X's gross income to the foreign branch and general categories is made by taking into account disregarded payments under § 1.904–4(f)(2)(vi), the assignment of gross receipts between the general category and foreign branch category must be determined by making similar adjustments to X's gross receipts under the principles of § 1.904–4(f)(2)(vi). See paragraph (d)(1)(iii) of this section. Foreign gross receipts of FDE from gasoline engines total $300,000x. However, those gross receipts are adjusted under the principles of § 1.904–4(f)(2)(vi) for purposes of apportioning the remaining R&E expenditures by reducing the gross receipts initially assigned to the foreign branch category by an amount equal to the ratio of the royalty income to FDE's gross income that is initially assigned to the foreign branch category. Accordingly, since the disregarded royalty payment of $10,000x caused an adjustment equal to 10% of FDE's initial gross income of $100,000x, 10% of the gross receipts or $30,000x (10% × $300,000x) are similarly assigned to the grouping of foreign source general category income, and the remaining $270,000x of gross receipts are assigned to the grouping of foreign source foreign branch category income. Therefore, under paragraph (d)(1) of this section, $1,125x ($30,000x × $30,000x/($500,000x + $270,000x + $30,000x)) is apportioned to the statutory grouping of X's gross intangible income attributable to foreign source general category income. $10,125x ($30,000x × $270,000x/($500,000x + $270,000x + $30,000x)) is apportioned to the statutory grouping of X's foreign source foreign branch category income. The remaining $18,750x ($30,000x × $500,000x/($500,000x + $270,000x + $30,000x)) is apportioned to the residual grouping of gross intangible income or U.S. source income.

(7) *Example 7: Indirectly derived gross intangible income*—(i) *Facts.* P, a domestic corporation, develops and publishes an internet website that persons use (referred to as ''users'' and collectively referred to as ''user base'') without a fee. P incurs R&E expenditures to update software code and write new software code to maintain the website and develop new products that are incorporated into the website. P's activities consist of services that fall within SIC code category 737 (computer programming, data processing, and other computer related services). P sells space on its website for businesses to advertise to its user base in exchange for a fee. P's technology allows it to collect data on users and to use that data to effectively target advertisements. P does not grant rights to the technology or other intangible property to the businesses advertising on its website. In Year 1, P incurs R&E expenditures of $60,000x, which it deducts under section 174. All the research and experimentation is performed in the United States. Also in Year 1, P earns gross receipts of $200,000x from the sale of advertisements, all of which gives rise to U.S. source gross income.

(ii) *Analysis*—(A) *Allocation.* The R&E expenditures were incurred in connection with developing intangible property used for P's website. Accordingly, they are definitely related and allocable to gross intangible income derived directly or indirectly (in whole or in part) from that intangible property. Because P's advertising sales are dependent on the users attracted to its website, P's gross income from advertising is indirectly derived from intangible property and is included in gross intangible income. Accordingly, under paragraph (b) of this section, the R&E expenditures are allocable to the class of gross intangible income related to SIC code category 737, which consists of U.S. source income.

(B) *Apportionment.* Because all gross receipts from services that the intangible property directly or indirectly benefits result in U.S. source income, no apportionment is required.

(h) *Applicability date.* This section applies to taxable years beginning after December 31, 2019. However, taxpayers may choose to apply this section to taxable years beginning on or after January 1, 2018, and before January 1, 2020, provided they apply this section in its entirety and for any subsequent year beginning before January 1, 2020.

■ **Par. 14.** Section 1.861–20 is added to read as follows:

§ 1.861–20 Allocation and apportionment of foreign income taxes.

(a) *Scope.* This section provides rules for the allocation and apportionment of foreign income taxes, including allocating and apportioning foreign income taxes to separate categories for purposes of the foreign tax credit. The rules of this section apply except as modified under the rules for an operative section (as described in § 1.861–8(f)(1)). See, for example, §§ 1.704–1(b)(4)(viii)(*d*)(*1*), 1.904–6, 1.960–1(d)(3)(ii), and 1.965–5(b)(2). Paragraph (b) of this section provides definitions for the purposes of this section. Paragraph (c) of this section provides the general rule for allocation and apportionment of foreign income taxes. Paragraph (d) of this section provides rules for assigning foreign gross income to statutory and residual groupings. Paragraph (e) of this section provides rules for allocating and apportioning foreign law deductions to foreign gross income in the statutory and residual groupings. Paragraph (f) of this section provides rules for apportioning foreign income taxes among statutory and residual groupings. Paragraph (g) of this section provides examples that illustrate the application of this section. Paragraph (h) of this section provides the applicability date for this section.

(b) *Definitions.* The following definitions apply for purposes of this section.

(1) *Corporation.* The term *corporation* has the same meaning as set forth in § 301.7701–2(b) of this chapter, and so includes a reverse hybrid.

(2) *Corresponding U.S. item.* The term *corresponding U.S. item* means the item of U.S. gross income or U.S. loss, if any, that arises from the same transaction or other realization event from which an item of foreign gross income also arises. An item of U.S. gross income or U.S. loss is a corresponding U.S. item even if the item of foreign gross income that arises from the same transaction or realization event differs in amount from the item of U.S. gross income or U.S. loss. A corresponding U.S. item does not include an item of gross income that is exempt, excluded, or eliminated from U.S. gross income, nor does it include an item of U.S. gross income or U.S. loss that is not realized, recognized or taken into account by the taxpayer in the U.S. taxable year in which the taxpayer paid or accrued the foreign income tax, except as provided in the next sentence. If a taxpayer pays or accrues a foreign income tax that is imposed on foreign taxable income that includes an item of foreign gross income by reason of a transaction or other realization event that also gave rise to an item of U.S. gross income or U.S. loss, but the U.S. and foreign taxable years end on different dates and the event occurred in the last U.S. taxable year that ends before the end of the foreign taxable year, then the item of U.S. gross income or U.S. loss is a corresponding U.S. item.

(3) *Disregarded entity.* The term *disregarded entity* means an entity described in § 301.7701–2(c)(2) of this chapter that is disregarded as an entity separate from its owner for Federal income tax purposes.

(4) *Foreign capital gain amount.* The term *foreign capital gain amount* means the portion of a distribution that under foreign law gives rise to gross income of a type described in section 301(c)(3)(A).

(5) *Foreign dividend amount.* The term *foreign dividend amount* means the portion of a distribution that is taxable as a dividend under foreign law.

(6) *Foreign gross income.* The term *foreign gross income* means the items of gross income included in the base upon which a foreign income tax is imposed. This includes all items of foreign gross income included in the foreign tax base, even if the foreign taxable year begins in the U.S. taxable year that precedes the U.S. taxable year in which the taxpayer pays or accrues the foreign income tax.

(7) *Foreign income tax.* The term *foreign income tax* means an income, war profits, or excess profits tax within the meaning of § 1.901–2(a) that is a separate levy within the meaning of § 1.901–2(d) and that is paid or accrued to any foreign country (as defined in § 1.901–2(g)).

(8) *Foreign law CFC.* The term *foreign law CFC* means an entity that is a body corporate under foreign law, certain of the earnings of which are taxable to its shareholder under a foreign law inclusion regime.

(9) *Foreign law disposition.* The term *foreign law disposition* means an event that foreign law treats as a taxable disposition or deemed disposition of property but that Federal income tax law does not treat as a disposition causing the recognition of gain or loss (for example, marking property to market under foreign law).

(10) *Foreign law distribution.* The term *foreign law distribution* means an event that foreign law treats as a taxable distribution (other than by reason of a foreign law inclusion regime) but that Federal income tax law does not treat as a distribution of property within the meaning of section 317(a) (for example, a stock dividend described in section 305 or a foreign law consent dividend).

(11) *Foreign law inclusion regime.* A *foreign law inclusion regime* is a foreign law tax regime similar to the subpart F or GILTI regime described in sections 951 through 959, or the PFIC regime described in sections 1293 through 1295 (relating to qualified electing funds), that imposes a tax on a shareholder of an entity based on an inclusion in the shareholder's taxable income of certain of the entity's current earnings, whether or not the foreign law deems the entity's earnings to be distributed.

(12) *Foreign law inclusion regime income.* The term *foreign law inclusion regime income* means the items of foreign gross income included by a taxpayer with respect to a foreign law CFC by reason of a foreign law inclusion regime.

(13) *Foreign law pass-through income.* The term *foreign law pass-through income* means the items of a reverse hybrid, computed under foreign law, that give rise to an inclusion in a taxpayer's foreign gross income under the laws of a foreign country imposing tax by reason of the taxpayer's ownership of the reverse hybrid.

(14) *Foreign taxable income.* The term *foreign taxable income* means foreign gross income reduced by the deductions that are allowed under foreign law.

(15) *Foreign taxable year.* The term *foreign taxable year* has the meaning set forth in section 7701(a)(23), applied by substituting ''under foreign law'' for the phrase ''under subtitle A.''

(16) *Partnership.* The term *partnership* has the same meaning as set forth in § 301.7701–2(c)(1) of this chapter.

(17) *Reverse hybrid.* The term *reverse hybrid* means a corporation that is a fiscally transparent entity (under the principles of § 1.894–1(d)(3)) or a branch under the laws of a foreign country imposing tax on the income of the entity.

(18) *Taxpayer.* The term *taxpayer* has the meaning described in § 1.901–2(f)(1).

(19) *U.S. capital gain amount.* The term *U.S. capital gain amount* means gain recognized by a taxpayer on the sale or exchange of stock or, in the case of a distribution with respect to stock, the portion of the distribution to which section 301(c)(3)(A) applies. However, a U.S. capital gain amount does not include any portion of the gain recognized by a taxpayer that is treated as a dividend under section 964(e) or 1248.

(20) *U.S. dividend amount.* The term *U.S. dividend amount* means the portion of a distribution that is made out of earnings and profits under Federal income tax law, including distributions out of previously taxed earnings and profits described in section 959(a) or (b). It also includes amounts included in gross income as a dividend by reason of section 1248 or section 964(e).

(21) *U.S. gross income.* The term *U.S. gross income* means the items of gross income that a taxpayer recognizes and includes in taxable income under Federal income tax law for its U.S. taxable year.

(22) *U.S. loss.* The term *U.S. loss* means the item of loss that a taxpayer recognizes and includes in taxable income under Federal income tax law for its U.S. taxable year.

(23) *U.S. return of capital amount.* The term *U.S. return of capital amount* means, in the case of the sale or exchange of stock, the adjusted basis of the stock, and in the case of a distribution with respect to stock, the portion of a distribution to which section 301(c)(2) applies.

(24) *U.S. taxable year.* The term *U.S. taxable year* has the same meaning as that of the term *taxable year* set forth in section 7701(a)(23).

(c) *General rule.* A foreign income tax is allocated and apportioned to the statutory and residual groupings that include the items of foreign gross income included in the base on which the tax is imposed. Each foreign income tax (that is, each separate levy) is allocated and apportioned separately under the rules in this section. A foreign income tax is allocated and apportioned to or among the statutory and residual groupings under the following steps:

(1) First, by assigning the items of foreign gross income to the groupings under the rules of paragraph (d) of this section;

(2) Second, by allocating and apportioning the deductions that are allowed under foreign law to the foreign gross income in the groupings under the rules of paragraph (e) of this section; and

(3) Third, by allocating and apportioning the foreign income tax by reference to the foreign taxable income in the groupings under the rules of paragraph (f) of this section.

(d) *Assigning items of foreign gross income to the statutory and residual groupings*—(1) *In general.* Each item of foreign gross income is assigned to a statutory or residual grouping. The amount of the item is determined under foreign law. However, Federal income tax law applies to characterize the item and the transaction or other realization event from which the item arose, and to assign it to a grouping. Except as provided in paragraph (d)(3) of this section, if a taxpayer pays or accrues a foreign income tax that is imposed on foreign taxable income that includes an item of foreign gross income with respect to which the taxpayer also realizes, recognizes, or takes into account a corresponding U.S. item, then the item of foreign gross income is assigned to the grouping to which the corresponding U.S. item is assigned. See paragraph (g)(2) of this section (*Example 1*). If the corresponding U.S. item is a U.S. loss (or zero), the foreign gross income is assigned to the grouping to which a gain would be assigned had the transaction or other realization event given rise to a gain, rather than a U.S. loss (or zero), for Federal income tax

purposes, and not (if different) to the grouping to which the U.S. loss is allocated and apportioned in computing U.S. taxable income. Paragraph (d)(3) of this section provides special rules regarding the assignment of the item of foreign gross income in particular circumstances.

(2) *Items of foreign gross income with no corresponding U.S. item*—(i) *In general.* The rules in paragraphs (d)(2)(ii) and (iii) of this section apply for purposes of characterizing an item of foreign gross income and assigning it to a grouping if the taxpayer does not realize, recognize, or take into account a corresponding U.S. item. But see paragraphs (d)(3)(i)(C) and (d)(3)(iii) of this section for special rules with respect to items of foreign gross income attributable to foreign law pass-through income and foreign law inclusion regime income.

(ii) *Foreign gross income from U.S. nonrecognition event, or U.S. recognition event that falls in a different U.S. taxable year*—(A) *In general.* If a taxpayer recognizes an item of foreign gross income arising from a transaction or other foreign realization event that does not result in the recognition of gross income or loss under Federal income tax law in the same U.S. taxable year in which the foreign income tax is paid or accrued or (in the circumstance described in the last sentence of paragraph (b)(2) of this section) in the immediately preceding U.S. taxable year, then the item of foreign gross income is characterized and assigned to the grouping to which the corresponding U.S. item (or the items described in paragraph (d)(3) of this section that are used to assign certain items of foreign gross income to the statutory and residual groupings) would be assigned if the event giving rise to the foreign gross income resulted in the recognition of gross income or loss under Federal income tax law in the U.S. taxable year in which the foreign income tax is paid or accrued.

(B) *Foreign law distributions.* An item of foreign gross income that a taxpayer includes as a result of a foreign law distribution with respect to either stock or a partnership interest is assigned to the same statutory or residual groupings to which the foreign gross income would be assigned if a distribution of property in the amount of the taxable distribution under foreign law were made for Federal income tax purposes on the date on which the foreign law distribution occurred. See paragraph (g)(6) of this section (*Example 5*). See paragraph (d)(3)(i)(B) of this section for rules regarding the assignment of foreign gross income arising from a distribution with respect to stock. For purposes of applying paragraph (d)(3)(i)(B) of this section to a foreign law distribution, the U.S. dividend amount, U.S. capital gain amount, and U.S. return of capital amount are computed as if the distribution occurred on the date the distribution occurs for foreign law purposes. See § 1.960–1(d)(3)(ii) for rules for assigning foreign gross income arising from a foreign law distribution to income groups or PTEP groups for purposes of section 960 as the operative section.

(C) *Foreign law dispositions.* A foreign gross income item of gain that a taxpayer includes as a result of a foreign law disposition of property is assigned to the grouping to which a corresponding U.S. item of gain or loss would be assigned on a taxable disposition of the property under Federal income tax law in exchange for an amount equal to the gross receipts or other value used under foreign law to determine the amount of the items of foreign gross income arising from the foreign law disposition in the U.S. taxable year in which the taxpayer paid or accrued the foreign income tax. For example, an item of foreign gross income that results from a deemed disposition of stock under a foreign law mark-to-market regime is assigned under the rules of this paragraph (d)(2)(ii)(C) as though a taxable disposition of the stock occurred under Federal income tax law for an amount equal to the fair market value determined under foreign law for purposes of marking the stock to market. See paragraph (g)(3) of this section (*Example 2*).

(iii) *Foreign gross income of a type that is recognized but excluded from U.S. gross income*—(A) *In general.* If a taxpayer recognizes an item of foreign gross income that is a type of recognized gross income that Federal income tax law excludes from U.S. gross income, then the item of foreign gross income is assigned to the grouping to which the item of gross income would be assigned if it were included in U.S. gross income. See paragraph (g)(4) of this section (*Example 3*). Notwithstanding the first sentence of this paragraph (d)(2)(iii)(A), foreign gross income that is attributable to a base difference is assigned under paragraph (d)(2)(iii)(B) of this section.

(B) *Base differences.* If a taxpayer recognizes an item of foreign gross income that is attributable to a base difference, then the item of foreign gross income is assigned to the residual grouping. But see § 1.904–6(b)(1) (assigning foreign gross income attributable to a base difference to foreign source income in the separate category described in section 904(d)(2)(H)(i)) for purposes of applying section 904 as the operative section). An item of foreign gross income is attributable to a base difference under this paragraph (d)(2)(iii)(B) only if the item results from the receipt of one of the following items:

(*1*) Death benefits described in section 101;

(*2*) Gifts and inheritances described in section 102;

(*3*) Contributions to capital described in section 118;

(*4*) Money or other property in exchange for stock described in section 1032 (including by reason of a transfer described in section 351(a)); or

(*5*) Money or other property in exchange for a partnership interest described in section 721.

(3) *Special rules for assigning certain items of foreign gross income to a statutory or residual grouping*—(i) *Items of foreign gross income that a taxpayer includes by reason of its ownership of an interest in a corporation*—(A) *Scope.* The rules of this paragraph (d)(3)(i) apply to characterize and assign to a statutory or residual grouping an item of foreign gross income that a taxpayer includes in foreign taxable income as a result of its ownership of an interest in a corporation with respect to which there is a distribution under both foreign and Federal income tax law or an inclusion of foreign law pass-through income.

(B) *Foreign gross income items arising from a distribution with respect to a corporation*—(*1*) *In general.* If there is a distribution by a corporation that is treated as a distribution of property for both foreign law and Federal income tax purposes, a taxpayer first applies the rules of paragraph (d)(3)(i)(B)(*2*) of this section, and then (if necessary) applies the rules of paragraph (d)(3)(i)(B)(*3*) of this section to characterize and assign to the statutory and residual groupings the items of foreign gross income that constitute the foreign dividend amount and the foreign capital gain amount, if any, that arise from the distribution. See paragraph (g)(5) of this section (*Example 4*). For purposes of this paragraph (d)(3)(i)(B), the U.S. dividend amount, U.S. capital gain amount, and U.S. return of capital amount that result from a distribution (including a distribution that occurs on the same date, but in different taxable years, for foreign law purposes and Federal income tax purposes) are computed on the date the distribution occurred for Federal income tax purposes. See paragraph (d)(2)(ii)(B) of this section for rules for assigning foreign gross income arising from any portion of a distribution that

is a foreign law distribution. See § 1.960–1(d)(3)(ii) for rules for assigning foreign gross income arising from a distribution described in this paragraph (d)(3)(i)(B) to income groups or PTEP groups for purposes of section 960 as the operative section.

(*2*) *Foreign dividend amounts.* The foreign dividend amount is, to the extent of the U.S. dividend amount, assigned to the same statutory and residual grouping (or ratably to the groupings) from which a distribution of the U.S. dividend amount is made under Federal income tax law. If the foreign dividend amount exceeds the U.S. dividend amount, the excess foreign dividend amount is an item of foreign gross income that is, to the extent of the U.S. return of capital amount, assigned to the same statutory and residual grouping (or ratably to the groupings) to which earnings equal to the U.S. return of capital amount would be assigned if they were recognized for Federal income tax purposes in the U.S. taxable year in which the distribution is made. These earnings are deemed to arise in the statutory and residual groupings in the same proportions as the proportions in which the tax book value of the stock of the distributing corporation is (or would be if the taxpayer were a United States person) assigned to the groupings under the asset method in § 1.861–9 in the U.S. taxable year in which the distribution is made. Any additional excess of the foreign dividend amount over the sum of the U.S. dividend amount and the U.S. return of capital amount is an item of foreign gross income that is assigned to the statutory or residual grouping (or ratably to the groupings) to which the U.S. capital gain amount is assigned.

(*3*) *Foreign capital gain amounts.* The foreign capital gain amount is, to the extent of the U.S. capital gain amount, assigned to the statutory and residual groupings to which the U.S. capital gain amount is assigned under Federal income tax law. If the foreign capital gain amount exceeds the U.S. capital gain amount, the excess is, to the extent of the U.S. return of capital amount, assigned to the statutory and residual groupings to which earnings equal to the U.S. return of capital amount would be assigned if they were recognized in the U.S. taxable year in which the distribution is made. These earnings are deemed to arise in the statutory and residual groupings in the same proportions as the proportions in which the tax book value of the stock of the distributing corporation is (or would be if the taxpayer were a United States person) assigned under the asset method in § 1.861–9 in the U.S. taxable year in which the distribution is made. Any excess of the foreign capital gain amount over the sum of the U.S. capital gain amount and the U.S. return of capital amount is assigned ratably to the statutory and residual groupings to which the U.S. dividend amount is assigned.

(C) *Foreign law pass-through income from a reverse hybrid.* An item of foreign law pass-through income that a taxpayer includes in its foreign taxable income as a result of its direct or indirect ownership of a reverse hybrid is assigned to a statutory or residual grouping by treating the taxpayer's items of foreign law pass-through income as the foreign gross income of the reverse hybrid, and applying the rules in this paragraph (d) by treating the reverse hybrid as the taxpayer in the reverse hybrid's U.S. taxable year with or within which its foreign taxable year (under the law of the foreign jurisdiction imposing the owner-level tax) ends. See § 1.904–6(f) for special rules that apply for purposes of section 904 with respect to items of foreign gross income that under this paragraph (d)(3)(iii) would be assigned to a separate category that includes income that gives rise to inclusions under section 951A.

(ii) [Reserved]

(iii) *Foreign law inclusion regime income.* A gross item of foreign law inclusion regime income that a taxpayer includes in its capacity as a shareholder under foreign law of a foreign law CFC under a foreign law inclusion regime is assigned to the same statutory and residual groupings as the item of foreign gross income of the foreign law CFC that gives rise to the item of foreign law inclusion regime income of the taxpayer. The assignment is made by treating the gross items of foreign law inclusion regime income of the taxpayer as the items of foreign gross income of the foreign law CFC and applying the rules in this paragraph (d) by treating the foreign law CFC as the taxpayer in its U.S. taxable year with or within which its foreign taxable year (under the law of the foreign jurisdiction imposing the shareholder-level tax) ends. See paragraphs (g)(7) and (8) of this section (*Examples 6* and *7*). See § 1.904–6(f) for special rules with respect to items of foreign gross income relating to items of the foreign law CFC that give rise to inclusions under section 951A for purposes of applying section 904 as the operative section.

(iv) *Gain on sale of disregarded entity.* An item of foreign gross income arising from gain recognized on the sale, exchange, or other disposition of a disregarded entity that is characterized as a disposition of assets for Federal income tax purposes is assigned to statutory and residual groupings in the same proportion as the gain that would be treated as foreign gross income in each grouping if the transaction were treated as a disposition of assets for foreign tax law purposes. See paragraph (g)(9) of this section (*Example 8*).

(e) *Allocating and apportioning deductions (allowed under foreign law) to foreign gross income in a grouping*—(1) *Application of foreign law expense allocation rules.* In order to determine foreign taxable income in each statutory grouping, or the residual grouping, foreign gross income in each grouping is reduced by deducting any expenses, losses, or other amounts that are deductible under foreign law that are specifically allocable to the items of foreign gross income in the grouping under the laws of that foreign country. If expenses are not specifically allocated under foreign law, then the expenses are allocated and apportioned among the groupings under the principles of foreign law. Thus, for example, if foreign law provides that expenses will be apportioned on a gross income basis, the foreign law deductions are apportioned on the basis of the relative amounts of foreign gross income assigned to each grouping.

(2) *Application of U.S. expense allocation rules in the absence of foreign law rules.* If foreign law does not provide rules for the allocation or apportionment of expenses, losses or other deductions to particular items of foreign gross income, then the principles of the section 861 regulations (as defined in § 1.861–8(a)(1)) apply in allocating and apportioning such expenses, losses, or other deductions to foreign gross income. For example, in the absence of foreign law expense allocation rules, the principles of the section 861 regulations apply to allocate definitely related expenses to particular categories of foreign gross income and provide the methods for apportioning foreign law expenses that are definitely related to more than one statutory grouping or that are not definitely related to any statutory grouping. For purposes of this paragraph (e)(2), the apportionment of expenses required to be made under the principles of the section 861 regulations need not be made on other than a separate company basis. If the taxpayer applies the principles of the section 861 regulations for purposes of allocating foreign law deductions under this paragraph (e), the taxpayer must apply the principles in the same manner as the taxpayer applies such principles in determining the income or earnings and profits for

Federal income tax purposes of the taxpayer (or of the foreign branch, controlled foreign corporation, or other entity that paid or accrued the foreign taxes, as the case may be). For example, a taxpayer must use the modified gross income method under § 1.861–9T when applying the principles of that section for purposes of this paragraph (e) to determine the amount of foreign taxable income in each grouping if the taxpayer applies the modified gross income method in determining the income and earnings and profits of a controlled foreign corporation for Federal income tax purposes.

(f) *Allocation and apportionment of foreign income tax.* Foreign income tax is allocated to the statutory or residual grouping or groupings to which the items of foreign gross income are assigned under the rules of paragraph (d) of this section. If foreign gross income is assigned to more than one grouping, then the foreign income tax is apportioned among the statutory and residual groupings by multiplying the foreign income tax by a fraction, the numerator of which is the foreign taxable income in a grouping and the denominator of which is all foreign taxable income on which the foreign income tax is imposed. If foreign law, including by reason of an income tax convention, exempts certain types of income from tax, or if foreign taxable income is reduced to or below zero by foreign law deductions, then no foreign income tax is allocated and apportioned to that income. A withholding tax (as defined in section 901(k)(1)(B)) is allocated and apportioned to the foreign gross income from which it is withheld. If foreign law, including by reason of an income tax convention, provides for a specific rate of tax with respect to certain types of income (for example, capital gains), or allows credits only against tax on particular items or types of income (for example, credit for foreign withholding taxes), then such provisions are taken into account in determining the amount of foreign tax imposed on such foreign taxable income.

(g) *Examples.* The following examples illustrate the application of this section and § 1.904–6.

(1) *Presumed facts.* Except as otherwise provided in this paragraph (g), the following facts are assumed for purposes of the examples in paragraphs (g)(2) through (9) of this section:

(i) USP and US2 are domestic corporations, which are unrelated;

(ii) USP elects to claim a foreign tax credit under section 901;

(iii) CFC, CFC1, and CFC2 are controlled foreign corporations organized in Country A, and are not reverse hybrids;

(iv) All parties have a U.S. dollar functional currency and a U.S. taxable year and foreign taxable year that correspond to the calendar year;

(v) No party has expenses for Country A tax purposes or expenses for U.S. tax purposes (other than foreign income tax expense); and

(vi) Section 904 is the operative section, and terms have the meaning provided in this section or §§ 1.904–4 and 1.904–5.

(2) *Example 1: Corresponding U.S. item*—(i) *Facts.* USP conducts business in Country A that gives rise to a foreign branch (as defined in § 1.904–4(f)(3)). In Year 1, in a transaction that is a sale for purposes of the laws of Country A and Federal income tax law, the foreign branch transfers Asset X to US2 for $1,000x. For Country A tax purposes, USP earns $600x of gross income from the sale of Asset X and incurs foreign income tax of $80x. For Federal income tax purposes, USP earns $800x of foreign branch category income from the sale of Asset X.

(ii) *Analysis.* For purposes of allocating and apportioning the $80x of Country A foreign income tax, the $600x of Country A gross income from the sale of Asset X is first assigned to separate categories. The $800x of foreign branch category income from the sale of Asset X is the corresponding U.S. item to the Country A item of gross income. Under paragraph (d)(1) of this section, because USP recognizes a corresponding U.S. item with respect to the Country A item of gross income in the same U.S. taxable year, the $600x of Country A gross income is assigned to the same separate category as the corresponding U.S. item. This is the case even though the amount of gross income recognized for Federal income tax purposes differs from the amount recognized for Country A tax purposes. Accordingly, the $600x of Country A gross income is assigned to the foreign branch category. Additionally, because all of the Country A taxable income is assigned to a single separate category, the $80x of Country A tax is also allocated to the foreign branch category. No apportionment of the $80x is necessary because the class of gross income to which the tax is allocated consists entirely of a single statutory grouping, foreign branch category income.

(3) *Example 2: Foreign law disposition*—(i) *Facts.* USP owns all of the outstanding stock of CFC, which conducts business in Country A. CFC sells Asset X for $1,000x. For Country A tax purposes, CFC's basis in Asset X is $600x, the sale of Asset X occurs in Year 1, and CFC recognizes $400x of foreign gross income and incurs $80x of foreign income tax. For Federal income tax purposes, CFC's basis in Asset X is $500x, the sale of Asset X occurs in Year 2, and CFC recognizes $500x of general category income.

(ii) *Analysis.* For purposes of allocating and apportioning the $80x of Country A foreign income tax in Year 1, the $400x of Country A gross income from the sale of Asset X is first assigned to separate categories. There is no corresponding U.S. item because the sale occurs on a different date and in a different U.S. taxable year for U.S. and foreign tax purposes. Under paragraph (d)(2)(ii)(C) of this section, the item of foreign gross income (the $400x from the sale of Asset X) is characterized and assigned to the groupings to which the corresponding U.S. item would be assigned if for Federal income tax purposes Asset X were sold for $1,000x in Year 1, the same U.S. taxable year in which the foreign income tax accrued. This is the case even though the amount of gross income that would be recognized for Federal income tax purposes differs from the amount recognized for Country A tax purposes. Accordingly, the $400x of Country A gross income is assigned to the general category. Additionally, because all of the Country A taxable income is assigned to a single separate category, the $80x of Country A tax is also allocated to the general category. No apportionment of the $80x is necessary because the class of gross income to which the deduction is allocated consists entirely of a single statutory grouping, general category income.

(4) *Example 3: Foreign gross income excluded from U.S. gross income*—(i) *Facts.* USP conducts business in Country A. In Year 1, USP earns $200x of interest income on a State or local bond. For Country A tax purposes, the $200x of income is included in gross income and incurs $10x of foreign income tax. For Federal income tax purposes, the $200x is excluded from gross income under section 103.

(ii) *Analysis.* For purposes of allocating and apportioning the $10x of Country A foreign income tax, the $200x of Country A gross income is first assigned to separate categories. There is no corresponding U.S. item because the interest income is excluded from U.S. gross income. Thus, the rules of paragraph (d)(2) of this section apply to characterize and assign the foreign gross income to the groupings to which a corresponding U.S. item would be assigned if it were recognized under Federal income tax law in that U.S. taxable year. The interest income is

excluded from U.S. gross income but is otherwise described or identified by section 103. Accordingly, under paragraph (d)(2)(iii)(A) of this section, the $200x of Country A gross income is assigned to the separate category to which the interest income would be assigned under Federal income tax law if the income were included in gross income. Under section 904(d)(2)(B)(i), the interest income would be passive category income. Accordingly, the $200x of Country A gross income is assigned to the passive category. Additionally, because all of the Country A taxable income is assigned to a single separate category, the $10x of Country A tax is also allocated to the passive category (subject to the rules in § 1.904–4(c)). No apportionment of the $10x is necessary because the class of gross income to which the deduction is allocated consists entirely of a single statutory grouping, passive category income.

(5) *Example 4: Actual distribution*—(1) *Facts.* USP owns all of the outstanding stock of CFC1, which in turn owns all of the outstanding stock of CFC2. CFC1 and CFC2 conduct business in Country A. In Year 1, CFC2 distributes $300x to CFC1. For Country A tax purposes, $100x of the distribution is the foreign dividend amount, $160x is treated as a nontaxable return of capital, and the remaining $40x is the foreign capital gain amount. CFC1 incurs $20x of foreign income tax with respect to the foreign dividend amount and $4x of foreign income tax with respect to the foreign capital gain amount. The $20x and $4x of foreign income tax are each a separate levy within the meaning of § 1.901–2(d). For Federal income tax purposes, $150x of the distribution is the U.S. dividend amount, $100x is the U.S. return of capital amount, and the remaining $50x is the U.S. capital gain amount. Under section 904(d)(3)(D) and §§ 1.904–4(d) and 1.904–5(c)(4), the $150x of U.S. dividend amount consists solely of general category income in the hands of CFC1. Under section 904(d)(2)(B)(i) and § 1.904–4(b)(2)(i)(A), the $50x of U.S. capital gain amount is passive category income to CFC1.

(ii) *Analysis*—(A) *In general.* Because the $20x of Country A foreign income tax and the $4x of Country A foreign income tax are separate levies, the taxes are allocated and apportioned separately. For purposes of allocating and apportioning each foreign income tax, the relevant item of Country A gross income (the foreign dividend amount or foreign capital gain amount) is first assigned to separate categories. The U.S. dividend amount and U.S. capital gain amount are corresponding U.S. items. However, paragraph (d)(3)(i)(B) of this section (and not paragraph (d)(1) of this section) applies to assign the items of foreign gross income arising from the distribution.

(B) *Foreign dividend amount.* Under paragraph (d)(3)(i)(B)(*2*) of this section, the foreign dividend amount ($100x) is, to the extent of the U.S. dividend amount ($150x), assigned to the same separate category from which the distribution of the U.S. dividend amount is made under Federal income tax law. Thus, $100x of foreign gross income that is the foreign dividend amount is assigned to the general category. Additionally, because all of the Country A taxable income included in the base on which the $20x of foreign income tax is imposed is assigned to a single separate category, the $20x of Country A tax on the foreign dividend amount is also allocated to the general category. No apportionment of the $20x is necessary because the class of gross income to which the deduction for foreign income tax is allocated consists entirely of a single statutory grouping, general category income. See also section 245A(d) for rules that may apply to disallow a credit or deduction for certain foreign taxes.

(C) *Foreign capital gain amount.* Under paragraph (d)(3)(i)(B)(*3*) of this section, the foreign capital gain amount ($40x) is, to the extent of the U.S. capital gain amount ($50x), assigned to the same separate category to which the U.S. capital gain is assigned under Federal income tax law. Thus, the $40x of foreign gross income that is the foreign capital gain amount is assigned to the passive category. Additionally, because all of the Country A taxable income in the base on which the $4x of foreign income tax is imposed is assigned to a single separate category, the $4x of Country A tax on the foreign dividend amount is also allocated to the passive category. No apportionment of the $4x is necessary because the class of gross income to which the deduction is allocated consists entirely of a single statutory grouping, passive category income.

(6) *Example 5: Foreign law distribution*—(i) *Facts.* USP owns all of the outstanding stock of CFC. In Year 1, for Country A tax purposes, CFC distributes $1,000x of its stock that is treated entirely as a dividend to USP, and Country A imposes a withholding tax on USP of $150x with respect to the $1,000x of foreign gross income. For Federal income tax purposes, the distribution is treated as a stock dividend described in section 305(a) and USP recognizes no U.S. gross income. At the time of the distribution, CFC has $800x of section 965(a) PTEP (as defined in § 1.960–3(c)(2)(vi)) in a single annual PTEP account (as defined in § 1.960–3(c)(1)), and $500x of earnings and profits described in section 959(c)(3). Section 965(g) is the operative section for purposes of this paragraph (g)(6). See § 1.965–5(b)(2). Section 904 is also a relevant operative section, but is not addressed in this paragraph (g)(6).

(ii) *Analysis.* For purposes of allocating and apportioning the $150x of Country A foreign income tax, the $1,000x of Country A gross income is first assigned to the relevant statutory and residual groupings for purposes of applying section 965(g) as the operative section. Under § 1.965–5(b)(2), the statutory grouping is the portion of the distribution that is attributable to section 965(a) previously taxed earnings and profits and the residual grouping is the portion of the distribution attributable to other earnings and profits. There is no corresponding U.S. item because under section 305(a) USP recognizes no U.S. gross income with respect to the distribution. Under paragraph (d)(2)(ii)(B) of this section, the item of foreign gross income (the $1,000x distribution) is assigned under the rules of paragraph (d)(3)(i)(B) of this section to the same statutory or residual groupings to which the foreign gross income would be assigned if a distribution of the same amount were made for Federal income tax purposes in Year 1 on the date the distribution occurs for foreign law purposes. If recognized for Federal income tax purposes, a $1,000x distribution in Year 1 would result in a U.S. dividend amount of $1,000x. Under paragraph (d)(3)(i)(B)(*2*) of this section, the foreign dividend amount ($1,000x) is, to the extent of the U.S. dividend amount ($1,000x), assigned to the same statutory or residual groupings from which a distribution of the U.S. dividend amount would be made under Federal income tax law. Thus, $800x of foreign gross income related to the foreign dividend amount is assigned to the statutory grouping for the portion of the distribution attributable to section 965(a) previously taxed earnings and profits and $200x of foreign gross income is assigned to the residual grouping. Under paragraph (f) of this section, $120x ($150x × $800x/$1,000x) of the Country A foreign income tax is apportioned to the statutory grouping and $30x ($150x × $200x/$1,000x) of the Country A foreign income tax is apportioned to the residual grouping. See section 965(g)(2) and § 1.965–5(b) for application of the applicable

percentage (as defined in § 1.965–5(d)) to the foreign income tax allocated and apportioned to the statutory grouping.

(7) *Example 6: Foreign law inclusion regime, CFC shareholder*—(i) *Facts.* USP owns all of the outstanding stock of CFC1, which in turn owns all of the outstanding stock of CFC2. CFC2 is organized and conducts business in Country B. Country A has a foreign law inclusion regime that imposes a tax on CFC1 for certain earnings of CFC2, a foreign law CFC. In Year 1, CFC2 earns $400x of interest income and $200x of royalty income. CFC2 incurs no foreign income tax. For Country A tax purposes, the $400x of interest income and $200x of royalty income are each an item of foreign law inclusion regime income of CFC2 that are included in the gross income of CFC1. CFC1 incurs $150x of Country A foreign income tax with respect to the foreign law inclusion regime income. For Federal income tax purposes, with respect to CFC2, the $400x of interest income is passive category income under section 904(d)(2)(B)(i) and the $200x of royalty income is general category income under § 1.904–4(b)(2)(iii).

(ii) *Analysis.* For purposes of allocating and apportioning CFC1's $150x of Country A foreign income tax, the $600x of Country A gross income is first assigned to separate categories. The $600x of foreign gross income is not included in the U.S. gross income of CFC1, and thus, there is no corresponding U.S. item. Under paragraph (d)(3)(iii) of this section, each item of foreign law inclusion regime income that is included in CFC1's foreign gross income is assigned to the same separate category as the items of foreign gross income of CFC2 that give rise to the foreign law inclusion regime income of CFC1. With respect to CFC2, the $400x of interest income and the $200x of royalty income would be corresponding U.S. items if CFC2 were the taxpayer. Accordingly, $400x of CFC1's foreign gross income is assigned to the passive category and $200x of CFC1's foreign gross income is assigned to the general category. Under paragraph (f) of this section, $100x ($150x × $400x/$600x) of the Country A foreign income tax is apportioned to the passive category and $50x ($150x × $200x/$600x) of the Country A foreign income tax is apportioned to the general category.

(8) *Example 7: Foreign law inclusion regime, U.S. shareholder*—(i) *Facts.* The facts are the same as in paragraph (g)(7)(i) of this section (the facts in *Example 6*), except that both CFC1 and CFC2 are organized and conduct business in Country B, all of the outstanding stock of CFC1 is owned by Individual X, a U.S. citizen resident in Country A, and Country A imposes tax of $150x on foreign gross income of $600x under its foreign law inclusion regime on Individual X, rather than on CFC1. For Federal income tax purposes, in the hands of CFC2, the $400x of interest income is passive category subpart F income and the $200x of royalty income is general category tested income (as defined in § 1.951A–2(b)(1)). CFC2's $400x of interest income gives rise to a passive category subpart F inclusion under section 951(a)(1)(A), and its $200x of tested income gives rise to a GILTI inclusion amount (as defined in § 1.951A–1(c)(1)) of $200x, with respect to Individual X.

(ii) *Analysis.* The analysis is the same as in paragraph (g)(7)(ii) of this section (the analysis in *Example 6*) except that under § 1.904–6(f), because $50x of the Country A foreign income tax is allocated and apportioned under paragraph (d)(3)(iii) of this section to CFC2's general category tested income group to which Individual X's inclusion under section 951A is attributable, the $50x of Country A foreign income tax is allocated and apportioned in the hands of Individual X to the section 951A category.

(9) *Example 8: Sale of disregarded entity*—(i) *Facts.* USP sells FDE, a disregarded entity that is organized and operates a trade or business in Country A, for $500x. FDE owns Asset X and Asset Y in Country A, each having a fair market value of $250x. For Country A tax purposes, FDE has a basis in Asset X of $100x and a basis in Asset Y of $200x, USP's basis in FDE is $100x, and the sale is treated as a sale of stock. Country A imposes foreign income tax of $40x on USP on the Country A gross income of $400x resulting from the sale of FDE, based on its rules for taxing capital gains of nonresidents selling stock of companies operating a trade or business in Country A. For Federal income tax purposes, USP has a basis of $150x in each of Assets X and Y, and so the sale of FDE results in $100x of passive category income with respect to the sale of Asset X and $100x of general category income with respect to the sale of Asset Y.

(ii) *Analysis.* For purposes of allocating and apportioning USP's $40x of Country A foreign income tax, the $400x of Country A gross income resulting from the sale of FDE is first assigned to separate categories. Under paragraph (d)(3)(iv) of this section, USP's $400x of Country A gross income is assigned among the statutory groupings in the same percentages as the foreign gross income in each grouping that would have resulted if the sale of FDE were treated as an asset sale for Country A tax purposes. Because for Country A tax purposes Asset X had a built-in gain of $150x and Asset Y had a built-in gain of $50x, $300x ($400x × $150x/$200x) of the Country A gross income is assigned to the passive category and $100x ($400x × $50x/$200x) is assigned to the general category. Under paragraph (f) of this section, $30x ($40x × $300x/$400x) of the Country A foreign income tax is apportioned to the passive category, and $10x ($40x × $100x/$400x) of the Country A foreign income tax is apportioned to the general category.

(h) [Reserved]

(i) *Applicability date.* This section applies to taxable years beginning after December 31, 2019.

■ **Par. 15.** Section 1.881–3 is amended by:

■ 1. Adding two sentences at the end of paragraph (a)(1).

■ 2. Revising paragraph (a)(2)(i)(C).

■ 3. In paragraph (a)(2)(ii)(B)(*1*) introductory text, removing ''one of the following'' and adding ''one or more of the following'' in its place.

■ 4. In paragraph (a)(2)(ii)(B)(*1*)(*ii*), removing the word ''or'' at the end of the paragraph.

■ 5. In paragraph (a)(2)(ii)(B)(*1*)(*iii*), removing the period at the end and adding ''; or'' in its place.

■ 6. Adding paragraph (a)(2)(ii)(B)(*1*)(*iv*) and reserved paragraph (a)(2)(ii)(B)(*1*)(*v*).

■ 7. In paragraph (c)(2)(ii), adding ''(as in effect for taxable years beginning before January 1, 2018)'' at the end of the last sentence.

■ 8. Adding reserved paragraph (d)(1)(iii).

■ 9. Adding a sentence at the end of paragraph (e) introductory text.

■ 10. In paragraph (e), designating Examples 1 through 26 as paragraphs (e)(1) through (26), respectively.

■ 11. Redesignating newly designated paragraphs (e)(4) through (26) as paragraphs (e)(5) through (27), respectively.

■ 12. Adding new paragraph (e)(4).

■ 13. For each paragraph listed in the table, remove the language in the ''Remove'' column and add in its place the language in the ''Add'' column:

Paragraph	Remove	Add
(a)(2)(i)(A)	*Examples 1, 2, 3* and *4* of paragraph (e) of this section	paragraphs (e)(1) through (5) of this section (*Examples 1* through *5*).
(a)(2)(i)(B)	*Examples 5* and *6* of paragraph (e) of this section	paragraphs (e)(6) and (7) of this section (*Examples 6* and *7*).
(a)(3)(ii)(E)(*2*)(*ii*)	*Example 7* of paragraph (e) of this section	paragraph (e)(8) of this section (*Example 8*).
(a)(4)(ii)(B)	*Examples 8* and *9* of paragraph (e) of this section	paragraphs (e)(9) and (10) of this section (*Examples 9* and *10*).
(b)(1)	*Examples 12* and *13* of paragraph (e) of this section	paragraphs (e)(13) and (14) of this section (*Examples 13* and *14*).
(b)(2)(i)	*Examples 14, 15* and *16* of paragraph (e) of this section	paragraphs (e)(15) through (17) of this section (*Examples 15* through *17*).
(b)(2)(iii)	*Example 17* of paragraph (e) of this section	paragraph (e)(18) of this section (*Example 18*).
(b)(2)(iv)	*Example 18* of paragraph (e) of this section	paragraph (e)(19) of this section (*Example 19*).
(b)(3)(i)	*Examples 22, 23* and *24* of paragraph (e) of this section	paragraphs (e)(23) through (25) of this section (*Examples 23* through *25*).
(d)(1)(i)	*Example 25* of paragraph (e) of this section	paragraph (e)(26) of this section (*Example 26*).
(d)(1)(ii)(A)	*Example 26* of paragraph (e)	paragraph (e)(27) of this section (*Example 27*).
newly designated paragraph (e)(3).	*Example 2*	paragraph (e)(2) of this section (the facts in *Example 2*).
newly designated paragraph (e)(3).	§ 301.7701–3	§ 301.7701–3 of this chapter.
newly designated paragraph (e)(8)(ii).	(a)(4)(i)	(a)(4)(i) of this section.
newly designated paragraph (e)(22)(i).	*Example 20*	paragraph (e)(21) of this section (the facts in *Example 21*).
newly designated paragraph (e)(22)(ii).	*Example 19*	paragraph (e)(20) of this section (*Example 20*).
newly designated paragraph (e)(22)(ii).	paragraph (i) of this *Example 21*	paragraph (e)(22)(i) of this section (this *Example 22*).
newly designated paragraph (e)(24)(i).	Example 22	paragraph (e)(23) of this section (the facts in *Example 23*).
newly designated paragraph (e)(25)(i).	*Example 22*	paragraph (e)(23) of this section (the facts in *Example 23*).
(f)	Paragraph (a)(2)(i)(C) and *Example 3* of paragraph (e) of this section.	Paragraphs (a)(2)(i)(C) and (e)(3) (*Example 3*) of this section.

■ 14. In paragraph (f), revising the heading and adding a sentence at the end of the paragraph.

The additions and revisions read as follows:

§ 1.881–3 Conduit financing arrangements.

(a) * * *

(1) * * * See § 1.1471–3(e)(5) for withholding rules applicable to conduit financing arrangements for purposes of sections 1471 and 1472. See also §§ 1.267A–1 and 1.267A–4 (disallowing a deduction for certain interest or royalty payments to the extent the income attributable to the payment is offset by a hybrid deduction).

(2) * * *

(i) * * *

(C) *Treatment of disregarded entities.* For purposes of this section, the term *person* includes a business entity that is disregarded as an entity separate from its single member owner under §§ 301.7701–1 through 301.7701–3 of this chapter and, therefore, such entity may, for example, be treated as a party to a financing transaction with its owner. See paragraph (e)(3) of this section (*Example 3*).

(ii) * * *

(B) * * *

(*1*) * * *

(*iv*) The stock or similar interest is treated as debt under the tax law of the issuer's country of residence or, if the issuer is not a tax resident of any country, such as a partnership, the tax law of the country in which the issuer is created, organized, or otherwise established.

* * * * *

(e) * * * For purposes of the examples in this paragraph (e), unless otherwise indicated, it is assumed that no stock is of the type described in paragraph (a)(2)(ii)(B)(*1*)(*iv*) of this section.

* * * * *

(4) *Example 4. Hybrid instrument as financing arrangement.* The facts are the same as in paragraph (e)(2) of this section (the facts in *Example 2*), except that FP assigns the DS note to FS in exchange for stock issued by FS. The stock issued by FS is in form convertible debt with a 49-year term that is treated as debt under the tax law of Country T. The FS stock is not subject to any of the redemption, acquisition, or payment rights or requirements specified in paragraphs (a)(2)(ii)(B)(*1*)(*i*) through (*iii*) of this section. However, because the FS stock is treated as debt under the tax law of Country T, the FS stock is a financing transaction under paragraph (a)(2)(ii)(B)(*1*)(*iv*) of this section. Therefore, the DS note held by FS and the FS stock held by FP are financing transactions within the meaning of paragraphs (a)(2)(ii)(A)(*1*) and (*2*) of this section, respectively, and together constitute a financing arrangement within the meaning of paragraph (a)(2)(i) of this section. See also § 1.267A–4 for rules applicable to disqualified imported mismatch amounts.

* * * * *

(f) *Applicability date.* * * * Paragraph (a)(2)(ii)(B)(*1*)(*iv*) of this section applies to payments made on or after November 12, 2020.

■ **Par. 16.** Section 1.904–1 is amended by revising the section heading and paragraph (a) as follows:

§ 1.904–1 Limitation on credit for foreign income taxes.

(a) *In general.* For each separate category described in § 1.904–5(a)(4)(v), the total credit for foreign income taxes (as defined in § 1.901–2(a)) paid or accrued (including those deemed to have been paid or accrued other than by reason of section 904(c)) to any foreign country (as defined in § 1.901–2(g)) does not exceed that proportion of the tax against which such credit is taken which the taxpayer's taxable income from foreign sources (but not in excess of the taxpayer's entire taxable income) in such separate category bears to the taxpayer's entire taxable income for the same taxable year.

* * * * *

■ **Par. 17.** Section 1.904–4 is amended by:

■ 1. Revising paragraph (c)(7)(i), the third and fourth sentences of paragraph (c)(7)(ii), and paragraph (c)(7)(iii).

■ 2. Adding paragraphs (c)(8)(v) through (viii).

■ 3. In paragraph (o), removing the language ''§ 1.904–6(b)'' and adding the language ''1.904–6(e)'' in its place.

■ 4. Revising paragraph (q).

The revisions and additions read as follows:

§ 1.904–4 Separate application of section 904 with respect to certain categories of income.

* * * * *

(c) * * *

(7) * * *

(i) *In general.* If the effective rate of tax imposed by a foreign country on income of a foreign corporation that is included in a taxpayer's gross income is reduced under foreign law on distribution of such income, the rules of this paragraph (c) apply at the time that the income is included in the taxpayer's gross income, without regard to the possibility of a subsequent reduction of foreign tax on the distribution. If the inclusion is considered to be high-taxed income, then the taxpayer must initially treat the inclusion as general category income, section 951A category income, or income in a specified separate category as provided in paragraph (c)(1) of this section. When the foreign corporation distributes the earnings and profits to which the inclusion was attributable and the foreign tax on the inclusion is reduced, then if a redetermination of U.S. tax liability is required under § 1.905–3(b)(2), the taxpayer must redetermine whether the revised inclusion (if any) is considered to be high-taxed income. See § 1.905–3(b)(2)(ii) (requiring a redetermination of the amount of the inclusion, the application of the high-tax exception under section 954(b)(4), and the amount of foreign taxes deemed paid). If, taking into account the reduction in foreign tax, the inclusion is not considered high-taxed income, then the taxpayer, in redetermining its U.S. tax liability for the year or years affected, must treat the inclusion and the associated taxes (as reduced on the distribution) as passive category income and taxes. For purposes of this paragraph (c), the foreign tax on an inclusion under section 951(a)(1) or 951A(a) is considered reduced on distribution of the earnings and profits associated with the inclusion if the total taxes paid and deemed paid on the inclusion and the distribution (taking into account any reductions in tax and any withholding taxes) is less than the total taxes deemed paid in the year of inclusion. Therefore, any foreign currency gain associated with the earnings and profits that are distributed with respect to the inclusion is not taken into account in determining whether there is a reduction of tax requiring a redetermination of whether the inclusion is high-taxed income.

(ii) * * * If, however, foreign law does not attribute a reduction in taxes to a particular year or years, then the reduction in taxes shall be attributable, on an annual last in-first out (LIFO) basis, to foreign taxes potentially subject to reduction that are associated with previously taxed income, then on a LIFO basis to foreign taxes associated with income that under paragraph (c)(7)(iii) of this section remains as passive income but that was excluded from subpart F income or tested income under section 954(b)(4) or section 951A(c)(2)(A)(i)(III), and finally on a LIFO basis to foreign taxes associated with other earnings and profits. Furthermore, in applying the ordering rules of section 959(c), distributions shall be considered made on a LIFO basis first out of earnings described in section 959(c)(1) and (2), then on a LIFO basis out of earnings and profits associated with income that remains passive income under paragraph (c)(7)(iii) of this section but that was excluded from subpart F income or tested income under section 954(b)(4) or section 951A(c)(2)(A)(i)(III), and finally on a LIFO basis out of other earnings and profits. * * *

(iii) *Treatment of income excluded under section 954(b)(4) or section 951A(c)(2)(A)(i)(III).* If the effective rate of tax imposed by a foreign country on income of a foreign corporation is reduced under foreign law on distribution of that income, the rules of section 954(b)(4) (including for purposes of determining tested income under section 951A(c)(2)(A)(i)(III)) are applied in the year of inclusion without regard to the possibility of a subsequent reduction of foreign tax. See §§ 1.954–1(d)(3)(iii) and 1.951A–2(c)(6)(iv). If a taxpayer excludes passive income from a controlled foreign corporation's foreign personal holding company income or tested income under section 954(b)(4) or section 951A(c)(2)(A)(i)(III), then, notwithstanding the general rule of § 1.904–5(d)(2), the income is considered to be passive category income until distribution of that income. At that time, if after the redetermination of U.S. tax liability required under § 1.905–3(b)(2) the taxpayer still elects to exclude the passive income under section 954(b)(4) or section 951A(c)(2)(A)(i)(III), the rules of this paragraph (c)(7)(iii) apply to determine whether the income is high-taxed income upon distribution and, therefore, income in another separate category. For purposes of determining whether a reduction in tax is attributable to taxes on income excluded under section 954(b)(4) or section 951A(c)(2)(A)(i)(III), the rules of paragraph (c)(7)(ii) of this section apply. The rules of paragraph (c)(7)(ii) of this section also apply for purposes of ordering distributions to determine whether such distributions are out of earnings and profits associated with such excluded income. For an example illustrating the operation of this paragraph (c)(7)(iii), see paragraph (c)(8)(vi) of this section (*Example 6*).

(8) * * *

(v) *Example 5.* CFC, a controlled foreign corporation, is a wholly-owned subsidiary of USP, a domestic corporation. USP and CFC are calendar year taxpayers. In Year 1, CFC's only earnings consist of $200x of pre-tax passive income that is foreign personal holding company income that is earned in foreign Country X. Under Country X's tax system, the corporate tax on particular earnings is reduced on distribution of those earnings and no withholding tax is imposed. In Year 1, CFC pays $100x of foreign tax with respect to its passive income. USP does not elect to exclude this income from subpart F under section 954(b)(4) and includes $200x in gross income ($100x of net foreign personal holding company income and $100x of the amount under section 78 (the ''section 78 dividend'')). At the time of the inclusion, the income is considered to be high-taxed income under paragraphs (c)(1) and (c)(6)(i) of this section and is general category income to USP ($100x > $42x (21% ×

$200x)). CFC does not distribute any of its earnings in Year 1. In Year 2, CFC has no additional earnings. On December 31, Year 2, CFC distributes the $100x of earnings from Year 1. At that time, CFC receives a $60x refund from Country X attributable to the reduction of the Country X corporate tax imposed on the Year 1 earnings. The refund is a foreign tax redetermination under § 1.905–3(a) that under §§ 1.905–3(b)(2) and 1.954–1(d)(3)(iii) requires a redetermination of CFC's Year 1 subpart F income and the application of section 954(b)(4), as well as a redetermination of USP's Year 1 inclusion under section 951(a)(1), its deemed paid taxes under section 960(a), and its Year 1 U.S. tax liability. As recomputed taking into account the $60x refund, CFC's Year 1 passive category net foreign personal holding company income is increased by $60x to $160x, CFC's foreign income taxes attributable to that income are reduced from $100x to $40x, and the income still qualifies to be excluded from CFC's subpart F income under section 954(b)(4) ($40x > $37.80x (90% × 21% × $200x)). Assuming USP does not change its Year 1 election, USP's Year 1 inclusion under section 951(a)(1) is increased by $60x to $160x, and the associated deemed paid tax and section 78 dividend are reduced by $60x to $40x. Under paragraph (c)(7)(i) of this section, in connection with the adjustments required under section 905(c), USP must redetermine whether the adjusted Year 1 inclusion is high-taxed income of USP. Taking into account the $60x refund, the inclusion is not considered high-taxed income of USP ($40x < $42x (21% × $200x)). Therefore, USP must treat the $200x of income ($160x inclusion plus $40x section 78 amount) and the $40x of taxes associated with the inclusion in Year 1 as passive category income and taxes. USP must also follow the appropriate procedures under § 1.905–4.

(vi) *Example 6.* The facts are the same as in paragraph (c)(8)(v) of this section (the facts in *Example 5*), except that in Year 1, USP elects to apply section 954(b)(4) to exclude CFC's passive income from its subpart F income, both before and after the recomputation of CFC's Year 1 subpart F income and USP's Year 1 U.S. tax liability that is required by reason of the Year 2 $60x foreign tax redetermination. Although the income is not considered to be subpart F income, under paragraph (c)(7)(iii) of this section it remains passive category income until distribution. In Year 2, the $100x distribution is a dividend to USP, because CFC has $160x of accumulated earnings and profits described in section 959(c)(3) (the $100x of earnings in Year 1 increased by the $60x refund received in Year 2 that under § 1.905–3(b)(2) is taken into account in Year 1). Under paragraph (c)(7)(iii) of this section, USP must determine whether the dividend income is high-taxed income to USP in Year 2. The treatment of the dividend as passive category income may be relevant in determining deductions allocable or apportioned to such dividend income or related stock that are excluded in the computation of USP's foreign tax credit limitation under section 904(a) in Year 2. See section 904(b)(4). Under paragraph (c)(1) of this section, the dividend income is passive category income to USP because the foreign taxes paid and deemed paid by USP ($0x) with respect to the dividend income do not exceed the highest U.S. tax rate on that income.

(vii) *Example 7.* The facts are the same as in paragraph (c)(8)(v) of this section (the facts in *Example 5*), except that the distribution in Year 2 is subject to a withholding tax of $25x. Under paragraph (c)(7)(i) of this section, USP must redetermine whether its Year 1 inclusion should be considered high-taxed income of USP because there is a net $35x reduction ($60x refund of foreign corporate tax—$25x withholding tax) of foreign tax. By taking into account both the reduction in foreign corporate tax and the additional withholding tax, the inclusion continues to be considered high-taxed income of USP in Year 1 ($65x > $42x (21% × $200)). USP must follow the appropriate section 905(c) procedures. USP must redetermine its U.S. tax liability for Year 1, but the Year 1 inclusion and the $65x taxes ($40x of deemed paid tax in Year 1 and $25x withholding tax in Year 2) will continue to be treated as general category income and taxes.

(viii) *Example 8.* (A) CFC, a controlled foreign corporation operating in Country G, is a wholly-owned subsidiary of USP, a domestic corporation. USP and CFC are calendar year taxpayers. Country G imposes a tax of 50% on CFC's earnings. Under Country G's system, the foreign corporate tax on particular earnings is reduced on distribution of those earnings to 30% and no withholding tax is imposed. Under Country G's law, distributions are treated as made out of a pool of undistributed earnings subject to the 50% tax rate. For Year 1, CFC's only earnings consist of passive income that is foreign personal holding company income that is earned in foreign Country G. CFC has taxable income of $110x for Federal income tax purposes and $100x for Country G purposes. Country G, therefore, imposes a tax of $50x on the Year 1 earnings of CFC. USP does not elect to exclude this income from subpart F under section 954(b)(4) and includes $110x in gross income ($60x of net foreign personal holding company income under section 951(a) and $50x of the section 78 dividend). The highest rate of tax under section 11 in Year 1 is 34%. Therefore, at the time of the section 951(a) inclusion, the income is considered to be high-taxed income under paragraph (c) of this section ($50x > $37.4x (34% × $110x)) and is general category income to USP. CFC does not distribute any of its earnings in Year 1.

(B) In Year 2, CFC earns general category income that is not subpart F income or tested income. CFC again has $110x in taxable income for Federal income tax purposes and $100x in taxable income for Country G purposes, and CFC pays $50x of tax to foreign Country G. In Year 3, CFC has no taxable income or earnings. On December 31, Year 3, CFC distributes $60x of its total $120x of earnings and receives a refund of foreign tax of $24x. The $24x refund is a foreign tax redetermination under § 1.905–3(a) that under § 1.905–3(b)(2) requires a redetermination of CFC's Year 1 subpart F income and USP's deemed paid taxes and Year 1 U.S. tax liability. Country G treats the distribution of earnings as out of the 50% tax rate pool of $200x of earnings accumulated in Year 1 and Year 2, as calculated for Country G tax purposes. However, under paragraph (c)(7)(ii) of this section, the distribution, and, therefore, the reduction of tax is treated as first attributable to the $60x of passive category earnings attributable to income previously taxed in Year 1, and none of the distribution is treated as made out of the $60x of earnings accumulated in Year 2 (which is not previously taxed). Because 40 percent (the reduction in tax rates from 50 percent to 30 percent is a 40 percent reduction in the tax) of the $50x of foreign taxes attributable to the $60x of Year 1 passive income as calculated for Federal income tax purposes is refunded, $20x of the $24x foreign tax refund reduces foreign taxes on CFC's Year 1 passive income from $50x to $30x. The other $4x of the tax refund reduces the taxes imposed in Year 2 on CFC's general category income from $50x to $46x.

(C) Under paragraph (c)(7) of this section, in connection with the section 905(c) adjustment USP must redetermine whether its Year 1 subpart F inclusion is considered high-taxed income. By taking into account the reduction in foreign tax, the inclusion is

increased by $20x to $80x, the deemed paid taxes are reduced by $20x to $30x, and the inclusion is not considered high-taxed income ($30x < 34% × $110x). Therefore, USP must treat the revised section 951(a) inclusion and the taxes associated with the section 951(a) inclusion as passive category income and taxes in Year 1. USP must follow the appropriate procedures under § 1.905–4.

* * * * *

(q) *Applicability date.* (1) Except as provided in paragraph (q)(2) and (3) of this section, this section applies for taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

(2) Paragraphs (c)(7)(i) and (iii) and (c)(8)(v) through (viii) apply to taxable years ending on or after December 16, 2019. For taxable years that both begin after December 31, 2017, and end on or after December 4, 2018, and also end before December 16, 2019, see § 1.904–4(c)(7)(i) and (iii) as in effect on December 17, 2019.

■ **Par. 18.** Section 1.904–6 is amended by:

■ 1. Revising the section heading and paragraph (a).

■ 2. Redesignating paragraph (b) as paragraph (e).

■ 3. Adding a new paragraph (b) and paragraph (c).

■ 4. Revising paragraph (d).

■ 5. In newly redesignated paragraph (e)(4)(i), removing the language ''paragraph (b)(4)(ii)'' and adding the language ''paragraph (e)(4)(ii)'' in its place.

■ 6. In newly redesignated paragraph (e)(4)(ii)(C), removing the language ''paragraph (b)(4)(ii)(B)'' and adding the language ''paragraph (e)(4)(ii)(B)'' in its place.

■ 7. Adding paragraphs (f) and (g).

The revisions and additions read as follows:

§ 1.904–6 Allocation and apportionment of foreign income taxes.

(a) *In general.* The amount of foreign income taxes paid or accrued with respect to a separate category (as defined in § 1.904–5(a)(4)(v)) of income (including U.S. source income assigned to the separate category) includes only those foreign income taxes that are allocated and apportioned to the separate category under the rules of § 1.861–20 (as modified by this section). In applying the foreign tax credit limitation under sections 904(a) and (d) to general category income described in section 904(d)(2)(A)(ii) and § 1.904–4(d), foreign source income in the general category is a statutory grouping. However, general category income is the residual grouping of income for purposes of assigning foreign income taxes to separate categories. In addition, in determining the numerator of the foreign tax credit limitation under sections 904(a) and (d), where U.S. source income is the residual grouping, the amount of foreign income taxes paid or accrued for which a deduction is allowed, for example, under section 901(k)(7), with respect to foreign source income in a separate category includes only those foreign income taxes that are allocated and apportioned to foreign source income in the separate category under the rules of § 1.861–20 (as modified by this section). For purposes of this section, unless otherwise stated, terms have the same meaning as provided in § 1.861–20(b). For examples illustrating the application of this section, see § 1.861–20(g).

(b) *Assigning an item of foreign gross income to a separate category.* For purposes of assigning an item of foreign gross income to a separate category or categories (or foreign source income in a separate category) under § 1.861–20, the rules of this paragraph (b) apply.

(1) *Base differences.* Any item of foreign gross income that is attributable to a base difference described in § 1.861–20(d)(2)(ii)(B) is assigned to the separate category described in section 904(d)(2)(H)(i), and to foreign source income in that category.

(2) [Reserved]

(c) *Allocating and apportioning deductions.* For purposes of applying § 1.861–20(e) to allocate and apportion deductions allowed under foreign law to foreign gross income in the separate categories, before undertaking the steps outlined in § 1.861–20(e), foreign gross income in the passive category is first reduced by any related person interest expense that is allocated to the income under the principles of section 954(b)(5) and § 1.904–5(c)(2)(ii)(C). In allocating and apportioning expenses not specifically allocated under foreign law, the principles of foreign law are applied only after taking into account the reduction of passive income by the application of section 954(b)(5). In allocating and apportioning expenses when foreign law does not provide rules for the allocation or apportionment of expenses, losses or other deductions to particular items of foreign gross income, then the principles of section 954(b)(5), in addition to the principles of the section 861 regulations (as defined in § 1.861–8(a)(1)), apply to allocate and apportion expenses, losses or other foreign law deductions to foreign gross income after reduction of passive income by the amount of related person interest expense allocated to passive income under section 954(b)(5) and § 1.904–5(c)(2)(ii)(C).

(d) *Apportionment of taxes for purposes of applying the high-tax income tests.* If taxes have been allocated and apportioned to passive income under the rules of paragraph (a) this section, the taxes must further be apportioned to the groups of income described in § 1.904–4(c)(3) through (5) for purposes of determining if the group is high-taxed income that is recharacterized as income in another separate category under the rules of § 1.904–4(c). See also § 1.954–1(c)(1)(iii)(B) (defining a single item of passive category foreign personal holding company income by reference to the grouping rules under § 1.904–4(c)(3) through (5)). Taxes are related to income in a particular group under the same rules as those in paragraph (a) of this section except that those rules are applied by apportioning foreign income taxes to the groups described in § 1.904–4(c)(3) through (5) instead of separate categories.

* * * * *

(f) *Treatment of certain foreign income taxes paid or accrued by United States shareholders.* Some or all of the foreign gross income of a United States shareholder of a controlled foreign corporation that is attributable to foreign law inclusion regime income with respect to a foreign law CFC described in § 1.861–20(d)(3)(iii) or foreign law pass-through income from a reverse hybrid described in § 1.861–20(d)(3)(i)(C) is assigned to the section 951A category if, were the controlled foreign corporation the taxpayer that recognizes the foreign gross income, the foreign gross income would be assigned to the controlled foreign corporation's tested income group (as defined in § 1.960–1(b)(33)) within the general category to which an inclusion under section 951A is attributable. The amount of the United States shareholder's foreign gross income that is assigned to the section 951A category (or a specified separate category associated with the section 951A category) is based on the inclusion percentage (as defined in § 1.960–2(c)(2)) of the United States shareholder. For example, if a United States shareholder has an inclusion percentage of 60 percent, then 60 percent of the foreign gross income of a United States shareholder that would be assigned (under § 1.861–20(d)(3)(iii)) to the tested income group within the general category income of a reverse hybrid that is a controlled foreign corporation to which an inclusion under section 951A is attributable is assigned to the section

951A category or the specified separate category for income resourced under a tax treaty, and not to the general category.

(g) *Applicability date.* This section applies to taxable years beginning after December 31, 2019. For taxable years that both begin after December 31, 2017, and end on or after December 4, 2018, and also begin before January 1, 2020, see § 1.904–6 as in effect on December 17, 2019.

■ **Par. 19.** Section 1.904(b)–3 is amended by revising the first sentence in paragraph (c)(1), adding paragraph (d)(2), and revising paragraph (f) to read as follows:

§ 1.904(b)–3 Disregard of certain dividends and deductions under section 904(b)(4).

* * * * *

(c) * * *

(1) * * * For purposes of applying the section 861 regulations (as defined in § 1.861–8(a)) to the deductions of a United States shareholder, the only gross income included in a section 245A subgroup is dividend income for which a deduction is allowed under section 245A. * * *

* * * * *

(d) * * *

(2) *Net operating losses.* If the taxpayer has a net operating loss in the current taxable year, then solely for purposes of determining the source and separate category of the net operating loss, the overall foreign loss rules in section 904(f) and the overall domestic loss rules in section 904(g) are applied without taking into account the adjustments required under section 904(b) and this section.

* * * * *

(f) *Applicability dates.* (1) Except as provided in paragraph (f)(2) of this section, this section applies to taxable years beginning after December 31, 2017.

(2) Paragraph (d)(2) of this section applies to taxable years ending on or after December 16, 2019.

■ **Par. 20.** Section 1.904(g)–3 is amended by:

■ 1. Adding a sentence at the end of paragraph (b)(1) and adding paragraph (j).

■ 2. Revising paragraph (l).

The additions and revision read as follows:

§ 1.904(g)–3 Ordering rules for the allocation of net operating losses, net capital losses, U.S. source losses, and separate limitation losses, and for the recapture of separate limitation losses, overall foreign losses, and overall domestic losses.

* * * * *

(b) * * *

(1) * * * See §§ 1.861–8(e)(8), 1.904(b)–3(d)(2), and 1.1502–4(c)(1)(iii) for rules to determine the source and separate category components of a net operating loss.

* * * * *

(j) *Step Nine: Dispositions that result in additional income recognition under the branch loss recapture and dual consolidated loss recapture rules*—(1) *In general.* If, after any gain is required to be recognized under section 904(f)(3) on a transaction that is otherwise a nonrecognition transaction, an additional amount of income is recognized under section 91(d), section 367(a)(3)(C) (as applicable to losses incurred before January 1, 2018), or § 1.1503(d)–6, and that additional income amount is determined by taking into account an offset for the amount of gain recognized under section 904(f)(3) and so is not initially taken into account in applying paragraph (b) of this section, then paragraphs (b) through (h) of this section are applied to determine the allocation of any additional net operating loss deduction and other deductions or losses and the applicable increases in the taxpayer's overall foreign loss, separate limitation loss, and overall domestic loss accounts, as well as any additional recapture and reduction of the taxpayer's separate limitation loss, overall foreign loss, and overall domestic loss accounts.

(2) *Rules for additional recapture of loss accounts.* For the purpose of recapturing and reducing loss accounts under paragraph (j)(1) of this section, the taxpayer also takes into account any creation of or addition to loss accounts that result from the application of paragraphs (b) through (i) of this section in the current tax year. If any of the additional income described in paragraph (j)(1) of this section is foreign source income in a separate category for which there is a remaining balance in an overall foreign loss account after applying paragraph (i) of this section, the section 904(f)(1) recapture amount under § 1.904(f)–2(c) for that additional income is determined by first computing a hypothetical recapture amount as it would have been determined prior to the application of paragraph (i) of this section but taking into account the additional foreign source income described in this paragraph (j)(2) and then subtracting the actual overall foreign loss recapture determined prior to the application of paragraph (i) of this section (that did not take into account the additional foreign source income). The remainder is the overall foreign loss recapture amount with respect to the additional foreign source income described in this paragraph (j)(2).

* * * * *

(l) *Applicability date.* This section applies to taxable years ending on or after November 2, 2020.

■ **Par. 21.** Section 1.905–3 is amended by:

■ 1. Revising the section heading and the first sentence of paragraph (a).

■ 2. Adding paragraphs (b)(2) and (3).

■ 3. Revising paragraph (d).

The revisions and additions read as follows:

§ 1.905–3 Adjustments to U.S. tax liability and to current earnings and profits as a result of a foreign tax redetermination.

(a) * * * For purposes of this section and § 1.905–4, the term *foreign tax redetermination* means a change in the liability for foreign income tax, as defined in § 1.960–1(b)(5), or certain other changes described in this paragraph (a) that may affect a taxpayer's U.S. tax liability, including by reason of a change in the amount of its foreign tax credit, the amount of its distributions or inclusions under section 951, 951A, or 1293, the application of the high-tax exception described in section 954(b)(4) (including for purposes of determining amounts excluded from gross tested income under section 951A(c)(2)(A)(i)(III) and § 1.951A–2(c)(1)(iii)), or the amount of tax determined under sections 1291(c)(2) and 1291(g)(1)(C)(ii). * * *

(b) * * *

(2) *Foreign income taxes paid or accrued by foreign corporations*—(i) *In general.* A redetermination of U.S. tax liability is required to account for the effect of a redetermination of foreign income taxes taken into account by a foreign corporation in the year accrued, or a refund of foreign income taxes taken into account by the foreign corporation in the year paid.

(ii) *Required adjustments.* If a redetermination of U.S. tax liability is required for any taxable year under paragraph (b)(2)(i) of this section, the foreign corporation's taxable income, earnings and profits, and current year taxes (as defined in § 1.960–1(b)(4)) must be adjusted in the year to which the redetermined tax relates (or, in the case of a foreign corporation that receives a refund of foreign income tax and uses the cash basis of accounting, in the year the tax was paid). The redetermination of U.S. tax liability is made by treating the redetermined amount of foreign tax as the amount of tax paid or accrued by the foreign corporation in such year. For example, in the case of a refund of foreign income

taxes taken into account in the year accrued, the foreign corporation's subpart F income, tested income, and current earnings and profits are increased, as appropriate, in the year to which the foreign tax relates to reflect the functional currency amount of the foreign income tax refund. The required redetermination of U.S. tax liability must account for the effect of the foreign tax redetermination on the characterization and amount of distributions or inclusions under section 951, 951A, or 1293 taken into account by each of the foreign corporation's United States shareholders, on the application of the high-tax exception described in section 954(b)(4) (including for purposes of determining the exclusions from gross tested income under section 951A(c)(2)(A)(i)(III) and § 1.951A–2(c)(1)(iii)), and the amount of tax determined under sections 1291(c)(2) and 1291(g)(1)(C)(ii), as well as on the amount of foreign taxes deemed paid under section 960 in such year, regardless of whether any such shareholder chooses to deduct or credit its foreign income taxes in any taxable year. In addition, a redetermination of U.S. tax liability is required for any subsequent taxable year in which the characterization or amount of a United States shareholder's distribution or inclusion from the foreign corporation is affected by the foreign tax redetermination, up to and including the taxable year in which the foreign tax redetermination occurs, as well as any year to which unused foreign taxes from such year were carried under section 904(c).

(iii) *Reduction of corporate level tax on distribution of earnings and profits.* If a United States shareholder of a controlled foreign corporation receives a distribution out of previously taxed earnings and profits described in section 959(c)(1) and (2) and a foreign country has imposed tax on the income of the controlled foreign corporation, which tax is reduced on distribution of the earnings and profits of the corporation (resulting in a foreign tax redetermination), then the United States shareholder must redetermine its U.S. tax liability for the year or years affected. See also § 1.904–4(c)(7)(i).

(iv) *Foreign tax redeterminations relating to taxable years beginning before January 1, 2018.* In the case of a foreign tax redetermination of a foreign corporation that relates to a taxable year of the foreign corporation beginning before January 1, 2018, a redetermination of U.S. tax liability is required under the rules of § 1.905–5.

(v) *Examples.* The following examples illustrate the application of this paragraph (b)(2).

(A) *Presumed Facts.* Except as otherwise provided in this paragraph (b)(2)(v), the following facts are assumed for purposes of the examples in paragraphs (b)(2)(v)(B) through (E) of this section:

(*1*) All parties are accrual basis taxpayers that use the calendar year as their taxable year both for Federal income tax purposes and for foreign tax purposes and use the average exchange rate to translate accrued foreign income taxes;

(*2*) CFC, CFC1, and CFC2 are controlled foreign corporations organized in Country X that use the ''u'' as their functional currency;

(*3*) No income adjustment is required to reflect exchange gain or loss (within the meaning of § 1.988–1(e)) with respect to the disposition of nonfunctional currency attributable to a refund of foreign income taxes received by any CFC, because all foreign income taxes are denominated and paid in the CFC's functional currency;

(*4*) The highest rate of U.S. tax in section 11 and the rate applicable to USP in all years is 21 percent;

(*5*) No election to exclude high-taxed income under section 954(b)(4) or § 1.951A–2(c)(7) is made with respect to CFC, CFC1, or CFC2; and

(*6*) USP's foreign tax credit limitation under section 904(a) exceeds the amount of foreign income taxes it is deemed to pay.

(B) *Example 1: Refund of tested foreign income taxes*—(*1*) *Facts.* CFC is a wholly-owned subsidiary of USP, a domestic corporation. In Year 1, CFC earns 3,660u of general category gross tested income and accrues and pays 300u of foreign income taxes with respect to that income. CFC has no allowable deductions other than the foreign income tax expense. Accordingly, CFC has tested income of 3,360u in Year 1. CFC has no qualified business asset investment (within the meaning of section 951A(d) and § 1.951A–3(b)). In Year 1, no portion of USP's deduction under section 250 (''section 250 deduction'') is reduced by reason of section 250(a)(2)(B)(ii). USP's inclusion percentage (as defined in § 1.960–2(c)(2)) is 100%. In Year 1, USP earns no other income and has no other expenses. The average exchange rate used to translate USP's inclusion under section 951A and CFC's foreign income taxes into dollars for Year 1 is $1x:1u. See section 989(b)(3) and §§ 1.951A–1(d)(1) and 1.986(a)–1(a)(1). Accordingly, for Year 1, USP's tested foreign income taxes (as defined in § 1.960–2(c)(3)) with respect to CFC are $300x. In Year 3, CFC carries back a loss for foreign tax purposes and receives a refund of foreign tax of 100u that relates to Year 1.

(*2*) *Analysis*—(*i*) *Result in Year 1.* In Year 1, CFC has tested income of 3,360u and tested foreign income taxes of $300x. Under section 951A(a) and § 1.951A–1(c)(1), USP has a GILTI inclusion amount of $3,360x (3,360u translated at $1x:1u). Under section 960(d) and § 1.960–2(c), USP is deemed to have paid $240x (80% × 100% × $300x) of foreign income taxes. Under section 78 and § 1.78–1(a), USP is treated as receiving a dividend of $300x (a ''section 78 dividend''). USP's section 250 deduction is $1,830x (50% × ($3,360x + $300x)). Accordingly, for Year 1, USP has taxable income of $1,830x ($3,360x + $300x − $1,830x) and pre-credit U.S. tax liability of $384.30x (21% × $1,830x). Accordingly, USP pays U.S. tax of $144.30x ($384.30x − $240x).

(*ii*) *Result in Year 3.* The refund of 100u to CFC in Year 3 is a foreign tax redetermination under paragraph (a) of this section. Under paragraph (b)(2)(ii) of this section, USP must account for the effect of the foreign tax redetermination on its GILTI inclusion amount and foreign taxes deemed paid in Year 1. In redetermining USP's U.S. tax liability for Year 1, USP must increase CFC's tested income and its earnings and profits in Year 1 by the refunded tax amount of 100u, must determine the effect of that increase on its GILTI inclusion amount, and must adjust the amount of foreign taxes deemed paid and the section 78 dividend to account for CFC's refund of foreign tax. Under § 1.986(a)–1(c), the refund is translated into dollars at the exchange rate that was used to translate such amount when initially accrued. As a result of the foreign tax redetermination, for Year 1, CFC has tested income of 3,460u (3,360u + 100u) and tested foreign income taxes of $200x ($300x − $100x). Under section 951A(a) and § 1.951A–1(c)(1), USP has a redetermined GILTI inclusion amount of $3,460x (3,460u translated at $1x:1u). Under section 960(d) and § 1.960–2(c), USP is deemed to have paid $160x (80% × 100% × $200x) of foreign income taxes. Under section 78 and § 1.78–1(a), USP's section 78 dividend is $200x. USP's redetermined section 250 deduction is $1,830x (50% × ($3,460x + $200x)). Accordingly, USP's redetermined taxable income is $1,830x ($3,460x + $200x − $1,830x) and its pre-credit U.S. tax liability is $384.30x (21% × $1,830x). Therefore, USP's redetermined U.S. tax liability is

$224.3x ($384.30x − $160x), an increase of $80x ($224.30x − $144.30x).

(C) *Example 2: Additional payment of foreign income taxes*—(*1*) *Facts.* CFC is a wholly-owned subsidiary of USP, a domestic corporation. In Year 1, CFC earns 1,000u of general category gross foreign base company sales income and accrues and pays 100u of foreign income taxes with respect to that income. CFC has no allowable deductions other than the foreign income tax expense. The average exchange rate used to translate USP's subpart F inclusion and CFC's foreign income taxes into dollars for Year 1 is $1x:1u. See section 989(b)(3) and § 1.986(a)–1(a)(1). In Year 1, USP earns no other income and has no other expenses. In Year 5, pursuant to a Country X audit CFC accrues and pays additional foreign income tax of 80u with respect to its 1,000u of general category foreign base company sales income earned in Year 1. The spot rate (as defined in § 1.988–1(d)) on the date of payment of the tax in Year 5 is $1x:0.8u. The foreign income taxes accrued and paid in Year 1 and Year 5 are properly attributable to CFC's foreign base company sales income that is included in income by USP under section 951(a)(1)(A) (''subpart F inclusion'') in Year 1 with respect to CFC.

(*2*) *Analysis*—(*i*) *Result in Year 1.* In Year 1, CFC has subpart F income of 900u (1,000u − 100u). Accordingly, USP has a $900x (900u translated at $1x:1u) subpart F inclusion. Under section 960(a) and § 1.960–2(b), USP is deemed to have paid $100x (100u translated at $1x:1u) of foreign income taxes. Under section 78 and § 1.78–1(a), USP's section 78 dividend is $100x. Accordingly, for Year 1, USP has taxable income of $1,000x ($900x + $100x) and pre-credit U.S. tax liability of $210x (21% × $1,000x). Accordingly, USP's U.S. tax liability is $110x ($210x − $100x).

(*ii*) *Result in Year 5.* CFC's payment of 80u of additional foreign income tax in Year 5 with respect to Year 1 is a foreign tax redetermination as defined in paragraph (a) of this section. Under paragraph (b)(2)(ii) of this section, USP must reduce CFC's subpart F income and its earnings and profits in Year 1 by the additional tax amount of 80u. Further, USP must reduce its subpart F inclusion, adjust the amount of foreign taxes deemed paid, and adjust the amount of the section 78 dividend to account for CFC's additional payment of foreign tax. Under section 986(a)(1)(B)(i) and § 1.986(a)–1(a)(2)(i), because CFC's payment of additional tax occurs more than 24 months after the close of the taxable year to which it relates, the additional tax is translated into dollars at the spot rate on the date of payment ($1x:0.8u). Therefore, CFC has foreign income taxes of $200x (100u translated at $1x:1u plus 80u translated at $1x:0.8u) that are properly attributable to CFC's foreign base company sales income that gives rise to USP's subpart F inclusion in Year 1. As a result of the foreign tax redetermination, for Year 1, USP has a subpart F inclusion of $820x (1,000u − 180u = 820u translated at $1x:1u). Under section 960(a) and § 1.960–2(b), USP is deemed to have paid $200x of foreign income taxes. Under section 78 and § 1.78–1(a), USP's section 78 dividend is $200x. USP's redetermined U.S. taxable income is $1,020x ($820x + $200x) and its pre-credit U.S. tax liability is $214.20x (21% × $1,020x). Therefore, USP's redetermined U.S. tax liability is $14.20x ($214.20x − $200x), a decrease of $95.80x ($110x − $14.20x). If USP makes a timely refund claim within the period allowed by section 6511, USP will be entitled to a refund of any overpayment resulting from the redetermination of its U.S. tax liability.

(D) *Example 3: Two-year rule*—(*1*) *Facts.* CFC is a wholly-owned subsidiary of USP, a domestic corporation. In Year 1, CFC earns 1,000u of general category gross foreign base company sales income and accrues 210u of foreign income taxes with respect to that income. In Year 1, USP earns no other income and has no other expenses. The average exchange rate used to translate USP's subpart F inclusion and CFC's foreign income taxes into dollars for Year 1 is $1x:1u. See sections 989(b)(3) and 986(a)(1)(A) and § 1.986(a)–1(a)(1). CFC does not pay its foreign income taxes for Year 1 until September 1, Year 5, when the spot rate is $0.8x:1u. The foreign income taxes accrued and paid in Year 1 and Year 5, respectively, are properly attributable to CFC's foreign base company sales income that gives rise to USP's subpart F inclusion in Year 1 with respect to CFC.

(*2*) *Analysis*—(*i*) *Result in Year 1.* In Year 1, CFC has subpart F income of 790u (1,000u − 210u). Accordingly, USP has a $790x (790u translated at $1x:1u) subpart F inclusion. Under section 960(a) and § 1.960–2(b), USP is deemed to have paid $210x (210u translated at $1x:1u) of foreign income taxes. Under section 78 and § 1.78–1(a), USP's section 78 dividend is $210x. Accordingly, for Year 1, USP has taxable income of $1,000x ($790x + $210x) and pre-credit U.S. tax liability of $210x (21% × $1,000x). Accordingly, USP owes no U.S. tax ($210x − $210x = 0).

(*ii*) *Result in Year 3.* CFC's failure to pay the tax by the end of Year 3 results in a foreign tax redetermination under paragraph (a) of this section. Because the taxes are not paid on or before the date 24 months after the close of the taxable year to which the tax relates, under paragraph (a) of this section CFC must account for the redetermination as if the unpaid 210u of taxes were refunded on the last day of Year 3. Under paragraph (b)(2)(ii) of this section, USP must increase CFC's subpart F income and its earnings and profits in Year 1 by the unpaid tax amount of 210u. Further, USP must increase its subpart F inclusion, and decrease the amount of foreign taxes deemed paid and the amount of the section 78 dividend to account for the unpaid taxes. As a result of the foreign tax redetermination, for Year 1, USP has a subpart F inclusion of $1,000x (1,000u translated at $1x:1u). Under section 960(a) and § 1.960–2(b), USP is deemed to have paid no foreign income taxes. Under section 78 and § 1.78–1(a), USP has no section 78 dividend. Accordingly, USP's redetermined taxable income is $1,000x and its pre-credit U.S. tax liability is unchanged at $210x (21% × $1,000x). However, USP has no foreign tax credits. Therefore, USP's redetermined U.S. tax liability for Year 1 is $210x, an increase of $210x.

(*iii*) *Result in Year 5.* CFC's payment of the Year 1 tax liability of 210u on September 1, Year 5, results in a second foreign tax redetermination under paragraph (a) of this section. Under paragraph (b)(2)(ii) of this section, USP must decrease CFC's subpart F income and its earnings and profits in Year 1 by the tax paid amount of 210u. Further, USP must reduce its subpart F inclusion, and adjust the amount of foreign taxes deemed paid and the amount of the section 78 dividend to account for CFC's payment of foreign tax. Under section 986(a)(1)(B)(i) and § 1.986(a)–1(a)(2)(i), because the tax was paid more than 24 months after the close of the year to which the tax relates, CFC must translate the 210u of tax at the spot rate on the date of payment of the foreign taxes in Year 5. Therefore, CFC has foreign income taxes of $168x (210u translated at $0.8x:1u) that are properly attributable to CFC's foreign base company sales income that gives rise to USP's subpart F inclusion in Year 1. As a result of the foreign tax redetermination, for Year 1, USP has a subpart F inclusion of $790x (1,000u − 210u = 790u translated at $1x:1u). Under section 960(a) and § 1.960–2(b), USP is deemed to have paid $168x of foreign income taxes.

Under section 78 and § 1.78–1(a), USP's section 78 dividend is $168x. Accordingly, USP's redetermined taxable income is $958x ($790x + $168x), its pre-credit U.S. tax liability is $201.18x (21% × $958x), and its redetermined U.S. tax liability is $33.18 ($201.18x − $168x), a decrease of $176.82x ($210x − $33.18x). If USP makes a timely refund claim within the period allowed by section 6511, USP will be entitled to a refund of any overpayment resulting from the redetermination of its U.S. tax liability.

(E) *Example 4: Contested tax*—(*1*) *Facts.* CFC is a wholly-owned subsidiary of USP, a domestic corporation. In Year 1, CFC earns 360u of general category gross tested income and accrues and pays 160u of current year taxes with respect to that income. CFC has no allowable deductions other than the foreign income tax expense. Accordingly, CFC has tested income of 200u in Year 1. CFC has no qualified business asset investment (within the meaning of section 951A(d) and § 1.951A–3(b)). In Year 1, no portion of USP's section 250 deduction is reduced by reason of section 250(a)(2)(B)(ii). USP's inclusion percentage (as defined in § 1.960–2(c)(2)) is 100%. In Year 1, USP earns no other income and has no other expenses. The average exchange rate used to translate USP's section 951A inclusion and CFC's foreign income taxes into dollars for Year 1 is $1x:1u. See section 989(b)(3) and §§ 1.951A–1(d)(1) and 1.986(a)–1(a)(1). Accordingly, for Year 1, CFC's tested foreign income taxes (as defined in § 1.960–2(c)(3)) with respect to USP are $160x. In Year 3, Country X assessed an additional 30u of tax with respect to CFC's Year 1 income. CFC did not pay the additional 30u of tax and contested the assessment. After exhausting all effective and practical remedies to reduce, over time, its liability for foreign income tax, CFC settled the contest with Country X in Year 4 for 20u, which CFC did not pay until January 15, Year 5, when the spot rate was $1.1x:1u. CFC did not earn any other income or accrue any other foreign income taxes in Years 2 through 6 and made no distributions to USP. The additional taxes paid in Year 5 are also tested foreign income taxes of CFC with respect to USP.

(*2*) *Analysis*—(*i*) *Result in Year 1.* In Year 1, CFC has tested income of 200u and tested foreign income taxes of $160x. Under section 951A(a) and § 1.951A–1(c)(1), USP has a GILTI inclusion amount of $200x (200u translated at $1x:1u). Under section 960(d) and § 1.960–2(c), USP is deemed to have paid $128x (80% × 100% × $160x) of foreign income taxes. Under section 78 and § 1.78–1(a), USP's section 78 dividend is $160x. USP's section 250 deduction is $180x (50% × ($200x + $160x)). Accordingly, for Year 1, USP has taxable income of $180x ($200x + $160x − $180x) and a pre-credit U.S. tax liability of $37.80x (21% × $180x). Under section 904(a), because all of USP's income is section 951A category income (see § 1.904–4(g)), USP's foreign tax credit limitation is $37.80x ($37.80x × $180x/$180x), which is less than the $128x of foreign income tax that USP is deemed to have paid. Accordingly, USP owes no U.S. tax ($37.80x − $37.80x = 0).

(*ii*) *Result in Year 5.* CFC's accrual and payment of the additional 20u of foreign income tax with respect to Year 1 is a foreign tax redetermination under paragraph (a) of this section. Under § 1.461–4(g)(6)(iii)(B), the additional taxes accrue when the tax contest is resolved, that is, in Year 4. However, because the taxes, which relate to Year 1, were not paid on or before the date 24 months after close of CFC's taxable year to which the tax relates, that is, Year 1, under section 905(c)(2) and paragraph (a) of this section CFC cannot take these taxes into account when they accrue in Year 4. Instead, the taxes are taken into account when they are paid in Year 5. Under paragraph (b)(2)(ii) of this section, USP must decrease CFC's tested income and its earnings and profits in Year 1 by the additional tax amount of 20u. Further, USP must adjust its GILTI inclusion amount, the amount of foreign taxes deemed paid, and the amount of the section 78 dividend to account for CFC's additional payment of tax. Under section 986(a)(1)(B)(i) and § 1.986(a)–1(a)(2)(i), because CFC's payment of additional tax occurs more than 24 months after the close of the taxable year to which it relates, the additional tax is translated into dollars at the spot rate on the date of payment ($1.1x:1u). Therefore, CFC has tested foreign income taxes of $182x (160u translated at $1x:1u plus 20u translated at $1.1x:1u). As a result of the foreign tax redetermination, for Year 1, CFC has tested income of 180u (200u − 20u). Under section 951A(a) and § 1.951A–1(c)(1), USP has a redetermined GILTI inclusion amount of $180x (180u, translated at $1x:1u). Under section 960(d) and § 1.960–2(c), USP is deemed to have paid $145.60x (80% × 100% × $182x) of foreign income taxes. Under section 78 and § 1.78–1(a), USP's section 78 dividend is $182x. USP's redetermined section 250 deduction is $181x (50% × ($180x + $182x)). Accordingly, USP's redetermined taxable income is $181x ($180x + $182x − $181x), its pre-credit U.S. tax liability is $38.01x (21% × $181x), and its redetermined U.S. tax liability is zero ($38.01x − $38.01x).

(3) *Foreign tax redeterminations of successors or transferees.* If at the time of a foreign tax redetermination the person with legal liability for the tax (or in the case of a refund, the legal right to such refund) (the ''successor'') is a different person than the person that had legal liability for the tax in the year to which the redetermined tax relates (the ''original taxpayer''), the required redetermination of U.S. tax liability is made as if the foreign tax redetermination occurred in the hands of the original taxpayer. Federal income tax principles apply to determine the tax consequences if the successor remits (or receives a refund of) a tax that in the year to which the redetermined tax relates was the legal liability of, and thus under § 1.901–2(f) is considered paid by, the original taxpayer.

* * * * *

(d) *Applicability dates.* This section applies to foreign tax redeterminations occurring in taxable years ending on or after December 16, 2019, and to foreign tax redeterminations of foreign corporations occurring in taxable years that end with or within a taxable year of a United States shareholder ending on or after December 16, 2019 and that relate to taxable years of foreign corporations beginning after December 31, 2017.

■ **Par. 22.** Section 1.905–4 is added to read as follows:

§ 1.905–4 Notification of foreign tax redetermination.

(a) *Application of this section.* The rules of this section apply if, as a result of a foreign tax redetermination (as defined in § 1.905–3(a)), a redetermination of U.S. tax liability is required under section 905(c) and § 1.905–3(b).

(b) *Time and manner of notification*—(1) *Redetermination of U.S. tax liability*—(i) *In general.* Except as provided in paragraphs (b)(1)(v) and (b)(2) through (4) of this section, any taxpayer for which a redetermination of U.S. tax liability is required must notify the Internal Revenue Service (IRS) of the foreign tax redetermination by filing an amended return, Form 1118 (Foreign Tax Credit—Corporations) or Form 1116 (Foreign Tax Credit (Individual, Estate, or Trust)), and the statement described in paragraph (c) of this section for the taxable year with respect to which a redetermination of U.S. tax liability is required. Such notification must be filed within the time prescribed by this

paragraph (b) and contain the information described in paragraph (c) of this section. If a foreign tax redetermination requires an individual to redetermine the individual's U.S. tax liability, and if, after taking into account such foreign tax redetermination, the amount of creditable foreign taxes (as defined in section 904(j)(3)(B)) that are paid or accrued by such individual during the taxable year does not exceed the applicable dollar limitation in section 904(j), the individual is not required to file Form 1116 with the amended return for such taxable year if the individual satisfies the requirements of section 904(j).

(ii) *Increase in amount of U.S. tax liability.* Except as provided in paragraphs (b)(1)(iv) and (v) and (b)(2) through (4) of this section, for each taxable year of the taxpayer with respect to which a redetermination of U.S. tax liability is required by reason of a foreign tax redetermination that increases the amount of U.S. tax liability, for example, by reason of a downward adjustment to the amount of foreign income taxes paid or accrued by the taxpayer or a foreign corporation with respect to which the taxpayer computes an amount of foreign taxes deemed paid, the taxpayer must file a separate notification by the due date (with extensions) of the original return for the taxpayer's taxable year in which the foreign tax redetermination occurs.

(iii) *Decrease in amount of U.S. tax liability.* Except as provided in paragraphs (b)(1)(iv) and (v) and (b)(2) through (4) of this section, for each taxable year of the taxpayer with respect to which a redetermination of U.S. tax liability is required by reason of a foreign tax redetermination that decreases the amount of U.S. tax liability and results in an overpayment, for example, by reason of an increase in the amount of foreign income taxes paid or accrued by the taxpayer or a foreign corporation with respect to which the taxpayer computes an amount of foreign taxes deemed paid, the taxpayer must file a claim for refund with the IRS within the period provided in section 6511. See section 6511(d)(3)(A) for the special refund period for refunds attributable to an increase in foreign tax credits.

(iv) *Multiple redeterminations of U.S. tax liability for same taxable year.* The rules of this paragraph (b)(1)(iv) apply except as provided in paragraphs (b)(1)(v) and (b)(2) through (4) of this section. If more than one foreign tax redetermination requires a redetermination of U.S. tax liability for the same affected taxable year of the taxpayer and those foreign tax redeterminations occur within the same taxable year or within two consecutive taxable years of the taxpayer, the taxpayer may file for the affected taxable year one amended return, Form 1118 or Form 1116, and the statement described in paragraph (c) of this section that reflects all such foreign tax redeterminations. If the taxpayer chooses to file one notification for such redeterminations, one or more of such redeterminations would increase the U.S. tax liability, and the net effect of all such redeterminations is to increase the U.S. tax liability for the affected taxable year, the taxpayer must file such notification by the due date (with extensions) of the original return for the taxpayer's taxable year in which the first foreign tax redetermination that would result in an increased U.S. tax liability occurred. If the taxpayer chooses to file one notification for such redeterminations, one or more of such redeterminations would decrease the U.S. tax liability, and the net effect of all such redeterminations is to decrease the total amount of U.S. tax liability for the affected taxable year, the taxpayer must file such notification as provided in paragraph (b)(1)(iii) of this section, within the period provided by section 6511. If a foreign tax redetermination with respect to the taxable year for which a redetermination of U.S. tax liability is required occurs after the date for providing such notification, more than one amended return may be required with respect to that taxable year.

(v) *Amended return required only if there is a change in amount of U.S. tax due.* If a redetermination of U.S. tax liability is required by reason of a foreign tax redetermination (or multiple foreign tax redeterminations, in the case of redeterminations described in paragraph (b)(1)(iv) of this section), but does not change the amount of U.S. tax due for any taxable year, the taxpayer may, in lieu of applying the applicable rules of paragraphs (b)(1)(i) through (iv) of this section, notify the IRS of such redetermination by attaching a statement to the original return for the taxpayer's taxable year in which the foreign tax redetermination occurs. The statement must be filed by the due date (with extensions) of the original return for the taxpayer's taxable year in which the foreign tax redetermination occurs and contain the information described in § 1.904–2(f). If a redetermination of U.S. tax liability is required by reason of a foreign tax redetermination (either alone, or if the taxpayer chooses to apply paragraph (b)(1)(iv) of this section, in combination with other foreign tax redeterminations, as provided therein) and the redetermination of U.S. tax liability results in a change to the amount of U.S. tax due for a taxable year, but does not change the amount of U.S. tax due for other taxable years, for example, because of a carryback or carryover of an unused foreign tax under section 904(c), the notification requirements for such other taxable years are deemed to be satisfied if the taxpayer complies with the applicable rules of paragraphs (b)(1)(i) through (iv) of this section with respect to each taxable year for which the foreign tax redetermination changes the amount of U.S. tax due.

(2) *Notification with respect to a change in the amount of foreign tax reported to an owner by a pass-through entity*—(i) *In general.* If a partnership, trust, or other pass-through entity that reports to its beneficial owners (or to any intermediary on behalf of its beneficial owners), including partners, shareholders, beneficiaries, or similar persons, an amount of creditable foreign tax expenditures, such pass-through entity must notify both the IRS and its owners of any foreign tax redetermination described in § 1.905–3(a) with respect to the foreign tax so reported. For purposes of this paragraph (b)(2), whether or not a redetermination has occurred within the meaning of § 1.905–3(a) is determined as if the pass-through entity were a domestic corporation which had elected to and claimed foreign tax credits in the amount reported for the year to which such foreign taxes relate. The notification required under this paragraph (b)(2) must include the statement described in paragraph (c) of this section along with any information necessary for the owners to redetermine their U.S. tax liability.

(ii) *Partnerships subject to subchapter C of chapter 63 of the Code.* Except as provided in paragraph (b)(4) of this section, if a redetermination of U.S. tax liability that is required under § 1.905–3(b) by reason of a foreign tax redetermination described in § 1.905–3(a) would require a partnership adjustment as defined in § 301.6241–1(a)(6) of this chapter, the partnership must file an administrative adjustment request under section 6227 and make any adjustments required under section 6227. See §§ 301.6227–2 and 301.6227–3 of this chapter for procedures for making adjustments with respect to an administrative adjustment request. An administrative adjustment request required under this paragraph (b)(2)(ii) must be filed by the due date (with extensions) of the original return for the partnership's taxable year in which the

foreign tax redetermination occurs, and the restrictions in section 6227(c) do not apply to such filing. However, unless the administrative adjustment request may otherwise be filed after applying the limitations contained in section 6227(c), such a request is limited to adjustments that are required to be made under section 905(c). The requirements of paragraph (b)(2)(i) of this section are deemed to be satisfied with respect to any item taken into account in an administrative adjustment request filed under this paragraph (b)(2)(ii).

(3) *Alternative notification requirements.* An amended return and Form 1118 (Foreign Tax Credit—Corporations) or Form 1116 (Foreign Tax Credit (Individual, Estate, or Trust)), is not required to notify the IRS of the foreign tax redetermination and redetermination of U.S. tax liability if the taxpayer satisfies alternative notification requirements that may be prescribed by the IRS through forms, instructions, publications, or other guidance.

(4) *Taxpayers under examination within the jurisdiction of the Large Business and International Division*—(i) *In general.* The alternative notification requirements of this paragraph (b)(4) apply if all of the conditions described in paragraphs (b)(4)(i)(A) through (E) of this section are satisfied.

(A) A foreign tax redetermination occurs while the taxpayer is under examination within the jurisdiction of the Large Business and International Division.

(B) The foreign tax redetermination results in an adjustment to the amount of foreign income taxes paid or accrued by the taxpayer or a foreign corporation with respect to which the taxpayer computes an amount of foreign income taxes deemed paid.

(C) The foreign tax redetermination requires a redetermination of U.S. tax liability that increases the amount of U.S. tax liability, and accordingly, but for this paragraph (b)(4), the taxpayer would be required to notify the IRS of such foreign tax redetermination under paragraph (b)(1)(ii) of this section (determined without regard to paragraphs (b)(1)(iv) and (v) of this section) or paragraph (b)(2)(ii) of this section. See paragraph (b)(4)(v) of this section regarding foreign tax redeterminations that decrease the amount of U.S. tax liability.

(D) The return for the taxable year for which a redetermination of U.S. tax liability is required is under examination.

(E) The due date specified in paragraph (b)(1)(ii) or (b)(2)(ii) of this section for providing notice of such foreign tax redetermination is not before the later of the opening conference or the hand-delivery or postmark date of the opening letter concerning an examination of the return for the taxable year for which a redetermination of U.S. tax liability is required by reason of such foreign tax redetermination.

(ii) *Notification requirements*—(A) *Foreign tax redetermination occurring before commencement of the examination.* If a foreign tax redetermination described in paragraphs (b)(4)(i)(B) and (C) of this section occurs before the later of the opening conference or the hand-delivery or postmark date of the opening letter and if the condition provided in paragraph (b)(4)(i)(E) of this section with respect to such foreign tax redetermination is met, the taxpayer, in lieu of applying the rules of paragraphs (b)(1)(i) and (ii) of this section (requiring the filing of an amended return, Form 1116 or 1118, and the statement described in paragraph (c) of this section) or paragraph (b)(2)(ii) of this section (requiring the filing of an administrative adjustment request), must notify the IRS of such redetermination by providing the statement described in paragraph (b)(4)(iii) of this section to the examiner no later than 120 days after the later of the date of the opening conference of the examination, or the hand-delivery or postmark date of the opening letter concerning the examination.

(B) *Foreign tax redetermination occurring within 180 days after commencement of the examination.* If a foreign tax redetermination described in paragraphs (b)(4)(i)(B) and (C) of this section occurs on or after the latest of the opening conference or the hand-delivery or postmark date of the opening letter and on or before the date that is 180 days after the later of the opening conference or the hand-delivery or postmark date of the opening letter, the taxpayer, in lieu of applying the rules of paragraph (b)(1)(i) and (ii) of this section or paragraph (b)(2) of this section, must notify the IRS of such redetermination by providing the statement described in paragraph (b)(4)(iii) of this section to the examiner no later than 120 days after the date the foreign tax redetermination occurs.

(C) *Foreign tax redetermination occurring more than 180 days after commencement of the examination.* If a foreign tax redetermination described in paragraphs (b)(4)(i)(B) and (C) of this section occurs after the date that is 180 days after the later of the opening conference or the hand-delivery or postmark date of the opening letter, the taxpayer must either apply the rules of paragraphs (b)(1)(i) and (ii) of this section or paragraph (b)(2) of this section, or, in lieu of applying paragraphs (b)(1)(i) and (ii) of this section or paragraph (b)(2) of this section, provide the statement described in paragraph (b)(4)(iii) of this section to the examiner within 120 days after the date the foreign tax redetermination occurs. However, the IRS, in its discretion, may either accept such statement or require the taxpayer to comply with the rules of paragraphs (b)(1)(i) and (ii) of this section or paragraph (b)(2) of this section, as applicable.

(iii) *Statement.* The statement required by paragraphs (b)(4)(ii)(A) and (B) of this section must provide the original amount of foreign income taxes paid or accrued, the revised amount of foreign income taxes paid or accrued, and documentation with respect to the revisions, including exchange rates and dates of accrual or payment, and, if applicable, the information described in paragraph (c)(8) of this section. The statement must include the following declaration signed by a person authorized to sign the return of the taxpayer: ''Under penalties of perjury, I declare that I have examined this written statement, and to the best of my knowledge and belief, this written statement is true, correct, and complete.''

(iv) *Penalty for failure to file notice of a foreign tax redetermination.* A taxpayer subject to the rules of this paragraph (b)(4) must satisfy the rules of paragraph (b)(4)(ii) of this section in order not to be subject to the penalty relating to the failure to file notice of a foreign tax redetermination under section 6689 and § 301.6689–1 of this chapter.

(v) *Notification of foreign tax redetermination that decreases U.S. tax liability in an affected year under audit.* A taxpayer may (but is not required to) notify the IRS as provided in this paragraph (b)(4)(v) if the taxpayer has a foreign tax redetermination that meets the conditions in paragraphs (b)(4)(i)(A), (B), and (D) of this section and results in a decrease in the amount of U.S. tax liability that, but for this paragraph (b)(4), would require the taxpayer to notify the IRS of such foreign tax redetermination under paragraph (b)(1)(iii) or (b)(2)(ii) of this section (determined without regard to paragraphs (b)(1)(iv) and (v) of this section). The notification should be made in the time and manner specified in paragraph (b)(4)(ii) of this section. The IRS, in its discretion, may either accept such alternate notification or require the taxpayer to comply with the

rules of paragraphs (b)(1)(i) and (iii) or paragraphs (b)(2) of this section, as applicable.

(5) *Examples.* The following examples illustrate the application of paragraph (b) of this section.

(i) *Example 1.* (A) X, a domestic corporation, is an accrual basis taxpayer and uses the calendar year as its U.S. taxable year. X conducts business through a branch in Country M, the currency of which is the m, and also conducts business through a branch in Country N, the currency of which is the n. X uses the average exchange rate to translate foreign income taxes. X is able to claim a credit under section 901 for all foreign income taxes paid or accrued.

(B) In Year 1, X accrued and paid 100m of Country M income taxes with respect to 400m of foreign source foreign branch category income. The average exchange rate for Year 1 was $1:1m. Also in Year 1, X accrued and paid 50n of Country N income taxes with respect to 150n of foreign source foreign branch category income. The average exchange rate for Year 1 was $1:1n. On its Year 1 Federal income tax return, X claimed a foreign tax credit under section 901 of $150 ($100 (100m translated at $1:1m) + $50 (50n translated at $1:1n)) with respect to its foreign source foreign branch category income. See § 1.986(a)–1(a)(1).

(C) In Year 2, X accrued and paid 100n of Country N income taxes with respect to 300n of foreign source foreign branch category income. The average exchange rate for Year 2 was $1.50:1n. On its Year 2 Federal income tax return, X claimed a foreign tax credit under section 901 of $150 (100n translated at $1.5:1n). See § 1.986(a)–1(a)(1).

(D) On June 15, Year 5, when the spot rate was $1.40:1n, X received a refund of 10n from Country N, and, on March 15, Year 6, when the spot rate was $1.20:1m, X was assessed by and paid Country M an additional 20m of tax. Both payments were with respect to X's foreign source foreign branch category income in Year 1. On May 15, Year 6, when the spot rate was $1.45:1n, X received a refund of 5n from Country N with respect to its foreign source foreign branch category income in Year 2.

(E) Both of the refunds and the assessment are foreign tax redeterminations under § 1.905–3(a). Under § 1.905–3(b)(1), X must redetermine its U.S. tax liability for both Year 1 and Year 2. With respect to Year 1, under paragraph (b)(1)(ii) of this section X must notify the IRS of the June 15, Year 5, refund of 10n from Country N that increased X's U.S. tax liability by filing an amended return, Form 1118, and the statement required by paragraph (c) of this section for Year 1 by the due date of the original return (with extensions) for Year 5. The amended return and Form 1118 would reflect the reduced amount of foreign income taxes claimed as a credit under section 901 and the increase in X's U.S. tax liability of $10 (10n refund translated at the average exchange rate for Year 1, or $1:1n (see § 1.986(a)–1(c)). With respect to the March 15, Year 6, additional assessment of 20m by Country M, under paragraph (b)(1)(iii) of this section X must notify the IRS within the time period provided by section 6511, increasing the foreign income taxes available as a credit and reducing X's U.S. tax liability by $24 (20m translated at the spot rate on the date of payment, or $1.20:1m). See sections 986(a)(1)(B)(i) and 986(a)(2)(A) and § 1.986(a)–1(a)(2)(i). X may so notify the IRS by filing a second amended return, Form 1118, and the statement described in paragraph (c) of this section for Year 1, within the time period provided by section 6511. Alternatively, under paragraph (b)(1)(iv) of this section, when X redetermines its U.S. tax liability for Year 1 to take into account the 10n refund from Country N that occurred in Year 5, X may also take into account the 20m additional assessment by Country M that occurred on March 15, Year 6. If X reflects both foreign tax redeterminations on the same amended return, Form 1118, and in the statement described in paragraph (c) of this section for Year 1, the amount of X's foreign income taxes available as a credit would be reduced by $10 (10n refund translated at $1:1n), and increased by $24 (20m additional assessment translated at the spot rate on the date of payment, March 15, Year 6, or $1.20:1m). The foreign income taxes available as a credit therefore would be increased by $14 ($24 (additional assessment) − $10 (refund)). Because the net effect of the foreign tax redeterminations is to increase the amount of foreign taxes paid or accrued and decrease X's U.S. tax liability for Year 1, under paragraph (b)(1)(iv) of this section the Year 1 amended return, Form 1118, and the statement required in paragraph (c) of this section reflecting foreign tax redeterminations in both years must be filed within the period provided by section 6511.

(F) With respect to Year 2, under paragraph (b)(1)(ii) of this section X must notify the IRS by filing an amended return, Form 1118, and the statement required by paragraph (c) of this section for Year 2, in addition to the amended return, Form 1118, and statement that are required by reason of the separate foreign tax redeterminations that affect Year 1. The amended return, Form 1118, and the statement required by paragraph (c) of this section for Year 2 must be filed by the due date (with extensions) of X's original return for Year 6. The amended return and Form 1118 must reflect the reduced amount of foreign income taxes claimed as a credit under section 901 and the increase in X's U.S. tax liability of $7.50 (5n refund translated at the average exchange rate for Year 2, or $1.50:1n).

(ii) *Example 2.* X, a taxpayer within the jurisdiction of the Large Business and International Division, uses the calendar year as its U.S. taxable year. On November 15, Year 2, X receives a refund of foreign income taxes that constitutes a foreign tax redetermination and necessitates a redetermination of U.S. tax liability for X's Year 1 taxable year. Under paragraph (b)(1)(ii) of this section, X is required to notify the IRS of the foreign tax redetermination that increased its U.S. tax liability by filing an amended return, Form 1118, and the statement described in paragraph (c) of this section for its Year 1 taxable year by October 15, Year 3 (the due date (with extensions) of the original return for X's Year 2 taxable year). On December 15, Year 3, the IRS hand delivers an opening letter concerning the examination of the return for X's Year 1 taxable year, and the opening conference for such examination is scheduled for January 15, Year 4. Because the date for notifying the IRS of the foreign tax redetermination under paragraph (b)(1)(ii) of this section (October 15, Year 3) is before the date of the opening conference concerning the examination of the return for X's Year 1 taxable year (January 15, Year 4), the condition of paragraph (b)(4)(i)(E) of this section is not met, and so paragraph (b)(4)(i) of this section does not apply. Accordingly, X must notify the IRS of the foreign tax redetermination by filing an amended return, Form 1118, and the statement described in paragraph (c) of this section for the Year 1 taxable year by October 15, Year 3.

(6) *Transition rule for certain foreign tax redeterminations.* In the case of foreign tax redeterminations occurring in taxable years ending on or after December 16, 2019, and before November 12, 2020, and foreign tax redeterminations of foreign corporations occurring in taxable years that end with or within a taxable year of a United States shareholder ending on or after December 16, 2019, and before November 12, 2020, any amended return or other notification that under paragraph (b)(1)(ii), (iv), or (v) or

(b)(2)(ii) of this section must be filed by the due date (with extensions) of, or attached to, the original return for the taxpayer's taxable year in which the foreign tax redetermination occurs must instead be filed by the due date (with extensions) of, or attached to, the original return for the taxpayer's first taxable year ending on or after November 12, 2020. For purposes of paragraph (b)(4)(i)(E) of this section, the relevant due date is the due date specified in this paragraph (b)(6).

(c) *Notification contents.* The statement required by paragraphs (b)(1)(i) through (iv) and (b)(2) of this section must contain information sufficient for the IRS to redetermine U.S. tax liability if such a redetermination is required under section 905(c). The information must be in a form that enables the IRS to verify and compare the original computation of U.S. tax liability, the revised computation resulting from the foreign tax redetermination, and the net changes resulting therefrom. The statement must include the following:

(1) The taxpayer's name, address, identifying number, the taxable year or years of the taxpayer that are affected by the foreign tax redetermination, and, in the case of foreign taxes deemed paid, the name and identifying number, if any, of the foreign corporation;

(2) The date or dates the foreign income taxes were accrued, if applicable; the date or dates the foreign income taxes were paid; the amount of foreign income taxes paid or accrued on each date (in foreign currency) and the exchange rate used to translate each such amount, as provided in § 1.986(a)–1(a) or (b);

(3) Information sufficient to determine any change to the characterization of a distribution, the amount of any inclusion under section 951(a), 951A, or 1293, or the deferred tax amount under section 1291;

(4) Information sufficient to determine any interest due from or owing to the taxpayer, including the amount of any interest paid by the foreign government to the taxpayer and the dates received;

(5) In the case of any foreign income tax that is refunded in whole or in part, the taxpayer must provide the date of each such refund; the amount of such refund (in foreign currency); and the exchange rate that was used to translate such amount when originally claimed as a credit (as provided in § 1.986(a)–1(c)) and the spot rate (as defined in § 1.988–1(d)) for the date the refund was received (for purposes of computing foreign currency gain or loss under section 988);

(6) In the case of any foreign income taxes that are not paid on or before the date that is 24 months after the close of the taxable year to which such taxes relate, the amount of such taxes in foreign currency, and the exchange rate that was used to translate such amount when originally claimed as a credit or added to PTEP group taxes (as defined in § 1.960–3(d)(1));

(7) If a redetermination of U.S. tax liability results in an amount of additional tax due, and the carryback or carryover of an unused foreign income tax under section 904(c) only partially eliminates such amount, the information required in § 1.904–2(f); and

(8) In the case of a pass-through entity, the name, address, and identifying number of each beneficial owner to which foreign taxes were reported for the taxable year or years to which the foreign tax redetermination relates, and the amount of foreign tax initially reported to each beneficial owner for each such year and the amount of foreign tax allocable to each beneficial owner for each such year after the foreign tax redetermination is taken into account.

(d) *Payment or refund of U.S. tax.* The amount of tax, if any, due upon a redetermination of U.S. tax liability is paid by the taxpayer after notice and demand has been made by the IRS. Subchapter B of chapter 63 of the Internal Revenue Code (relating to deficiency procedures) does not apply with respect to the assessment of the amount due upon such redetermination. In accordance with sections 905(c) and 6501(c)(5), the amount of additional tax due is assessed and collected without regard to the provisions of section 6501(a) (relating to limitations on assessment and collection). The amount of tax, if any, shown by a redetermination of U.S. tax liability to have been overpaid is credited or refunded to the taxpayer in accordance with subchapter B of chapter 66 (sections 6511 through 6515).

(e) *Interest and penalties*—(1) *In general.* If a redetermination of U.S. tax liability is required by reason of a foreign tax redetermination, interest is computed on the underpayment or overpayment in accordance with sections 6601 and 6611. No interest is assessed or collected on any underpayment resulting from a refund of foreign income taxes for any period before the receipt of the refund, except to the extent interest was paid by the foreign country or possession of the United States on the refund for the period before the receipt of the refund. See section 905(c)(5). In no case, however, will interest assessed and collected pursuant to the preceding sentence for any period before receipt of the refund exceed the amount that otherwise would have been assessed and collected under section 6601 for that period. Interest is assessed from the time the taxpayer (or the foreign corporation, partnership, trust, or other pass-through entity of which the taxpayer is a shareholder, partner, or beneficiary) receives a refund until the taxpayer pays the additional tax due the United States.

(2) *Imposition of penalty.* Failure to comply with the provisions of this section subjects the taxpayer to the penalty provisions of section 6689 and § 301.6689–1 of this chapter.

(f) *Applicability date.* This section applies to foreign tax redeterminations (as defined in § 1.905–3(a)) occurring in taxable years ending on or after December 16, 2019, and to foreign tax redeterminations of foreign corporations occurring in taxable years that end with or within a taxable year of a United States shareholder ending on or after December 16, 2019.

§ 1.905–4T [REMOVED]

■ **Par. 23.** Section 1.904–4T is removed.

■ **Par. 24.** Section 1.905–5 is added to read as follows:

§ 1.905–5 Foreign tax redeterminations of foreign corporations that relate to taxable years of the foreign corporation beginning before January 1, 2018.

(a) *In general*—(1) *Effect of foreign tax redetermination of a foreign corporation.* Except as provided in paragraph (e) of this section, a foreign tax redetermination (as defined in § 1.905–3(a)) of a foreign corporation that relates to a taxable year of the foreign corporation beginning before January 1, 2018, and that may affect a taxpayer's foreign tax credit in any taxable year, must be accounted for by adjusting the foreign corporation's taxable income and earnings and profits, post-1986 undistributed earnings as defined in § 1.902–1(a)(9), and post-1986 foreign income taxes as defined in § 1.902–1(a)(8) (or its pre-1987 accumulated profits as defined in § 1.902–1(a)(10)(i) and pre-1987 foreign income taxes as defined in § 1.902–1(a)(10)(iii), as applicable) in the taxable year of the foreign corporation to which the foreign taxes relate.

(2) *Required redetermination of U.S. tax liability.* Except as provided in paragraph (e) of this section, a redetermination of U.S. tax liability is required to account for the effect of the foreign tax redetermination on the earnings and profits and taxable income

of the foreign corporation, the taxable income of a United States shareholder, and the amount of foreign taxes deemed paid by the United States shareholder under section 902 or 960 (as in effect before December 22, 2017), in the year to which the redetermined foreign taxes relate. For example, in the case of a refund of foreign income taxes, the subpart F income, earnings and profits, and post-1986 undistributed earnings (or pre-1987 accumulated profits, as applicable) of the foreign corporation are increased in the year to which the foreign tax relates to reflect the functional currency amount of the foreign income tax refund. The required redetermination of U.S. tax liability must account for the effect of the foreign tax redetermination on the characterization and amount of distributions or inclusions under section 951 or 1293 taken into account by each of the foreign corporation's United States shareholders and on the application of the high-tax exception described in section 954(b)(4), as well as on the amount of foreign income taxes deemed paid in such year. In addition, a redetermination of U.S. tax liability is required for any subsequent taxable year in which the United States shareholder received or accrued a distribution or inclusion from the foreign corporation, up to and including the taxable year in which the foreign tax redetermination occurs, as well as any year to which unused foreign taxes from such year were carried under section 904(c).

(b) *Notification requirements*—(1) *In general.* The notification requirements of § 1.905–4, as modified by paragraphs (b)(2) and (3) of this section, apply if a redetermination of U.S. tax liability is required under paragraph (a) or (e) of this section.

(2) *Notification relating to post-1986 undistributed earnings and post-1986 foreign income taxes.* In the case of foreign tax redeterminations with respect to taxes included in post-1986 foreign income taxes, in addition to the information required by § 1.905–4(c), the taxpayer must provide the balances of the pools of post-1986 undistributed earnings and post-1986 foreign income taxes before and after adjusting the pools, the dates and amounts of any dividend distributions or other inclusions made out of earnings and profits for the affected year or years, and the amount of earnings and profits from which such dividends were paid or such inclusions were made for the affected year or years.

(3) *Notification relating to pre-1987 accumulated profits and pre-1987 foreign income taxes.* In the case of foreign tax redeterminations with respect to pre-1987 accumulated profits, in addition to the information required by § 1.905–4(c), the taxpayer must provide the following: The dates and amounts of any dividend distributions made out of earnings and profits for the affected year or years; the rate of exchange on the date of any such distribution; and the amount of earnings and profits from which such dividends were paid for the affected year or years.

(c) *Currency translation rules for adjustments to pre-1987 foreign income taxes.* Foreign income taxes paid with respect to pre-1987 accumulated profits that are deemed paid under section 960 (or under section 902 in the case of an amount treated as a dividend under section 1248) are translated into dollars at the spot rate for the date of the payment of the foreign income taxes, and refunds of such taxes are translated into dollars at the spot rate for the date of the refund. Foreign income taxes deemed paid by a taxpayer under section 902 with respect to an actual distribution of pre-1987 accumulated profits and refunds of such taxes are translated into dollars at the spot rate for the date of the distribution of the earnings to which the foreign income taxes relate. See section 902(c)(6) (as in effect before December 22, 2017) and § 1.902–1(a)(10)(iii). For purposes of this section, the term *spot rate* has the meaning provided in § 1.988–1(d).

(d) *Timing and effect of pooling adjustments.* The redetermination of U.S. tax liability required by paragraphs (a) and (e) of this section is made in accordance with section 905(c) as in effect for those taxable years, without regard (except as provided in paragraph (e) of this section) to rules that required adjustments to a foreign corporation's pools of post-1986 undistributed earnings and post-1986 foreign income taxes in the year of the foreign tax redetermination rather than in the year to which the redetermined foreign tax relates. No underpayment or overpayment of U.S. tax liability results from a foreign tax redetermination unless the required adjustments change the U.S. tax liability. Consequently, no interest is paid by or to a taxpayer as a result of adjustments, required by reason of a foreign tax redetermination, to a foreign corporation's pools of post-1986 undistributed earnings and post-1986 foreign income taxes in the year to which the redetermined foreign tax relates (or a subsequent year) that did not result in a change to U.S. tax liability, for example, because no foreign taxes were deemed paid in that year.

(e) *Election to account for certain foreign tax redeterminations with respect to pre-2018 taxable years in the foreign corporation's last pooling year*—(1) *In general.* A taxpayer may elect under the rules in paragraph (e)(2) of this section to account for foreign tax redeterminations of a foreign corporation that occur in the foreign corporation's taxable years ending with or within a taxable year of a United States shareholder of the foreign corporation ending on or after November 2, 2020, and that relate to taxable years of the foreign corporation beginning before January 1, 2018, by treating such foreign tax redeterminations as if they occurred in the foreign corporation's last taxable year beginning before January 1, 2018 (the ''last pooling year''), and applying the rules in §§ 1.905–3T(d) and 1.905–5T for purposes of determining whether the foreign tax redetermination is accounted for in the foreign corporation's last pooling year or must be accounted for in the year to which the redetermined foreign tax relates. Except with respect to determining under the preceding sentence whether the foreign tax redetermination is accounted for in the foreign corporation's last pooling year or in the year to which the redetermined foreign tax relates, the rules of this section apply to foreign tax redeterminations covered by an election under this paragraph (e). Therefore, unless an exception in § 1.905–3T(d)(3) applies, a foreign tax redetermination to which an election under this paragraph (e) applies is accounted for under paragraph (a)(2) of this section by adjusting the foreign corporation's pools of post-1986 undistributed earnings and post-1986 foreign income taxes in the last pooling year, rather than in the year to which the redetermined foreign tax relates. For purposes of this paragraph (e), references to §§ 1.905–3T and 1.905–5T are to such provisions as contained in 26 CFR part 1, revised as of April 1, 2019.

(2) *Rules regarding the election*—(i) *Time and manner of election.* For a foreign corporation's first taxable year that ends with or within a taxable year of a United States shareholder of the foreign corporation ending on or after November 2, 2020 in which the foreign corporation has a foreign tax redetermination (the ''first redetermination year''), the controlling domestic shareholders (as defined in § 1.964–1(c)(5)) of the foreign corporation make the election described in paragraph (e)(1) of this section by—

(A) Filing the statement required under § 1.964–1(c)(3)(ii) with a timely filed original income tax return for the taxable year of each controlling

domestic shareholder of the foreign corporation in which or with which the foreign corporation's first redetermination year ends;

(B) Providing any notices required under § 1.964–1(c)(3)(iii);

(C) Filing amended returns as required under § 1.905–4 and this section for each controlling domestic shareholder's taxable year with or within which ends the foreign corporation's last pooling year and each other affected year before the controlling domestic shareholder's taxable year with or within which ends the foreign corporation's first redetermination year reflecting a redetermination of the controlling domestic shareholder's U.S. tax liability for each such taxable year, in cases where a redetermination of the shareholder's U.S. tax liability for taxable years ending before the foreign corporation's last pooling year ends is not required under the rules in §§ 1.905–3T(d) and 1.905–5T;

(D) Filing amended returns as required under § 1.905–4 and this section with respect to each affected year before the controlling domestic shareholder's taxable year with or within which ends the foreign corporation's first redetermination year reflecting a redetermination of the controlling domestic shareholder's U.S. tax liability for each such taxable year, in cases where a redetermination of the shareholder's U.S. tax liability for taxable years ending before the foreign corporation's last pooling year ends is required under the rules in §§ 1.905–3T(d) and 1.905–5T and this section; and

(E) Providing any additional information required by applicable administrative pronouncements.

(ii) *Scope, duration, and effect of election.* An election under paragraph (e)(1) of this section with respect to the first redetermination year of a foreign corporation is binding on all persons who are, or were in a prior year to which the election applies, United States shareholders of the foreign corporation. In addition, such election applies to all foreign tax redeterminations in the first redetermination year and all subsequent taxable years of such foreign corporation and cannot be revoked. For foreign tax redeterminations that occur in taxable years after the first redetermination year, all United States shareholders of such foreign corporation must account for the foreign tax redeterminations under the rules in paragraph (e)(1) of this section by filing amended returns and providing other information as required by § 1.905–4 and paragraphs (e)(2)(i)(C) through (E) of this section.

(iii) *Requirements for valid election.* An election under paragraph (e)(1) of this section is valid only if all of the requirements in paragraph (e)(2)(i) of this section, including the requirement to provide notice under paragraph (e)(2)(i)(B) of this section, are satisfied by each of the controlling domestic shareholders with respect to the first redetermination year.

(iv) *CFC group conformity requirement*—(A) *In general.* An election made under paragraph (e)(1) of this section applies to all controlled foreign corporations that are members of the same CFC group, and the rules in paragraphs (e)(1) and (e)(2)(i) through (iii) of this section apply by reference to the CFC group. Therefore, an election by the controlling domestic shareholders of any controlled foreign corporation with respect to that controlled foreign corporation's first redetermination year also applies to foreign tax redeterminations of all members of the CFC group that includes that controlled foreign corporation, determined as of the close of that controlled foreign corporation's first redetermination year. The election is binding on all persons who are, or were in a prior year to which the election applies, United States shareholders of any member of the CFC group, applies with respect to foreign tax redeterminations of each member that occur in and after that member's first taxable year with or within which ends such controlled foreign corporation's first redetermination year, and cannot be revoked.

(B) *Determination of the CFC group*—(*1*) *Definition.* Subject to the rules in paragraphs (b)(2)(iv)(B)(*2*) and (*3*) of this section, the term *CFC group* means an affiliated group as defined in section 1504(a) without regard to section 1504(b)(1) through (6), except that section 1504(a) is applied by substituting ''more than 50 percent'' for ''at least 80 percent'' each place it appears, and section 1504(a)(2)(A) is applied by substituting ''or'' for ''and.'' For purposes of this paragraph (e)(2)(iv)(B)(*1*), stock ownership is determined by applying the constructive ownership rules of section 318(a), other than section 318(a)(3)(A) and (B), by applying section 318(a)(4) only to options (as defined in § 1.1504–4(d)) that are reasonably certain to be exercised as described in § 1.1504–4(g), and by substituting in section 318(a)(2)(C) ''5 percent'' for ''50 percent.''

(*2*) *Member of a CFC group.* The determination of whether a controlled foreign corporation is included in a CFC group is made as of the close of the first redetermination year of any controlled foreign corporation for which an election is made under paragraph (e)(1) of this section. One or more controlled foreign corporations are members of a CFC group if the requirements of paragraph (e)(2)(iv)(B)(*2*) of this section are satisfied as of the end of the first redetermination year of at least one of the controlled foreign corporations, even if the requirements are not satisfied as of the end of the first redetermination year of all controlled foreign corporations. If the controlling domestic shareholders do not have the same taxable year, the determination of whether a controlled foreign corporation is a member of a CFC group is made with respect to the first redetermination year that ends with or within the taxable year of the majority of the controlling domestic shareholders (determined based on voting power) or, if no such majority taxable year exists, the calendar year.

(*3*) *Controlled foreign corporations included in only one CFC group.* A controlled foreign corporation cannot be a member of more than one CFC group. If a controlled foreign corporation would be a member of more than one CFC group under paragraph (e)(2)(iv)(B)(*2*) of this section, then ownership of stock of the controlled foreign corporation is determined by applying paragraph (e)(2)(iv)(B)(*2*) of this section without regard to section 1504(a)(2)(B) or, if applicable, by reference to the ownership existing as of the end of the first redetermination year of a controlled foreign corporation that would cause a CFC group to exist.

(3) *Rules for successor entities.* All of the United States persons that own equity interests in a successor entity to a foreign corporation (''U.S. owners'') may elect under the principles of paragraph (e)(2) of this section to apply the rules in paragraph (e)(1) to foreign tax redeterminations of such foreign corporation that occur in taxable years of the successor entity that end with or within taxable years of its U.S. owners ending on or after November 2, 2020.

(f) *Applicability date.* This section applies to foreign tax redeterminations (as defined in § 1.905–3(a)) of foreign corporation and successor entities that occur in taxable years that end with or within taxable years of a United States shareholder or other United States persons ending on or after November 2, 2020, and that relate to taxable years of such foreign corporations beginning before January 1, 2018.

§ 1.905–5T [REMOVED]

■ **Par. 25.** Section 1.905–5T is removed.

■ **Par. 26.** Section 1.951A–2 is amended by adding paragraph (c)(6) to read as follows:

§ 1.951A–2 Tested income and tested loss.

* * * * *

(c) * * *

(6) *Allocation of deductions attributable to disqualified payments*—(i) *In general.* A deduction related directly or indirectly to a disqualified payment is allocated and apportioned solely to residual CFC gross income, and any deduction related to a disqualified payment is not properly allocable to property produced or acquired for resale under section 263, 263A, or 471.

(ii) *Definitions.* The following definitions apply for purposes of this paragraph (c)(6).

(A) *Disqualified payment.* The term *disqualified payment* means a payment made by a person to a related recipient CFC during the disqualified period with respect to the related recipient CFC, to the extent the payment would constitute income described in section 951A(c)(2)(A)(i) and paragraph (c)(1) of this section without regard to whether section 951A applies.

(B) *Disqualified period.* The term *disqualified period* has the meaning provided in § 1.951A–3(h)(2)(ii)(C)(*1*), substituting ''related recipient CFC'' for ''transferor CFC.''

(C) *Related recipient CFC.* The term *related recipient CFC* means, with respect to a payment by a person, a recipient of the payment that is a controlled foreign corporation that bears a relationship to the payor described in section 267(b) or 707(b) immediately before or after the payment.

(iii) *Treatment of partnerships.* For purposes of determining whether a payment is made by a person to a related recipient CFC for purposes of paragraph (c)(6)(ii)(A) of this section, a payment by or to a partnership is treated as made proportionately by or to its partners, as applicable.

(iv) *Examples.* The following examples illustrate the application of this paragraph (c)(6).

(A) *Example 1: Deduction related directly to disqualified payment to related recipient CFC*—(*1*) *Facts.* USP, a domestic corporation, owns all of the stock in CFC1 and CFC2, each a controlled foreign corporation. Both USP and CFC2 use the calendar year as their taxable year. CFC1 uses a taxable year ending November 30. On October 15, 2018, before the start of its first CFC inclusion year, CFC1 receives and accrues a payment from CFC2 of $100x of prepaid royalties with respect to a license. The $100x payment is excluded from subpart F income pursuant to section 954(c)(6) and would constitute income described in section 951A(c)(2)(A)(i) and paragraph (c)(1) of this section without regard to whether section 951A applies.

(*2*) *Analysis.* CFC1 is a related recipient CFC (within the meaning of paragraph (c)(6)(ii)(C) of this section) with respect to the royalty prepayment by CFC2 because it is related to CFC2 within the meaning of section 267(b). The royalty prepayment is received by CFC1 during its disqualified period (within the meaning of paragraph (c)(6)(ii)(B) of this section) because it is received during the period beginning January 1, 2018, and ending November 30, 2018. Because it would constitute income described in section 951A(c)(2)(A)(i) and paragraph (c)(1) of this section without regard to whether section 951A applies, the payment is a disqualified payment. Accordingly, CFC2's deductions related to such payment accrued during taxable years ending on or after April 7, 2020, are allocated and apportioned solely to residual CFC gross income under paragraph (c)(6)(i) of this section.

(B) *Example 2: Deduction related indirectly to disqualified payment to partnership in which related recipient CFC is a partner*—(*1*) *Facts.* The facts are the same as in paragraph (c)(6)(iv)(A)(*1*) of this section (the facts in *Example 1*), except that CFC1 and USP own 99% and 1%, respectively of FPS, a foreign partnership, which has a taxable year ending November 30. USP receives a prepayment of $110x from CFC2 for the performance of future services. USP subcontracts the performance of these future services to FPS for which FPS receives and accrues a $100x prepayment from USP. The services will be performed in the same country under the laws of which CFC1 and FPS are created or organized, and the $100x prepayment is not foreign base company services income under section 954(e) and § 1.954–4(a). The $100x prepayment would constitute income described in section 951A(c)(2)(A)(i) and paragraph (c)(1) of this section without regard to whether section 951A applies.

(*2*) *Analysis.* CFC1 is a related recipient CFC (within the meaning of paragraph (c)(6)(ii)(C) of this section) with respect to the services prepayment by USP because, under paragraph (c)(6)(iii) of this section, it is treated as receiving $99x (99% of $100x) of the services prepayment from USP, and it is related to USP within the meaning of section 267(b). The services prepayment is received by CFC1 during its disqualified period (within the meaning of paragraph (c)(6)(ii)(B) of this section) because it is received during the period beginning January 1, 2018, and ending November 30, 2018. Because it would constitute income described in section 951A(c)(2)(A)(i) and paragraph (c)(1) of this section without regard to whether section 951A applies, the prepayment is a disqualified payment. In addition, CFC2's deductions related to its prepayment to USP are indirectly related to the disqualified payment by USP. Accordingly, CFC2's deductions related to such payment accrued during taxable years ending on or after April 7, 2020 are allocated and apportioned solely to residual CFC gross income under paragraph (c)(6)(i) of this section.

* * * * *

■ **Par. 27.** Section 1.951A–7 is amended by adding reserved paragraph (c) and paragraph (d) to read as follows:

§ 1.951A–7 Applicability dates.

* * * * *

(d) *Deduction for disqualified payments.* Section 1.951A–2(c)(6) applies to taxable years of foreign corporations ending on or after April 7, 2020, and to taxable years of United States shareholders in which or with which such taxable years end.

■ **Par. 28.** Section 1.954–1 is amended by:

■ 1. In paragraph (c)(1)(i)(C), removing the language ''reduced by related person'' and adding the language ''reduced (but not below zero) by related person'' in its place.

■ 2. Adding two sentences to the end of paragraph (d)(3)(iii).

■ 3. Revising paragraph (h)(1).

The revision and additions read as follows:

§ 1.954–1 Foreign base company income.

* * * * *

(d) * * *

(3) * * *

(iii) * * * In addition, foreign income taxes that have not been paid or accrued because they are contingent on a future distribution of earnings are not taken into account for purposes of this paragraph (d)(3). If, pursuant to section 905(c) and § 1.905–3(b)(2), a redetermination of U.S. tax liability is required to account for the effect of a foreign tax redetermination (as defined in § 1.905–3(a)), this paragraph (d) is applied in the adjusted year taking into account the adjusted amount of the redetermined foreign tax.

* * * * *

(h) * * *

(1) *Paragraph (d)(3) of this section.* Paragraph (d)(3) of this section applies to taxable years of a controlled foreign corporation ending on or after December

16, 2019. For taxable years of a controlled foreign corporation ending on or after December 4, 2018, but ending before December 16, 2019, see § 1.954–1(d)(3) as contained in 26 CFR part 1 revised as of April 1, 2019.

* * * * *

■ **Par. 29.** Section 1.954–2 is amended by:

■ 1. Removing the text ''and'' from paragraph (h)(2)(i)(H).

■ 2. Redesignating paragraph (h)(2)(i)(I) as paragraph (h)(2)(i)(J).

■ 3. Adding a new paragraph (h)(2)(i)(I).

■ 4. Adding a sentence to the end of paragraph (i)(3).

The additions read as follows:

§ 1.954–2 Foreign personal holding company income.

* * * * *

(h) * * *

(2) * * *

(i) * * *

(I) Any guaranteed payments for the use of capital under section 707(c); and

* * * * *

(i) * * *

(3) * * * Paragraph (h)(2)(i)(I) of this section applies to taxable years of controlled foreign corporations ending on or after December 16, 2019, and to taxable years of United States shareholders in which or with which such taxable years end.

■ **Par. 30.** Section 1.960–1 is amended by:

■ 1. Adding a sentence at the end of paragraph (c)(2).

■ 2. Revising paragraphs (d)(3)(ii)(A) and (B).

■ 3. Removing paragraph (d)(3)(ii)(C).

The addition and revisions read as follows:

§ 1.960–1 Overview, definitions, and computational rules for determining foreign income taxes deemed paid under section 960(a), (b), and (d).

* * * * *

(c) * * *

(2) * * * An item of income with respect to a current taxable year does not include an amount included as subpart F income of a controlled foreign corporation by reason of the recharacterization of a recapture account established in a prior U.S. taxable year (and the corresponding earnings and profits) of the controlled foreign corporation under section 952(c)(2) and § 1.952–1(f).

* * * * *

(d) * * *

(3) * * *

(ii) * * *

(A) *In general.* A current year tax is allocated and apportioned among the section 904 categories under the rules of § 1.904–6. An amount of the current year tax that is allocated and apportioned to a section 904 category is then allocated and apportioned among the income groups within the section 904 category under § 1.861–20 (as modified by § 1.904–6(c)) by treating each income group as a statutory grouping and treating the residual income group as the residual grouping. Therefore, foreign gross income attributable to a base difference is assigned to the residual income grouping under § 1.861–20(d)(2)(ii)(B). See, however, paragraph (d)(3)(ii)(B) of this section for special rules for applying § 1.861–20 in the case of PTEP groups. For purposes of determining foreign income taxes deemed paid under the rules in §§ 1.960–2 and 1.960–3, the U.S. dollar amount of a current year tax is assigned to the section 904 categories, income groups, and PTEP groups (to the extent provided in paragraph (d)(3)(ii)(B) of this section) to which the current year tax is allocated and apportioned.

(B) *Foreign taxable income that includes previously taxed earnings and profits.* For purposes of allocating and apportioning a current year tax under this paragraph (d)(3)(ii), a PTEP group that is increased under § 1.960–3(c)(3) as a result of the receipt of a section 959(b) distribution in the current taxable year of the controlled foreign corporation is treated as an income group within the section 904 category. In such case, under § 1.861–20, the portion of the foreign gross income (as defined in § 1.861–20(b)(5)) that is characterized under Federal income tax principles as a distribution of previously taxed earnings and profits that results in the increase in the PTEP group in the current taxable year is assigned to that PTEP group. If a PTEP group is not treated as an income group under the first sentence of this paragraph (d)(3)(ii)(B), and the rules of § 1.861–20 would otherwise apply to assign foreign gross income to a PTEP group, that foreign gross income is instead assigned to the subpart F income group or tested income group to which the income that gave rise to the previously taxed earnings and profits would be assigned if the income were recognized by the recipient controlled foreign corporation under Federal income tax principles in the current taxable year. For example, a net basis or withholding tax imposed on a controlled foreign corporation's receipt of a section 959(b) distribution is allocated or apportioned to a PTEP group. In contrast, a withholding tax imposed on a disregarded payment from a disregarded entity to its controlled foreign corporation owner is never treated as related to a PTEP group, even if all of the controlled foreign corporation's earnings are previously taxed earnings and profits, because the payment that gives rise to the foreign gross income from which the tax was withheld does not constitute a section 959(b) distribution in the current taxable year. That foreign gross income, however, may be assigned to a subpart F income group or tested income group.

* * * * *

■ **Par. 31.** Section 1.960–2 is amended by adding a sentence at the end of paragraph (b)(3)(iii) to read as follows:

§ 1.960–2 Foreign income taxes deemed paid under sections 960(a) and (d).

* * * * *

(b) * * *

(3) * * *

(iii) * * * See § 1.960–1(c)(2) for a rule regarding the treatment of an increase in the subpart F income of a controlled foreign corporation by reason of the recharacterization of a recapture account and the corresponding accumulated earnings and profits under section 952(c) and § 1.952–1(f).

* * * * *

§ 1.960–3 [Amended]

■ **Par. 32.** Section 1.960–3 is amended by removing the language ''§ 1.951A–6(b)(2)'' from the twelfth sentence of paragraph (e)(2)(i) and adding the language ''§ 1.951A–5(b)(2)'' in its place.

■ **Par. 33.** Section 1.960–4 is amended in table 2 to paragraph (f)(1) by revising the entry ''Limitation for Year 2 before increase under section 960(c)(1) ($10.50x × $0/$50x)'' to read as follows:

§ 1.960–4 Additional foreign tax credit in year of receipt of previously taxed earnings and profits.

* * * * *

(f) * * *

(1) * * *

TABLE 2 TO PARAGRAPH (f)(1)

*	*	*	*	*	*	*
Limitation for Year 2 before increase under section 960(c)(1) ($10.50x × $0/$50x)						0
*	*	*	*	*	*	*

* * * * *

■ **Par. 34.** Section 1.960–7 is revised to read as follows:

§ 1.960–7 Applicability dates.

(a) Except as provided in paragraph (b) of this section, §§ 1.960–1 through 1.960–6 apply to each taxable year of a foreign corporation ending on or after December 4, 2018, and to each taxable year of a domestic corporation that is a United States shareholder of the foreign corporation in which or with which such taxable year of such foreign corporation ends.

(b) Section 1.960–1(c)(2) and (d)(3)(ii) applies to taxable years of a foreign corporation beginning after December 31, 2019, and to each taxable year of a domestic corporation that is a United States shareholder of the foreign corporation in which or with which such taxable year of such foreign corporation ends. For taxable years of a foreign corporation that end on or after December 4, 2018, and also begin before January 1, 2020, see § 1.960–1(c)(2) and (d)(3)(ii) as in effect on December 17, 2019.

■ **Par. 35.** Section 1.965–5 is amended by:

■ 1. Designating the text of paragraph (b) as paragraph (b)(1).

■ 2. Adding a heading for newly designated paragraph (b)(1).

■ 3. Adding paragraph (b)(2).

The revision and additions read as follows:

§ 1.965–5 Allowance of a credit or deduction for foreign income taxes.

* * * * *

(b) * * *

(1) *In general.* * * *

(2) *Attributing taxes to section 959(a) distributions of section 965 previously taxed earnings and profits.* For purposes of paragraph (b)(1) of this section, foreign income taxes are attributable to a distribution of section 965(a) previously taxed earnings and profits or section 965(b) previously taxed earnings and profits if such taxes would be allocated and apportioned to a distribution of such previously taxed earnings and profits under the principles of § 1.904–6(a)(1)(iv), regardless of whether an actual distribution is made or recognized for Federal income tax purposes. Therefore, for example, a credit or deduction for the applicable percentage of foreign income taxes imposed on a United States shareholder that pays foreign tax on a distribution that is not recognized for Federal income tax purposes (for example, in the case of a consent dividend or stock dividend upon which a withholding tax is imposed) is not allowed under paragraph (b)(1) of this section to the extent it is attributable to a distribution of section 965(a) previously taxed earnings and profits or section 965(b) previously taxed earnings and profits under the principles of § 1.904–6(a)(1)(iv). For taxable years of foreign corporations beginning after December 31, 2019, in lieu of applying the principles of § 1.904–6 under this paragraph (b)(2), the rules in § 1.861–20 apply by treating the portion of a distribution attributable to section 965(a) previously taxed earnings and profits and the portion of a distribution attributable to section 965(b) previously taxed earnings and profits each as a statutory grouping, and the portion of the distribution that is attributable to other earnings and profits as the residual grouping. See § 1.861–20(g)(7) (*Example 6*).

* * * * *

■ **Par. 36.** Section 1.965–9 is amended by adding a sentence to the end of paragraph (c) to read as follows:

§ 1.965–9 Applicability dates.

* * * * *

(c) * * * Section 1.965–5(b)(2) applies to taxable years of foreign corporations that end on or after December 16, 2019, and with respect to a United States person, to the taxable years in which or with which such taxable years of the foreign corporations end.

■ **Par. 37.** Section 1.1502–4 is revised to read as follows:

§ 1.1502–4 Consolidated foreign tax credit.

(a) *In general.* The foreign tax credit under section 901 is allowed to the group only if the agent for the group (as defined in § 1.1502–77(a)) chooses to use the credit in the computation of the consolidated tax liability of the group for the consolidated return year. If that choice is made, section 275(a)(4) provides that no deduction against taxable income may be taken on the consolidated return for foreign taxes paid or accrued by any member. However, if section 275(a)(4) does not apply, a deduction against consolidated taxable income may be allowed for certain taxes for which a credit is not allowed, even though the choice is made to claim a credit for other taxes. See, for example, sections 901(j)(3), 901(k)(7), 901(l)(4), 901(m)(6), and 908(b).

(b) *Computation of foreign tax credit.* The foreign tax credit for the consolidated return year is determined on a consolidated basis under the principles of sections 901 through 909 and 960. All foreign income taxes paid or accrued by members of the group for the year (including those deemed paid under section 960 and paragraph (d) of this section) must be aggregated.

(c) *Computation of limitation on credit.* For purposes of computing the group's limiting fraction under section 904, the following rules apply:

(1) *Computation of taxable income from foreign sources*—(i) *Separate categories.* The group must compute a separate foreign tax credit limitation for income in each separate category (as defined in § 1.904–5(a)(4)(v)) for purposes of this section. The numerator of the limiting fraction in any separate category is the consolidated taxable income of the group determined in accordance with § 1.1502–11, taking into account adjustments required under section 904(b), if any, from sources without the United States in that category, determined in accordance with the rules of §§ 1.904–4 and 1.904–5 and the section 861 regulations (as defined in § 1.861–8(a)(1)).

(ii) *Adjustments under sections 904(f) and (g).* The rules for allocation and recapture of separate limitation losses and overall foreign losses under section 904(f) and § 1.1502–9 apply to determine the foreign source and U.S. source taxable income in each separate category of the consolidated group. Similarly, the rules for allocation and recapture of overall domestic losses under section 904(g) and § 1.1502–9 apply to determine the foreign source and U.S. source taxable income in each separate category of the consolidated group. See § 1.904(g)–3 for allocation rules under sections 904(f) and 904(g).

The rules of sections 904(f) and 904(g) do not operate to recharacterize foreign income tax attributable to any separate category.

(iii) *Computation of consolidated net operating loss.* The source and separate category of the group's consolidated net operating loss (''CNOL''), as that term is defined in § 1.1502–21(e), for the taxable year, if any, is determined based on the amounts of any separate limitation losses and U.S. source loss that are not allocated to reduce U.S. source income or income in other separate categories under the rules of sections 904(f) and 904(g) in computing the group's consolidated foreign tax credit limitations for the taxable year under paragraphs (c)(1)(i) and (ii) of this section.

(iv) *Characterization of CNOL carried to a separate return year*—(A) *In general.* The total amount of CNOL attributable to a member that is carried to a separate return year is determined under the rules of § 1.1502–21(b)(2). The source and separate category of the portion of the CNOL that is attributable to a member is determined under this paragraph (c)(1)(iv).

(B) *Tentative apportionment.* For the portion of the CNOL that is attributable to the member described in paragraph (c)(1)(iv) of this section, the consolidated group determines a tentative allocation and apportionment to each statutory and residual grouping (as described in § 1.861–8(a)(4) with respect to section 904 as the operative section) under the principles of § 1.1502–9(c)(2)(i), (ii), (iv), and (v) by treating the portion of the group's CNOL in each statutory and residual grouping as if it were a CSLL account, as that term is described in § 1.1502–9(b)(4). This determination is made as of the end of the taxable year of the consolidated group in which the CNOL arose or, if earlier and applicable, when the member leaves the consolidated group.

(C) *Adjustments.* (*1*) If the total tentative apportionment for all statutory and residual groupings exceeds the portion of the CNOL attributable to the member described in paragraph (c)(1)(iv)(A) of this section (the ''excess amount''), then the tentative apportionment in each grouping is reduced by an amount equal to the excess amount multiplied by a fraction, the numerator of which is the tentative apportionment in that grouping, and the denominator of which is the total tentative apportionments in all groupings.

(*2*) If the total tentative apportionment for all statutory and residual groupings is less than the total CNOL attributable to the member described in paragraph (c)(1)(iv)(A) (the ''deficiency''), then the tentative apportionment in each grouping is increased by an amount equal to the deficiency multiplied by a fraction, the numerator of which is the CNOL in that grouping that was not tentatively apportioned, and the denominator of which is the total CNOL in all groupings that was not tentatively apportioned.

(v) *Consolidated net capital losses.* The principles of the rules in paragraphs (c)(1)(i) through (iv) of this section apply for purposes of determining the source and separate category of consolidated net capital losses described in § 1.1502–22(e).

(2) *Computation of consolidated taxable income.* The denominator of the limiting fraction in any separate category is the consolidated taxable income of the group determined in accordance with § 1.1502–11, taking into account adjustments required under section 904(b), if any.

(3) *Computation of tax against which credit is taken.* The tax against which the limiting fraction under section 904(a) is applied will be the consolidated tax liability of the group determined under § 1.1502–2, but without regard to § 1.1502–2(a)(2) through (4) and (8) and (9), and without regard to any credit against such liability. See sections 26(b) and 901(a).

(d) *Carryover and carryback of unused foreign tax*—(1) *Allowance of unused foreign tax as consolidated carryover or carryback.* The consolidated group's carryovers and carrybacks of unused foreign tax (as defined in § 1.904–2(c)(1)) to the taxable year is determined on a consolidated basis under the principles of section 904(c) and § 1.904–2 and is deemed to be paid or accrued to a foreign country or possession for that year. The consolidated group's unused foreign tax carryovers and carrybacks to the taxable year consist of any unused foreign tax of the consolidated group, plus any unused foreign tax of members for separate return years, which may be carried over or back to the taxable year under the principles of section 904(c) and § 1.904–2. The consolidated group's unused foreign tax carryovers and carrybacks do not include any unused foreign taxes apportioned to a corporation for a separate return year pursuant to § 1.1502–79(d). A consolidated group's unused foreign tax in each separate category is the excess of the foreign taxes paid, accrued or deemed paid under section 960 by the consolidated group over the limitation in the applicable separate category for the consolidated return year. See paragraph (c) of this section.

(2) *Absorption rules.* For purposes of determining the amount, if any, of an unused foreign tax which can be carried to a taxable year (whether a consolidated or separate return year), the amount of the unused foreign tax that is absorbed in a prior consolidated return year under section 904(c) shall be determined by—

(i) Applying all unused foreign taxes which can be carried to a prior year in the order of the taxable years in which those unused foreign taxes arose, beginning with the taxable year that ends earliest; and

(ii) Applying all unused foreign taxes which can be carried to such prior year from taxable years ending on the same date on a pro rata basis.

(e) *Example.* The following example illustrates the application of this section:

(1) *Facts.* (i) Domestic corporation P is incorporated on January 1, Year 1. On that same day, P incorporates domestic corporations S and T as wholly owned subsidiaries. P, S, and T file consolidated returns for Years 1 and 2 on the basis of a calendar year. T engages in business solely through a qualified business unit in Country A. S engages in business solely through qualified business units in Countries A and B. P does business solely in the United States. During Year 1, T sold an item of inventory to P at a gain of $2,000. Under § 1.1502–13 the intercompany gain has not been taken into account as of the close of Year 1. The taxable income of each member for Year 1 from foreign and U.S. sources, and the foreign taxes paid on such foreign income, are as follows:

TABLE 1 TO PARAGRAPH (e)(1)(i)

Corporation	U.S. source taxable income	Foreign branch category foreign source taxable income	Foreign branch category foreign tax paid	Total taxable income
P	$40,000			$40,000
T		$20,000	$12,000	20,000
S		20,000	9,000	20,000
Group	40,000	40,000	21,000	80,000

(ii) The separate taxable income of each member was computed by taking into account the rules under § 1.1502–12. Accordingly, T's intercompany gain of $2,000 is not included in T's taxable income for Year 1. The group's consolidated taxable income (computed in accordance with § 1.1502–11) is $80,000. The consolidated tax liability against which the credit may be taken (computed in accordance with paragraph (c)(3) of this section) is $16,800.

(2) *Analysis.* Under section 904(d) and paragraph (c)(1)(i) of this section, the aggregate amount of foreign income taxes paid to all foreign countries with respect to the foreign branch category income of $21,000 ($12,000 + $9,000) that may be claimed as a credit in Year 1 is limited to $8,400 ($16,800 × $40,000/$80,000). Assuming P, as the agent for the group, chooses to use the foreign taxes paid as a credit, the group may claim a $8,400 foreign tax credit.

(f) *Applicability date.* This section applies to taxable years for which the original consolidated Federal income tax return is due (without extensions) after January 11, 2021.

■ **Par. 38.** Section 1.1502–21 is amended by adding a sentence to the end of paragraph (b)(2)(iv)(B)(*1*) to read as follows:

§ 1.1502–21 Net operating losses.

* * * * *

(b) * * *

(2) * * *

(iv) * * *

(B) * * *

(*1*) * * * The source and section 904(d) separate category of the CNOL attributable to a member is determined under § 1.1502–4(c)(1)(iii).

* * * * *

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 39.** The authority citation for part 301 is amended by adding an entry for § 301.6689–1 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805.

* * * * *

Section 301.6689–1 also issued under 26 U.S.C. 6689(a), 26 U.S.C. 6227(d), and 26 U.S.C. 6241(11).

* * * * *

■ **Par. 40.** Section 301.6227–1 is amended by adding paragraph (g) to read as follows:

§ 301.6227–1 Administrative adjustment request by partnership.

* * * * *

(g) *Notice requirement and partnership adjustments required as a result of a foreign tax redetermination.* For special rules applicable when an adjustment to a partnership related item (as defined in section 6241(2)) is required as part of a redetermination of U.S. tax liability under section 905(c) and § 1.905–3(b) of this chapter as a result of a foreign tax redetermination (as defined in § 1.905–3(a) of this chapter), see § 1.905–4(b)(2)(ii) of this chapter.

* * * * *

■ **Par. 41.** Section 301.6689–1 is added to read as follows:

§ 301.6689–1 Failure to file notice of redetermination of foreign income taxes.

(a) *Application of civil penalty.* If a foreign tax redetermination occurs, and the taxpayer failed to notify the Internal Revenue Service (IRS) on or before the date and in the manner prescribed in § 1.905–4 of this chapter, or as required under section 404A(g)(2), for giving notice of a foreign tax redetermination, then, unless paragraph (d) of this section applies, there is added to the deficiency (or the imputed underpayment as determined under section 6225) attributable to such redetermination an amount determined under paragraph (b) of this section. Subchapter B of chapter 63 of the Internal Revenue Code (relating to deficiency proceedings) does not apply with respect to the assessment of the amount of the penalty.

(b) *Amount of the penalty.* The amount of the penalty shall be equal to—

(1) Five percent of the deficiency (or imputed underpayment) if the failure is for not more than one month; plus

(2) An additional five percent of the deficiency (or imputed underpayment) for each month (or fraction thereof) during which the failure continues, but not to exceed in the aggregate twenty-five percent of the deficiency (or imputed underpayment).

(c) *Foreign tax redetermination defined.* For purposes of this section, a foreign tax redetermination is any redetermination for which a notice is required under sections 905(c) or 404A(g)(2). See §§ 1.905–3 through 1.905–5 of this chapter for rules relating to the notice requirement under section 905(c).

(d) *Reasonable cause.* The penalty set forth in this section shall not apply if it is established to the satisfaction of the IRS that the failure to file the notification within the prescribed time was due to reasonable cause and not due to willful neglect. An affirmative showing of reasonable cause must be made in the form of a written statement that sets forth all the facts alleged as reasonable cause for the failure to file the notification on time and that contains a declaration by the taxpayer that the statement is made under the penalties of perjury. This statement must be filed with the Internal Revenue Service Center in which the notification was required to be filed. The taxpayer must file this statement with the notice required under section 905(c) or 404A(g)(2). If the taxpayer exercised ordinary business care and prudence and was nevertheless unable to file the notification within the prescribed time, then the delay will be considered to be due to reasonable cause and not willful neglect.

(e) *Applicability date.* This section applies to foreign tax redeterminations occurring in taxable years ending on or after December 16, 2019, and to foreign tax redeterminations of foreign corporations occurring in taxable years that end with or within a taxable year of a United States shareholder ending on or after December 16, 2019.

§ 301.6689–1T [REMOVED]

■ **Par. 42.** Section 301.6689–1T is removed.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: September 18, 2020.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2020–21819 Filed 11–2–20; 11:15 am]

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Part III

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Guidance Related to the Foreign Tax Credit; Clarification of Foreign-Derived Intangible Income; Proposed Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–101657–20]

RIN 1545–BP70

Guidance Related to the Foreign Tax Credit; Clarification of Foreign-Derived Intangible Income

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the foreign tax credit, including guidance on the disallowance of a credit or deduction for foreign income taxes with respect to dividends eligible for a dividends-received deduction; the allocation and apportionment of interest expense, foreign income tax expense, and certain deductions of life insurance companies; the definition of a foreign income tax and a tax in lieu of an income tax; transition rules relating to the impact on loss accounts of net operating loss carrybacks allowed by reason of the Coronavirus Aid, Relief, and Economic Security Act; the definition of foreign branch category and financial services income; and the time at which foreign taxes accrue and can be claimed as a credit. This document also contains proposed regulations clarifying rules relating to foreign-derived intangible income. The proposed regulations affect taxpayers that claim credits or deductions for foreign income taxes, or that claim a deduction for foreign-derived intangible income.

DATES: Written or electronic comments and requests for a public hearing must be received by February 10, 2021.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–101657–20) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The IRS expects to have limited personnel available to process public comments that are submitted on paper through mail. The Department of the Treasury (the ''Treasury Department'') and the IRS will publish for public availability any comment submitted electronically, and to the extent practicable on paper, to its public docket. Send paper submissions to: CC:PA:LPD:PR (REG–101657–20), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations under §§ 1.245A(d)–1, 1.336–2, 1.338–9, 1.861–3, 1.861–20, 1.904–6, 1.960–1, and 1.960–2, Suzanne M. Walsh, (202) 317–4908; concerning §§ 1.250(b)–1, 1.861–8, 1.861–9, and 1.861–14, Jeffrey P. Cowan, (202) 317–4924; concerning § 1.250(b)–5, Brad McCormack, (202) 317–6911; concerning §§ 1.164–2, 1.901–1, 1.901–2, 1.903–1, 1.905–1, and 1.905–3, Tianlin (Laura) Shi, (202) 317–6987; concerning §§ 1.367(b)–3, 1.367(b)–4, and 1.367(b)–10, Logan Kincheloe, (202) 317–6075; concerning §§ 1.367(b)–7, 1.861–10, 1.904–2, 1.904–4, 1.904–5, and 1.904(f)–12, Jeffrey L. Parry, (202) 317–4916; concerning submissions of comments and requests for a public hearing, Regina Johnson, (202) 317–5177 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2018, the Treasury Department and the IRS published proposed regulations (REG–105600–18) relating to foreign tax credits in the **Federal Register** (83 FR 63200) (the ''2018 FTC proposed regulations''). Those regulations addressed several significant changes that the Tax Cuts and Jobs Act (Pub. L. 115–97, 131 Stat. 2054, 2208 (2017)) (the ''TCJA'') made with respect to the foreign tax credit rules and related rules for allocating and apportioning deductions in determining the foreign tax credit limitation. On December 17, 2019, portions of the 2018 FTC proposed regulations were finalized in TD 9882, published in the **Federal Register** (84 FR 69022) (the ''2019 FTC final regulations''). On the same date, new proposed regulations were issued addressing changes made by the TCJA as well as other related foreign tax credit rules (the ''2019 FTC proposed regulations''). Correcting amendments to the 2019 FTC final regulations and the 2019 FTC proposed regulations were published in the **Federal Register** on May 15, 2020, see 85 FR 29323 (2019 FTC final regulations) and 85 FR 29368 (2019 FTC proposed regulations). The 2019 FTC proposed regulations are finalized in the Rules and Regulations section of this issue of the **Federal Register** (the ''2020 FTC final regulations'').

On July 15, 2020, the Treasury Department and the IRS finalized regulations under section 250 (the ''section 250 regulations'') in TD 9901, published in the **Federal Register** (85 FR 43042).

This document contains proposed regulations (the ''proposed regulations'') addressing: (1) The determination of foreign income taxes subject to the credit and deduction disallowance provision of section 245A(d); (2) the determination of oil and gas extraction income from domestic and foreign sources and of electronically supplied services under the section 250 regulations; (3) the impact of the repeal of section 902 on certain regulations issued under section 367(b); (4) the sourcing of inclusions under sections 951, 951A, and 1293; (5) the allocation and apportionment of interest deductions, including rules for allocating interest expense of foreign bank branches and certain regulated utility companies, an election to capitalize research and experimental expenditures and advertising expenses for purposes of calculating tax basis, and a revision to the controlled foreign corporation (''CFC'') netting rule; (6) the allocation and apportionment of section 818(f) expenses of life insurance companies that are members of consolidated groups; (7) the allocation and apportionment of foreign income taxes, including taxes imposed with respect to disregarded payments; (8) the definitions of a foreign income tax and a tax in lieu of an income tax, including the addition of a jurisdictional nexus requirement and changes to the net gain requirement, the treatment of certain tax credits, the treatment of foreign tax law elections for purposes of the noncompulsory payment rules, and the substitution requirement under section 903; (9) the allocation of the liability for foreign income taxes in connection with certain mid-year transfers or reorganizations; (10) transition rules to account for the effect on loss accounts of net operating loss carrybacks to pre-2018 taxable years that are allowed under the Coronavirus Aid, Relief, and Economic Security Act, Public Law 116–136, 134 Stat. 281 (2020); (11) the foreign branch category rules in § 1.904–4(f) and the definition of a financial services entity for purposes of section 904; and (12) the time at which credits for foreign income taxes can be claimed pursuant to sections 901(a) and 905(a).

Explanation of Provisions

I. Foreign Income Taxes With Respect to Dividends for Purposes of Section 245A(d)

Section 245A(d)(1) provides that no credit is allowed under section 901 for any taxes paid or accrued (or treated as paid or accrued) with respect to any

dividend for which a deduction is allowed under that section. Section 245A(d)(2) disallows a deduction under chapter 1 for any tax for which a credit is not allowable under section 901 by reason of section 245A(d)(1). Section 245A(e)(3) also provides that no credit or deduction is allowed for foreign income taxes paid or accrued with respect to a hybrid dividend or a tiered hybrid dividend.

Proposed § 1.245A(d)–1(a) generally provides that neither a foreign tax credit under section 901 nor a deduction is allowed for foreign income taxes (as defined in § 1.901–2(a)) that are ''attributable to'' certain amounts. For this purpose, the proposed regulations rely on the rules in § 1.861–20, contained in the 2020 FTC final regulations and proposed to be modified in these proposed regulations, that allocate and apportion foreign income taxes to income for purposes of various operative sections, including sections 904, 960, and 965(g). Specifically, proposed § 1.245A(d)–1 provides that § 1.861–20 (which includes portions contained in these proposed regulations as well as in the 2020 FTC final regulations) applies for purposes of determining foreign income taxes paid or accrued that are attributable to any dividend for which a deduction is allowed under section 245A(a), to a hybrid dividend or tiered hybrid dividend, or to previously taxed earnings and profits that arose as a result of a sale or exchange that by reason of section 964(e)(4) or 1248 gave rise to a deduction under section 245A(a) or as a result of a tiered hybrid dividend that by reason of section 245A(e)(2) gave rise to an inclusion in the gross income of a United States shareholder (collectively, such previously taxed earnings and profits are referred to as ''section 245A(d) PTEP'').

In addition, the rules apply to foreign income taxes that are imposed with respect to certain foreign taxable events, such as a deemed distribution under foreign law or an inclusion under a foreign law CFC inclusion regime, even though such event does not give rise to a distribution or inclusion for Federal income tax purposes. Proposed § 1.245A(d)–1(a) provides that foreign income taxes that are attributable to ''specified earnings and profits'' are also subject to the disallowance under section 245A(d). Under proposed § 1.245A(d)–1(b), § 1.861–20 applies to determine whether foreign income taxes are attributable to specified earnings and profits. Under § 1.861–20, foreign income taxes may be allocated and apportioned by reference to specified earnings and profits, even though the person paying or accruing the foreign income tax does not have a corresponding U.S. item in the form of a distribution of, or income inclusion with respect to, such earnings and profits. See, for example, § 1.861–20(d)(2)(ii)(B), (C), or (D) (foreign law distribution or foreign law disposition and certain foreign law transfers between taxable units), (d)(3)(i)(C) (income from a reverse hybrid), (d)(3)(iii) (foreign law inclusion regime), and proposed § 1.861–20(d)(3)(v)(C)(*1*)(*i*) (disregarded payment treated as a remittance). Specified earnings and profits means earnings and profits that would give rise to a section 245A deduction (without regard to the holding period requirement under section 246 or the rules under § 1.245A–5 that disallow a deduction under section 245A(a) for certain dividends), a hybrid dividend, or a tiered hybrid dividend, or a distribution sourced from section 245A(d) PTEP if an amount of money equal to all of the foreign corporation's earnings and profits were distributed. Therefore, for example, a credit or deduction for foreign income taxes paid or accrued by a domestic corporation that is a United States shareholder (''U.S. shareholder'') with respect to a distribution that is not recognized for Federal income tax purposes (for example, in the case of a consent dividend under foreign tax law that is not regarded for Federal income tax purposes, or a distribution of stock that is excluded from gross income under section 305(a) but is treated as a taxable dividend under foreign tax law) is not allowed under section 245A(d) to the extent those foreign income taxes are attributable to specified earnings and profits.

An anti-avoidance rule is included in proposed § 1.245A(d)–1 to address situations in which taxpayers engage in transactions with a principal purpose of avoiding the purposes of section 245A(d), which is to disallow a foreign tax credit or deduction with respect to foreign income taxes imposed on income that is effectively exempt from tax (due to the availability of a deduction under section 245A(a)) or with respect to foreign income taxes imposed on a hybrid dividend or tiered hybrid dividend. Such transactions may include transactions to separate foreign income taxes from the income to which they relate in situations that are not explicitly covered under § 1.861–20 (including, for example, loss sharing transactions under group relief regimes). Such transactions may also include successive distributions (under foreign law) out of earnings and profits that, under the rules in § 1.861–20, are treated as distributed out of previously taxed earnings and profits (and therefore foreign income taxes attributable to such amounts are not generally subject to the disallowance under section 245A(d)), when there is no reduction of such previously taxed earnings and profits due to the absence of a distribution under Federal income tax law. See proposed § 1.245A(d)–1(e)(4) (*Example 3*). The Treasury Department and the IRS are concerned that because the rules in § 1.861–20(d) addressing foreign law distributions and dispositions do not currently make adjustments to a foreign corporation's earnings and profits to reflect distributions that are not recognized for Federal income tax purposes, such foreign law transactions could be used to circumvent the purposes of section 245A(d). Comments are requested on potential revisions to § 1.861–20(d) that could address these concerns, including the possibility of maintaining separate earnings and profits accounts, characterized with reference to the relevant statutory and residual groupings, for each taxable unit whereby the accounts would be adjusted annually to reflect transactions that occurred under foreign law but not under Federal income tax law.

II. Clarifications to Regulations Under Section 250

A. Definition of Domestic and Foreign Oil and Gas Extraction Income

Section 250 provides a domestic corporation a deduction (''section 250 deduction'') for its foreign-derived intangible income (''FDII'') as well as its global intangible low-taxed income (''GILTI'') inclusion amount and the amount treated as a dividend under section 78 that is attributable to its GILTI inclusion. The section 250 deduction attributable to FDII is calculated in part by determining the foreign-derived portion of a corporation's deduction eligible income (''DEI''). DEI is defined as the excess of gross DEI over the deductions (including taxes) properly allocable to such gross income. See section 250(b)(3)(A) and § 1.250(b)–1(c)(2). Gross DEI is determined without regard to domestic oil and gas extraction income (''DOGEI''), which is defined as income described in section 907(c)(1) determined by substituting ''within the United States'' for ''without the United States.'' See section 250(b)(3)(B) and § 1.250(b)–1(c)(7). Similarly, foreign oil and gas extraction income (''FOGEI'') as defined in section 907(c)(1) is excluded from the computation of gross tested

income which is used to determine a U.S. shareholder's GILTI inclusion amount. See § 1.951A–2(c)(1)(v).

The Treasury Department and the IRS have determined that it would be inappropriate for taxpayers to use inconsistent methods to determine the amounts of DOGEI and FOGEI from the sale of oil or gas that has been transported or processed. Taxpayers with both types of income may have an incentive to minimize their DOGEI in order to maximize their potential section 250 deduction attributable to FDII, while in contrast maximizing their FOGEI in order to minimize their gross tested income, even though this would also decrease the amount of the section 250 deduction attributable to their GILTI inclusion amount. Accordingly, the proposed regulations provide that taxpayers must use a consistent method for purposes of determining both DOGEI and FOGEI. See proposed § 1.250(b)–1(c)(7). Similarly, for purposes of allocating and apportioning deductions, taxpayers are already required under existing regulations to use the same method of allocation and the same principles of apportionment where more than one operative section, for example sections 250 and 904, apply. See § 1.861–8(f)(2)(i).

B. Definition of Electronically Supplied Service

Section 1.250(b)–5(c)(5) defines the term ''electronically supplied service'' to mean a general service (other than an advertising service) that is delivered primarily over the internet or an electronic network, and provides that such services include, by way of examples, cloud computing and digital streaming services.

Since the publication of the section 250 regulations, the Treasury Department and the IRS have determined that the definition of electronically supplied services could be interpreted in a manner that includes services that were not primarily electronic and automated in nature but rather where the renderer applies human effort or judgment, such as professional services that are provided through the internet or an electronic network. Therefore, these proposed regulations clarify that the value of the service to the end user must be derived primarily from the service's automation or electronic delivery in order to be an electronically supplied service. The regulations further provide that services that primarily involve the application of human effort by the renderer to provide the service (not including the effort involved in developing or maintaining the technology to enable the electronic service) are not electronically supplied services. For example, certain services for which automation or electronic delivery is not a primary driver of value, such as legal, accounting, medical, or teaching services delivered electronically and synchronously, are not electronically supplied services.

III. Carryover of Earnings and Profits and Taxes When One Foreign Corporation Acquires Assets of Another Foreign Corporation in a Section 381 Transaction

Section 1.367(b)–7 provides rules regarding the manner and the extent to which earnings and profits and foreign income taxes of a foreign corporation carry over when one foreign corporation (''foreign acquiring corporation'') acquires the assets of another foreign corporation (''foreign target corporation'') in a transaction described in section 381 (the combined corporation, the ''foreign surviving corporation''). See § 1.367(b)–7(a). Before the repeal of section 902 in the TCJA, these rules were primarily relevant for determining the foreign income taxes of the foreign surviving corporation that were considered deemed paid by its U.S. shareholder with respect to a distribution or inclusion under section 902 or 960, respectively.

Section 1.367(b)–7 applies differently with respect to ''pooling corporations'' and ''nonpooling corporations.'' A pooling corporation is a foreign corporation with respect to which certain ownership requirements were satisfied in pre-2018 taxable years and that, as a result, maintained ''pools'' of post-1986 undistributed earnings and related post-1986 foreign income taxes. See § 1.367(b)–2(l)(9). In general, if the foreign surviving corporation was a pooling corporation, the post-1986 undistributed earnings and post-1986 foreign income taxes of the foreign acquiring corporation and the foreign target corporation were combined on a separate category-by-separate category basis. See § 1.367(b)–7(d)(1). However, the regulations required the foreign surviving corporation to combine the taxes related to a deficit in a separate category of post-1986 undistributed earnings of one or both of the foreign acquiring corporation or foreign target corporation (a ''hovering deficit'') with other post-1986 foreign income taxes in that separate category only on a pro rata basis as the hovering deficit was absorbed by post-transaction earnings in the same separate category. See § 1.367(b)–7(d)(2)(iii). Similarly, a hovering deficit in a separate category of post-1986 undistributed earnings could offset only earnings and profits accumulated by the foreign surviving corporation after the section 381 transaction. Under § 1.367(b)–7(d)(2)(ii), the reduction or offset was generally deemed to occur as of the first day of the foreign surviving corporation's first taxable year following the year in which the post-transaction earnings accumulated.

A nonpooling corporation is a foreign corporation that is not a pooling corporation and, as a result, maintains ''annual layers'' of pre-1987 accumulated profits and pre-1987 foreign income taxes. See § 1.367(b)–2(l)(10). In general, a foreign surviving corporation maintains the annual layers of pre-1987 accumulated profits and pre-1987 foreign income taxes, and the taxes related to a deficit in an annual layer cannot be associated with post-section 381 transaction earnings of the foreign surviving corporation.

As a result of the repeal of section 902 in the TCJA, post-1986 foreign income taxes and pre-1987 foreign income taxes of foreign corporations are generally no longer relevant for taxable years beginning on or after January 1, 2018. In addition, consistent with the TCJA, the Treasury Department and the IRS issued regulations under section 960 clarifying that only current year taxes are taken into account in determining taxes deemed paid under section 960. See § 1.960–1(c)(2). Current year tax means certain foreign income tax paid or accrued by a controlled foreign corporation in a current taxable year. See § 1.960–1(b)(4).

In light of the changes made by the TCJA and subsequent implementing regulations, the proposed regulations provide rules to clarify the treatment of foreign income taxes of a foreign surviving corporation in taxable years of foreign corporations beginning on or after January 1, 2018, and for taxable years of U.S. shareholders in which or with which such taxable years of foreign corporations end (''post-2017 taxable years''). The proposed regulations provide that all foreign target corporations, foreign acquiring corporations, and foreign surviving corporations are treated as nonpooling corporations in post-2017 taxable years and that any amounts remaining in the post-1986 undistributed earnings and post-1986 foreign income taxes of any such corporation as of the end of the foreign corporation's last taxable year beginning before January 1, 2018, are treated as earnings and taxes in a single pre-pooling annual layer in the foreign corporation's post-2017 taxable years.

The proposed regulations also clarify that foreign income taxes that are

related to non-previously taxed earnings of a foreign acquiring corporation and a foreign target corporation that were accumulated in taxable years before the current taxable year of the foreign corporation, or in a foreign target corporation's taxable year that ends on the date of the section 381 transaction, are not treated as current year taxes (as defined in § 1.960–1(b)(4)) of a foreign surviving corporation in any post-2017 taxable year. Furthermore, the proposed regulations clarify that foreign income taxes related to hovering deficits are not current year taxes in the year that the hovering deficit is absorbed, in part because the hovering deficit is not considered to offset post-1986 undistributed earnings until the first day of the foreign surviving corporation's first taxable year following the year in which the post-transaction earnings accumulated. In addition, because such taxes were paid or accrued by a foreign corporation in a prior taxable year, they are not considered paid or accrued by the foreign corporation in the current taxable year and therefore are not current year taxes under § 1.960–1(b)(4). Finally, foreign income taxes related to a hovering deficit in pre-1987 accumulated profits generally will not be reduced or deemed paid unless a foreign tax refund restores a positive balance to the associated earnings pursuant to section 905(c); therefore, such foreign income taxes are never included in current year taxes.

In addition to the proposed changes to § 1.367(b)–7, the proposed regulations remove some references to section 902 in other regulations issued under section 367(b) that are no longer relevant as a result of the repeal of section 902. For example, pursuant to § 1.367(b)–4(b)(2), a deemed dividend inclusion is required in certain cases upon the receipt of preferred stock by an exchanging shareholder, in order to prevent the excessive potential shifting of earnings and profits, notwithstanding that the exchanging shareholder's status as a section 1248 shareholder is preserved. One of the conditions for application of the rule requires a domestic corporation to meet the ownership threshold of section 902(a) or (b) and, thus, be eligible for a deemed paid credit on distributions from the transferee foreign corporation. § 1.367(b)–4(b)(2)(i)(B). These proposed rules generally retain the substantive ownership threshold of this requirement, but without reference to section 902 and by modifying the ownership threshold requirement to consider not only voting power but value as well. Specifically, § 1.367(b)–4(b)(2)(i)(B) is revised to require that a domestic corporation owns at least 10 percent of the transferee foreign corporation by vote or value.

Comments are requested as to whether further changes to § 1.367(b)–4 or 1.367(b)–7, or any changes to other regulations issued under section 367, are appropriate in order to clarify their application after the repeal of section 902. In addition, the Treasury Department and the IRS are studying the interaction of § 1.367(b)–4(b)(2) with section 245A and other Code provisions and considering whether additional revisions to the regulation are appropriate in light of TCJA generally. Comments are specifically requested with respect to the proposed revisions to § 1.367(b)–4(b)(2), including whether there is a continuing need to prevent excessive potential shifting of earnings and profits through the use of preferred stock in light of the TCJA generally. For example, the Treasury Department and the IRS are considering, and request comments on, the extent to which, in certain transactions described in § 1.367(b)–4(b)(2), (1) an exchanging shareholder who would not qualify for a deduction under section 245A could potentially shift earnings and profits of a foreign acquired corporation to a transferee foreign corporation with a domestic corporate shareholder that would qualify for a deduction under section 245A, or (2) a domestic corporate exchanging shareholder of a foreign acquired corporation with no earnings and profits could access the earnings and profits of a transferee foreign corporation.

IV. Source of Inclusions Under Sections 951, 951A, 1293, and Associated Section 78 Dividend

Sections 861(a) and 862(a) contain rules to determine the source of certain items of gross income. Section 863(a) provides that the source of items of gross income not specified in sections 861(a) and 862(a) will be determined under regulations prescribed by the Secretary. As a result of changes to section 960 made by the TCJA, the Treasury Department and the IRS revised the regulations under section 960. As part of that revision, the Treasury Department and the IRS removed former § 1.960–1(h)(1), which contained a source rule for the amount included in gross income under section 951 and the associated section 78 dividend. Section 1.960–1(h)(1) provided that, for purposes of section 904, the amount included in gross income of a domestic corporation under section 951 with respect to a foreign corporation, plus any section 78 dividend to which such section 951 inclusion gave rise by reason of taxes deemed paid by such domestic corporation, was derived from sources within the foreign country or possession of the United States under the laws of which such foreign corporation, or the first-tier corporation in the same chain of ownership as such foreign corporation, was created or organized.

Although section 904(h)(1) treats as from sources within the United States certain amounts included in gross income under section 951(a) that otherwise would be treated as derived from sources without the United States, absent former § 1.960–1(h)(1), no rule specifies the source of inclusions under section 951 before the application of section 904(h)(1). In addition, the rule in former § 1.960–1(h)(1) only provided for the source of a domestic corporation's section 951 inclusions for purposes of section 904. A similar lack of guidance exists with respect to the source of inclusions under section 951A. See section 951A(f)(1)(A) (requiring the application of section 904(h)(1) with respect to amounts included in gross income under section 951A(a) in the same manner as amounts included under section 951(a)(1)(A)). The removal of former § 1.960–1(h)(1) also left uncertain the source of amounts included in gross income as a result of an election under section 1293(a), because under section 1293(f)(1), such amounts are treated for purposes of section 960 as amounts included in gross income under section 951(a).

To clarify the source of income inclusions after the removal of former § 1.960–1(h)(1), the proposed regulations include a new rule in § 1.861–3(d), which provides that for purposes of the sourcing provisions an amount included in the gross income of a United States person under section 951 is treated as a dividend received by the United States person directly from the foreign corporation that generated the inclusion.

This proposed rule differs from former § 1.960–1(h)(1) in two respects. First, former § 1.960–1(h)(1) provided that if the foreign corporation that generated the income included under section 951 was held indirectly through other foreign corporations, the amount included was treated as if it had been paid through such intermediate corporations and as received from the first-tier foreign corporation. The Treasury Department and the IRS have determined that, in light of the repeal of section 902, and because a section 951 inclusion with respect to a lower-tier CFC is not treated as a deemed distribution through the first-tier CFC,

the source of the inclusion should be determined by reference to the lower-tier CFC.

Second, former § 1.960–1(h)(1) treated the entire amount of the inclusion under section 951 as derived from sources without the United States. However, the Treasury Department and the IRS have determined that because dividends and inclusions of the same earnings and profits should be sourced in the same manner, the general rule for inclusions under section 951 should be consistent with the rule in section 861(a)(2)(B) and § 1.861–3(a)(3) that treats dividends as derived from sources within the United States to the extent that the dividend is from a foreign corporation with significant income effectively connected with the conduct of a trade or business in the United States. This is particularly appropriate in circumstances in which effectively connected income is not excluded from subpart F income under section 952(b) (which could arise as a result of a treaty obligation of the United States precluding the effectively connected income from being taxed by the United States in the hands of the CFC). In addition, the Treasury Department and the IRS have determined that the source of a taxpayer's gross income from an inclusion of CFC earnings that are subject to a high rate of foreign tax should be the same, regardless of whether the taxpayer includes the income under subpart F or elects the high-taxed exception of section 954(b)(4) and repatriates the earnings as a dividend. Therefore, the proposed regulations provide that the source of an inclusion under section 951 is determined under the same rules as those for dividends. However, the resourcing rules in section 904(h) and § 1.904–5(m) independently operate to ensure that dividends and inclusions under section 951(a) that are attributable to U.S. source income of the CFC retain that U.S. source in the hands of the United States shareholder.

The proposed regulations also clarify that the source of section 78 dividends associated with inclusions under section 951 follows the rules for sourcing dividends. See also § 1.78–1(a).

Finally, and consistent with sections 951A(f)(1)(A) and 1293(f)(1), the proposed regulations apply the same rules with respect to inclusions under sections 951A and 1293 and the associated section 78 dividend.

V. Allocation and Apportionment of Expenses Under Section 861 Regulations

A. Election To Capitalize R&E and Advertising Expenditures

A taxpayer determines its foreign tax credit limitation under section 904, in part, based on the taxpayer's taxable income from sources without the United States. Taxable income from sources without the United States is determined by deducting from the items of gross income from sources without the United States the expenses, losses, and other deductions properly allocated and apportioned to that income, and a ratable part of any expenses, losses, or other deductions that cannot definitely be allocated to some item or class of gross income. See section 862(b). Section 864(e)(2) generally requires taxpayers to allocate and apportion interest expense on the basis of assets, rather than income. Under the asset method, a taxpayer apportions interest expense to the various statutory or residual groupings based on the average total value of assets within each grouping for the taxable year as determined under the asset valuation rules of § 1.861–9T(g).

The preamble to the 2019 FTC proposed regulations stated that the Treasury Department and the IRS continue to study the rules for allocating and apportioning interest deductions, and requested comments on a potential proposal to provide for the capitalization and amortization of certain expenses solely for purposes of § 1.861–9 to better reflect asset values under the tax book value method. One comment supported the adoption of such a rule.

The Treasury Department and the IRS recognize that internally-developed intangible assets (including intangible assets such as goodwill that are created as a result of advertising) that have no tax book value because the costs of generating them have been currently deducted may nevertheless have continuing economic value, and that debt financing may support the generation and maintenance of that value. Accordingly, proposed § 1.861–9(k) provides an election for taxpayers to capitalize and amortize their research and experimental (''R&E'') and advertising expenditures incurred in a taxable year. This election is analogous to the election under § 1.861–9(i) to determine asset values based on the alternative tax book value method, since both elections allow taxpayers to determine the tax book value of an asset in a manner that is different from the general rules that apply under Federal income tax law, but solely for purposes of allocating and apportioning interest expense under § 1.861–9, and not for any other Federal income tax purpose (such as determining the amount of any deduction actually allowed for depreciation or amortization).

Proposed § 1.861–9(k)(1) and (2) generally provides that for purposes of allocating and apportioning interest expense under § 1.861–9, an electing taxpayer capitalizes and amortizes its R&E expenditures under the rules in section 174 as contained in Public Law 115–97, title I, § 13206(a), which generally requires that beginning in taxable years beginning in 2022, R&E expenditures must be capitalized and then amortized.

Similarly, proposed § 1.861–9(k)(1) and (3) generally requires an electing taxpayer to capitalize and amortize its advertising expenditures. The definition of advertising expenditures and the method of cost recovery contained in proposed § 1.861–9(k)(3) is based on prior legislative proposals (which have not been enacted) proposing that certain advertising expenditures be capitalized. See, for example, H.R.1, 113th Cong. Section 3110 (2014). Comments are requested on whether a different definition of advertising expenditures or a different method of cost recovery should be adopted for purposes of the election in proposed § 1.861–9(k).

B. Nonrecourse Debt of Certain Utility Companies

Section 1.861–10T provides certain exceptions to the general asset-based apportionment of interest expense requirement under section 864(e)(2), including rules that directly allocate interest expense to the income generated by certain assets that are subject to ''qualified nonrecourse indebtedness.'' See § 1.861–10T(b).

A comment to the 2019 FTC proposed regulations asserted that interest expense incurred on certain debt of regulated utility companies should be directly allocated to income from assets of the utility business because the debt must be approved by a regulatory agency and relates directly to the underlying needs of the utility business. The comment suggested that the existing rules for qualified nonrecourse indebtedness were insufficient because utility indebtedness is often subject to guarantees and cross collateralizations that permit the lender to seek recovery beyond any identified property, and because the cash flows of a regulated utility company used to support utility indebtedness are broader than the permitted cash flows described in § 1.861–10T(b).

In response to this comment, the proposed regulations provide that certain interest expense of regulated utility companies is directly allocated to assets of the utility business. See proposed § 1.861–10(f). The type of utility companies that qualify for the rule, and the rules for tracing debt to assets, are modeled on similar rules provided in regulations under section 163(j). See §§ 1.163(j)–1(b)(15) and 1.163(j)–10(d)(2). Consistent with the approach taken in § 1.163(j)–10(d)(2), the proposed regulations expand the scope of permitted cash flows under § 1.861–10T(b) but do not modify the requirement that the creditor look to particular assets as security for payment on the loan because unsecured debt generally is supported by all of the assets of the borrower. See also Part XI.L.2 of the Summary of Comments and Explanation of Revisions to TD 9905 (85 FR 56686).

C. Revision to CFC Netting Rule Relating to CFC-to-CFC Loans

Section 1.861–10(e)(8)(v) provides that for purposes of applying the CFC netting rule of § 1.861–10(e), certain loans made by one CFC to another CFC are treated as loans made by a U.S. shareholder to the borrower CFC, to the extent the U.S. shareholder makes capital contributions directly or indirectly to the lender CFC, and are treated as related group indebtedness. No income derived from the U.S. shareholder's ownership of the lender CFC stock is treated as interest income derived from related group indebtedness, including subpart F inclusions related to the interest income earned by the lender CFC. As a result, no interest expense is generally allocated to income related to the CFC-to-CFC debt, but the debt may nevertheless increase the amount of allocable related group indebtedness for which a reduction in assets is required under § 1.861–10(e)(7).

The Treasury Department and the IRS have determined that the failure to account for income related to the CFC-to-CFC debt can distort the general allocation and apportionment of other interest expense under § 1.861–9. Therefore, the proposed regulations revise § 1.861–10(e)(8)(v) to provide that CFC-to-CFC debt is not treated as related group indebtedness for purposes of the CFC netting rule. Proposed § 1.861–10(e)(8)(v) also provides that CFC-to-CFC debt is not treated as related group indebtedness for purposes of determining the foreign base period ratio, which is based on the average of related group debt-to-asset ratios in the five prior taxable years, even if the CFC-to-CFC debt was otherwise properly treated as related group indebtedness in a prior year. This is necessary to prevent distortions that would otherwise arise in comparing the ratio in a year in which CFC-to-CFC debt was treated as related group indebtedness to the ratio in a year in which the CFC-to-CFC debt is not treated as related group indebtedness.

D. Direct Allocation of Interest Expense for Foreign Bank Branches

Under §§ 1.861–8 through 1.861–13, the combined interest expense of a domestic corporation and its foreign branches is allocated and apportioned to income categories on the basis of the tax book value of their combined assets. Comments received with respect to the 2018 and 2019 FTC proposed regulations asserted that special rules were needed for financial institutions for allocating and apportioning interest expense to foreign branch category income. The comments asserted that the general approach under §§ 1.861–8 through 1.861–13 fails to take into account the fact that foreign branches of financial institutions have assets and liabilities that reflect interest rates that differ from interest rates related to assets and liabilities of the home office held in the United States. As a result, the general approach results in over- or under-allocation of interest expense to the foreign branch category income.

In response to this comment, the proposed regulations provide that interest expense reflected on a foreign banking branch's books and records is directly allocated against the foreign branch category income of that foreign branch, to the extent it has foreign branch category income. The proposed regulations also provide for a corresponding reduction in the value of the assets of the foreign branch for purposes of allocating other interest expense of the foreign branch owner. See proposed § 1.861–10(g).

Comments are requested as to whether additional rules are needed to account for disregarded interest payments between foreign branches and between a foreign branch and a foreign branch owner. Comments are also requested as to whether adjustments to the amount of foreign branch liabilities subject to this rule are necessary to account for differing asset-to-liability ratios in a foreign branch and a foreign branch owner.

E. Treatment of Section 818(f) Expenses for Consolidated Groups

Section 818(f)(1) provides that a life insurance company's deduction for life insurance reserves and certain other deductions (''section 818(f) expenses'') are treated as items which cannot definitely be allocated to an item or class of gross income. Proposed § 1.861–14(h) in the 2019 FTC proposed regulations provided that section 818(f) expenses are allocated and apportioned on a separate company basis instead of on a life subgroup basis. In the 2020 FTC final regulations, this rule was withdrawn in response to comments. As discussed in Part I.C of the Summary of Comments and Explanation of Revisions to the 2020 FTC final regulations, the Treasury Department and the IRS have determined that there are merits and drawbacks to both the separate company and the life subgroup approaches.

These proposed regulations provide that section 818(f) expenses must be allocated and apportioned on a life subgroup basis, but that a one-time election is allowed for consolidated groups to choose instead to apply a separate company approach. A consolidated group's use of the separate entity method constitutes a binding choice to use the method chosen for that year for all members of the group and all taxable years thereafter.

F. Allocation and Apportionment of Foreign Income Taxes

1. Background

These proposed regulations repropose certain of the 2019 FTC proposed regulations in order to provide more detailed and comprehensive guidance regarding the assignment of foreign gross income, and the allocation and apportionment of the associated foreign income tax expense, to the statutory and residual groupings in certain cases. Comments to the 2019 FTC proposed regulations had requested more detailed guidance regarding the assignment to the statutory and residual groupings of foreign gross income arising from transactions that are dispositions of stock under Federal income tax law. In response to these comments, the Treasury Department and IRS have determined that it is appropriate to propose a comprehensive set of rules for dispositions of both stock and partnership interests, as well as rules that, similar to rules in the 2020 FTC final regulations for distributions with respect to stock, provide detailed rules for transactions that are distributions with respect to a partnership interest under Federal income tax law. The proposed regulations also address comments requesting that the rules for the assignment to the statutory and residual groupings of foreign gross income arising from disregarded payments distinguish between disregarded payments that would be

deductible if regarded under Federal income tax law and disregarded payments that would, if the payor (or recipient) were a corporation under Federal income tax law, be distributions with respect to stock or contributions to capital. See also Part IV.B of the Summary of Comments and Explanation of Revisions in the 2020 FTC final regulations.

2. Dispositions of Stock

Proposed § 1.861–20(d)(3)(i)(D) contains rules assigning to statutory and residual groupings the foreign gross income and associated foreign tax that arise from a transaction that is treated for Federal income tax purposes as a sale or other disposition of stock. These rules assign the foreign gross income first to the statutory and residual groupings to which any U.S. dividend amount, a term that applies in the disposition context when there is an amount of gain to which section 1248(a) or 964(e) applies, is assigned, to the extent thereof. Foreign gross income is next assigned to the grouping to which the U.S. capital gain amount is assigned, to the extent thereof.

Any excess of the foreign gross income recognized by reason of the transaction over the sum of the U.S. dividend amount and the U.S. capital gain amount is assigned to the statutory and residual groupings in the same proportions as the proportions in which the tax book value of the stock is (or would be if the taxpayer were a United States person) assigned to the groupings under the rules of § 1.861–9(g) in the U.S. taxable year in which the disposition occurs. This rule, which uses the asset apportionment percentages of the tax book value of the stock as a surrogate for earnings of the corporation that are not recognized for U.S. tax purposes, associates foreign tax on a U.S. return of capital amount (that is, foreign tax on foreign gain in excess of the amount of gain recognized for U.S. tax purposes) with the same groupings to which the tax would be assigned under § 1.861–20(d)(3)(i)(B)(*2*) of the 2020 FTC final regulations if the item of foreign gross income arose from a distribution made by the corporation, rather than a sale or other disposition of the stock.

As discussed in Part III.B of the Summary of Comments and Explanation of Revisions to the 2020 FTC final regulations, the Treasury Department and the IRS have determined that it is appropriate to treat foreign tax on a U.S. return of capital amount resulting from a distribution as a timing difference in the recognition of corporate earnings. The proposed regulations adopt the same rule in the case of a foreign tax on a U.S. return of capital amount resulting from a disposition of stock. The Treasury Department and the IRS have determined that this result is appropriate because a foreign country generally recognizes more gain on a disposition of stock than is recognized for U.S. tax purposes when the shareholder's tax basis in the stock is greater for U.S. tax purposes than for foreign tax purposes, and this disparity typically occurs when the shareholder's U.S. tax basis in the stock has been increased under section 961 to reflect subpart F or GILTI inclusions of earnings attributable to the stock. Comments are requested on whether other situations more commonly result in this disparity, such that different rules might be appropriate for distributions and sales in order to better match foreign tax on income included in the foreign tax base with income included in the U.S. tax base.

3. Partnership Transactions

The proposed regulations contain new rules on the treatment of distributions from partnerships and sales of partnership interests, including partnerships that are treated as corporations for foreign law purposes. In general, these rules follow similar principles as the rules for distributions from corporations and sales of stock.

The rule in proposed § 1.861–20(d)(3)(ii)(B), like the rule for assigning foreign tax on a return of capital with respect to stock, uses the asset apportionment percentages of the tax book value of the partner's distributive share of the partnership's assets (or, in the case of a limited partner with less than a 10 percent interest, the tax book value of the partnership interest) as a surrogate for the partner's distributive share of earnings of the partnership that are not recognized in the year in which the distribution is made for U.S. tax purposes. Proposed § 1.861–20(d)(3)(ii)(C) similarly associates foreign tax on a U.S. return of capital amount in connection with the sale or other disposition of a partnership interest with a hypothetical distributive share. The Treasury Department and the IRS have determined that this rule is appropriate because foreign tax on a return of capital distribution from a partnership most commonly occurs in the case of hybrid partnerships (that is, entities that are treated as partnerships for U.S. tax purposes but as corporations for foreign tax purposes). In this case, earnings that have been recognized and capitalized into basis by the partner for U.S. tax purposes as a distributive share of income in prior years are not subject to foreign tax until the earnings are distributed. Similarly, the higher U.S. tax basis in an interest in a hybrid partnership accounts for the most common cases where the amount of foreign gross income that results from a sale of a partnership interest exceeds the amount of taxable gain for U.S. tax purposes. Comments are requested on whether a different ordering rule or matching convention may better match foreign tax on income included in the foreign tax base with income included in the U.S. tax base. Comments are also requested on whether special rules are needed to associate foreign gross income and the associated foreign tax on distributions from partnerships and sales of partnership interests with items that are subject to special treatment for U.S. tax purposes (such as gain recharacterized as ordinary income under section 751).

4. Disregarded Payments

i. Background

The proposed regulations contain a new comprehensive set of rules addressing the allocation and apportionment of foreign income taxes relating to disregarded payments. In general, the 2019 FTC proposed regulations assigned foreign gross income included by reason of a disregarded payment by a branch owner to the residual grouping and assigned foreign gross income included by reason of a disregarded payment by a branch to its owner by reference to the asset apportionment percentages of the tax book value of the branch assets in the statutory and residual groupings. Comments noted that this rule, in the context of section 960, could lead to the assignment of foreign income taxes to the residual grouping rather than a grouping to which an inclusion under section 951 or 951A is attributable, resulting in the disallowance of foreign tax credits. Comments requested that, for purposes of assigning foreign gross income included by reason of a disregarded payment to a statutory or residual grouping, the rule should identify disregarded payments that should be treated as made out of current earnings, and distinguish those payments from other types of disregarded payments.

ii. Reattribution Payments

Proposed § 1.861–20(d)(3)(v) contains new rules that generally assign foreign gross income arising from the receipt of disregarded payments and the associated foreign tax to the recipient's statutory and residual groupings based on the current or accumulated income

of the payor (as computed for U.S. tax purposes) out of which the disregarded payment is considered to be made. For this purpose, the regulations refer to disregarded payments made to or by a taxable unit. In the case of a taxpayer that is an individual or a domestic corporation, a taxable unit means a foreign branch, a foreign branch owner, or a non-branch taxable unit, as defined in proposed § 1.904–4(f)(3). In the case of a taxpayer that is a foreign corporation, a taxable unit means a tested unit as such term is defined in proposed § 1.954–1(d)(2), as contained in proposed regulations (REG–127732–19) addressing the high-tax exception under section 954(b)(4), published in the **Federal Register** (85 FR 44650) on July 23, 2020 (the ''2020 HTE proposed regulations''). See proposed § 1.861–20(d)(3)(v)(A) and (d)(3)(v)(E)(*10*).

Proposed § 1.861–20(d)(3)(v)(B)(*1*) addresses the assignment of foreign gross income that arises from the portion of a disregarded payment that results in a reattribution of U.S. gross income from the payor taxable unit to the recipient taxable unit. Under proposed § 1.861–20(d)(3)(v)(B)(*1*), the foreign gross income is assigned to the statutory and residual groupings to which the amount of U.S. gross income that is reattributed (a ''reattribution amount'') is initially assigned upon receipt of the disregarded payment by a taxable unit, before taking into account reattribution payments made by the recipient taxable unit. For this purpose, under proposed § 1.861–20(d)(3)(v)(B)(*2*), in the case of a taxpayer that is an individual or a domestic corporation, the attribution rules in § 1.904–4(f)(2) apply to determine the section 904 separate categories of reattribution amounts received by foreign branches, foreign branch owners, and non-branch taxable units. In the case of a taxpayer that is a foreign corporation, the attribution rules in proposed § 1.954–1(d)(1)(iii) (as contained in the 2020 HTE proposed regulations) [1] apply to determine the reattribution amounts received by a tested unit in the tested income and subpart F income groupings of its tested units for purposes of the applying the high-tax exception of section 954(b)(4). Under proposed § 1.861–20(d)(3)(v)(B)(*2*), the rules in the 2020 HTE proposed regulations for attributing U.S. gross income to tested units also apply to attribute items of foreign gross income to tested units for purposes of allocating and apportioning the associated foreign income taxes in computing the amount of an inclusion and deemed-paid taxes under sections 951, 951A, and 960.

For purposes of applying all other operative sections, the U.S. gross income that is attributable to a taxable unit is determined under the principles of the foreign branch category rules (for U.S. taxpayers) or the high-tax exception rules (for foreign corporations). The foreign branch category rules of § 1.904–4(f)(2) generally attribute U.S. gross income to taxable units on the basis of books and records, as modified to reflect Federal income tax principles, and reattribute U.S. gross income between the general category and the foreign branch category by reason of certain disregarded payments between a foreign branch and its owner, or another foreign branch, that would be deductible if regarded for Federal income tax purposes. The reattribution is made by reference to the statutory and residual groupings of the payor to which the disregarded payment would be allocated and apportioned if it were regarded for Federal income tax purposes.

Proposed § 1.954–1(d)(1)(iii), as contained in the 2020 HTE proposed regulations, generally adopts the principles of § 1.904–4(f)(2) for purposes of assigning U.S. gross income to tested units of a controlled foreign corporation for purposes of the high-tax exception. However, although § 1.904–4(f)(2)(vi) does not treat disregarded interest payments as a disregarded reallocation transaction, under proposed § 1.954–1(d)(1)(iii)(B) of the 2020 HTE proposed regulations, disregarded interest payments are treated as reattribution payments to the extent they are deductible for foreign law purposes in the country where the payor taxable unit is a tax resident. Proposed § 1.954–1(d)(1)(iii)(B)(*4*) provides that these disregarded interest payments are treated as made ratably out of the payor's current year U.S. gross income to the extent thereof, and provides ordering rules when the same taxable unit both makes and receives disregarded interest payments. Comments are requested on additional ordering rules that should be included in the final regulations, including rules that apply when multiple taxable units both make and receive disregarded payments, such as rules for determining the starting point for assigning reattribution payments received by taxable units, and the order in which particular types of disregarded payments made by taxable units are allocated and apportioned to U.S. gross income (including income attributable to reattribution payments received by the payor taxable unit) of the payor taxable unit. In addition, because proposed § 1.861–20(d)(3)(v) more clearly coordinates with the provisions in proposed § 1.954–1(d)(1), the proposed regulations propose to update proposed § 1.954–1(d)(1)(iv)(A) (as contained in the 2020 HTE proposed regulations) to clarify that the rules in § 1.861–20 (rather than the principles of § 1.904–6(b)(2)) apply in the case of disregarded payments. In order to achieve consistency with the new tested unit rules in proposed § 1.954–1(d) and taxable unit rules in § 1.861–20(d)(3)(v), the proposed regulations also contain a modification to the high-tax kickout rules in § 1.904–4(c)(4) to provide that the grouping rules at the CFC level are applied on a tested unit (instead of foreign QBU) basis.

Proposed § 1.861–20(d)(3)(v)(B)(*3*) provides that the statutory or residual grouping to which foreign gross income of a taxable unit (including foreign gross income that arises from the receipt of a disregarded payment) is assigned is determined without regard to reattribution payments made by the taxable unit, and that no item of foreign gross income is reassigned to another taxable unit by reason of a reattribution payment that reattributes U.S. gross income of the payor taxable unit to another taxable unit by reason of such reattribution payments. Under this rule, if foreign gross income is associated under § 1.861–20(d)(1) with a corresponding U.S. item initially attributed to a payor taxable unit, that foreign gross income is always assigned to the grouping that includes the U.S. gross income of that payor taxable unit. The effect of this rule and proposed § 1.861–20(d)(3)(v)(B)(*1*) is to allocate and apportion foreign tax imposed on foreign gross income that is associated either with a corresponding U.S. item that is initially attributed to a payor taxable unit or with a reattribution amount that is attributed to a recipient taxable unit (before taking into account reattribution payments made by the recipient taxable unit) to the grouping that includes the U.S. gross income of the taxable unit that paid the foreign tax; no portion of the foreign tax is associated with U.S. gross income that is reattributed to another taxable unit by reason of a reattribution payment.

In the case of foreign income tax imposed on the basis of foreign taxable income for a taxable period (that is, net basis taxes), this rule will generally produce appropriate results because foreign gross income of a taxable unit will generally be reduced by foreign law deductions for disregarded payments

[1] References to § 1.954–1(d) in these proposed regulations are to proposed § 1.954–1(d) as contained in the 2020 HTE proposed regulations.

made by that taxable unit, so that the amount of the payor's foreign taxable income will approximate the amount of U.S. taxable income attributed to the taxable unit after accounting for reattribution payments made and received by that taxable unit. Foreign gross basis taxes (such as withholding taxes) imposed on foreign gross income of a taxable unit, if not reassigned along with the associated U.S. gross income that is reattributed to another taxable unit as the result of a reattribution payment, however, may in some cases distort the effective foreign tax rate of the payor taxable unit. The Treasury Department and the IRS have determined that rules reattributing foreign gross basis taxes among taxable units by reason of reattribution payments would require complex ordering rules that would be unduly burdensome for taxpayers to apply and for the IRS to administer. Comments are requested on whether the final regulations should include different rules, including anti-abuse rules, to account for the assignment of foreign gross basis taxes paid by taxable units that make disregarded payments.

iii. Remittances and Contributions

Similar to the rules in the 2019 FTC proposed regulations, proposed § 1.861–20(d)(3)(v)(C)(*1*)(*i*) assigns foreign gross income that arises from a disregarded payment that is treated as a remittance for U.S. tax purposes by reference to the statutory and residual groupings to which the assets of the payor taxable unit are assigned (or would be assigned if the taxable unit were a United States person) under the rules of § 1.861–9 for purposes of apportioning interest expense. This rule uses the payor's asset apportionment percentages as a proxy for the accumulated earnings of the payor taxable unit from which the remittance is made. Proposed § 1.861–20(d)(3)(v)(C)(*1*)(*ii*) provides that for this purpose the assets of the taxable unit making the remittance are determined in accordance with the rules of § 1.987–6(b) that apply in determining the source and separate category of exchange gain or loss on a section 987 remittance, as modified in two respects.

First, for purposes of § 1.860–20(d)(3)(v)(C)(*1*)(*i*) the assets of the remitting taxable unit include stock owned by the taxable unit, even though for purposes of section 987 such stock may be treated as owned directly by the owner of the taxable unit. This rule helps to ensure that foreign tax on remittances are properly associated with earnings of corporations that may be distributed through the taxable unit.

Second, proposed § 1.861–20(d)(3)(v)(C)(*1*)(*ii*) modifies the determination of assets under § 1.987–6(b)(2) to provide that the assets of a taxable unit that give rise to U.S. gross income that is assigned to another taxable unit by reason of a reattribution payment are treated as assets of the recipient taxable unit. The Treasury Department and the IRS have determined that reassigning the tax book value of assets among taxable units in proportion to the U.S. gross income attributed to a taxable unit, after taking into account all reattribution payments made and received by the taxable unit, for purposes of determining the statutory and residual groupings to which foreign tax on a remittance is assigned is appropriate to properly match the foreign tax with the accumulated earnings out of which the remittance is made. In addition, because it uses asset values that are already required to be computed and maintained for other Federal income tax purposes, this reattribution rule is less complicated to apply than a rule that would treat disregarded assets and liabilities as if they were regarded for U.S. tax purposes in applying this rule.

However, the Treasury Department and the IRS acknowledge that any asset method for associating foreign gross income included by the remittance recipient with the payor's accumulated earnings may lead to inexact determinations of the groupings of the accumulated earnings out of which a remittance is paid, particularly when a taxable unit makes a remittance in conjunction with reattribution payments. The potential for distortions exist to the extent the tax book value of assets does not reflect their income-producing value, as in the case of self-developed intangibles the costs of which are currently expensed, as well as to the extent the characterization of the tax book value of an asset based on the income generated by the asset in the current taxable year does not reflect the characterization of the income generated by the asset over time. Comments are requested on whether a different method of determining the statutory and residual groupings to which a remittance is assigned, such as the maintenance of historical accounts of accumulated earnings of taxable units, including adjustments to reflect disregarded payments among taxable units, could produce more accurate results without unduly increasing administrative burdens.

Similar to the rule in the 2019 FTC proposed regulations, proposed § 1.861–20(d)(3)(v)(C)(*2*) provides that foreign gross income and the associated foreign tax that arise from the receipt of a contribution are assigned to the residual category, except as provided under the rules for an operative section (such as under proposed § 1.904–6(b)(2)(ii), which assigns foreign tax on contributions to a foreign branch to the foreign branch category). Proposed § 1.861–20(d)(3)(v)(E)(*2*) defines a contribution as a disregarded transfer of property that would be treated as a transaction described in section 118 or 351 if the recipient taxable unit were treated as a corporation for Federal income tax purposes, or the excess amount of a disregarded payment made to a taxable unit that the payor unit owns over the amount that is treated as a reattribution payment.

Foreign tax paid by a foreign corporation that is allocated and apportioned to the residual category is not eligible to be deemed paid under section 960. See § 1.960–1(e). However, because proposed § 1.861–20(d)(3)(v) treats most disregarded payments as reattribution payments or remittances, and contributions (as characterized for corporate law purposes) are rarely subject to foreign tax, the Treasury Department and the IRS expect this rule will have limited application.

Proposed § 1.861–20(d)(3)(v)(C)(*3*) provides an ordering rule attributing the amount of foreign gross income that arises from the receipt of a disregarded payment that includes both a reattribution payment and a remittance or contribution first to the portion of the disregarded payment that is a reattribution payment. Any excess amount of the foreign gross income item is attributed to the portion of the disregarded payment that is a remittance or contribution.

In addition, proposed § 1.861–20(d)(2)(ii)(D) provides that if an item of foreign gross income arises from an event that for foreign law purposes is treated as a distribution, contribution, accrual, or payment between taxable units, but that is not treated as a disregarded payment for Federal income tax purposes (for example, a consent dividend from a disregarded entity), the foreign gross income and associated foreign tax are assigned in the same way as if a transfer of property in the amount of the foreign gross income item resulted in a disregarded payment in the year the foreign tax is paid or accrued.

Finally, in light of the heightened importance of the rules in § 1.904–4(f), which are being applied in connection with § 1.861–20 as well as the high-tax exception rules in § 1.951A–2(c)(7), the proposed regulations include some technical changes to the rules in § 1.904–4(f) that will facilitate this

interaction. See Part XI.A of this Explanation of Provisions.

iv. Disregarded Payments With Respect to Disregarded Sales of Property

Proposed § 1.861–20(d)(3)(v)(D) clarifies that an item of foreign gross income attributable to gain recognized under foreign law by reason of a disregarded payment received in exchange for property is characterized and assigned under § 1.861–20(d)(2)(ii)(A) of the 2020 FTC final regulations, that is, as a timing difference in the taxation of the property's built-in gain. Proposed § 1.861–20(d)(3)(v)(D) further provides that if a taxpayer recognizes U.S. gross income as a result of a disposition of property that was previously received in exchange for a disregarded payment, any item of foreign gross income that the taxpayer recognizes as a result of that same disposition is assigned to a statutory or residual grouping under the U.S. corresponding item rules in § 1.861–20(d)(1) of the 2020 FTC final regulations. Because in this situation the seller's basis in the property initially acquired in a disregarded sale is not adjusted for U.S. tax purposes, but is assumed to reflect the purchase price for foreign tax purposes, the assignment of the foreign gross income resulting from the regarded sale of the property is made without regard to any reattribution of the gain that is recognized for U.S. tax purposes under § 1.904–4(f)(2)(vi)(A) or (D), which apply to attribute U.S. gross income in the amount of the property's built-in gain at the time of the initial acquisition to the foreign branch or foreign branch owner that originally transferred the property in the disregarded sale. The same result obtains with respect to all taxable units under proposed § 1.861–20(d)(3)(v)(B)(*3*).

5. Group-Relief Regimes

The Treasury Department and the IRS are concerned about the use of certain foreign law group-relief regimes (that is, regimes that allow for the sharing of losses of one member of a group with another member) to create a mismatch in how foreign income taxes are characterized under § 1.861–20 for purposes of various operative sections, including sections 245A(d), 904, and 960. Comments are requested on the appropriate treatment of foreign income taxes paid or accrued in connection with the sharing of losses.

VI. Creditability of Foreign Taxes Under Sections 901 and 903

A. Definition of Foreign Income Tax

1. Background and Overview

Section 901 allows a credit for foreign income, war profits, and excess profits taxes, and section 903 provides that such taxes include a tax in lieu of a generally-imposed foreign income, war profits, or excess profits tax.[2] Section 1.901–2, which was originally promulgated in 1983 in TD 7918 (the ''1983 final regulations''), sets forth conditions for determining when a foreign levy is a foreign income, war profits, and excess profits tax (collectively, an ''income tax'') that is creditable under section 901. Under the existing regulations, a foreign levy is an income tax if and only if (1) it is a tax, and (2) the predominant character of that tax is that of an income tax in the U.S. sense. See § 1.901–2(a)(1). Under § 1.901–2(a)(3), the predominant character of a foreign tax is that of an income tax in the U.S. sense if it meets two requirements: (1) The foreign tax is likely to reach net gain in the normal circumstances in which it applies (the ''net gain requirement''), and (2) it is not a ''soak-up'' tax. To satisfy the net gain requirement, a tax must meet the realization, gross receipts, and net income requirements in § 1.901–2(b)(2), (3), and (4), respectively. Under § 1.901–2(a)(1), a foreign tax either is or is not a foreign income tax, in its entirety, for all persons subject to the foreign tax. This all-or-nothing rule ensures consistent outcomes for taxpayers and minimizes the administrative burdens on the IRS that would result if the creditability of a foreign tax instead varied depending on each taxpayer's particular facts.

The Treasury Department and the IRS have determined that it is necessary and appropriate to require that a foreign tax conform to traditional international norms of taxing jurisdiction as reflected in the Internal Revenue Code in order to qualify as an income tax in the U.S. sense, or as a tax in lieu of an income tax. As discussed in more detail in Part VI.A.2 of this Explanation of Provisions, this requirement will ensure that the foreign tax credit operates in accordance with its purpose to mitigate double taxation of income that is attributable to a taxpayer's activities or investment in a foreign country.

In addition, the Treasury Department and the IRS have determined that it is necessary and appropriate to revise the net gain requirement in order to better align the regulatory tests with norms reflected in the Internal Revenue Code that define an income tax in the U.S. sense, as well as to simplify and clarify the application of the rules. In particular, the existing regulations provide that the net gain requirement is met if a foreign tax reaches net gain in the ''normal circumstances'' in which it applies. However, this rule leads to inappropriate results and presupposes an empirical analysis requiring access to information that is difficult for taxpayers and the IRS to obtain. Therefore, the proposed regulations narrow the situations in which an empirical analysis is relevant in analyzing the nature of a foreign tax. See Part VI.A.3 of this Explanation of Provisions.

The proposed regulations make other changes to improve or clarify the rules, and to address issues that have arisen since the 1983 final regulations were issued. In particular, the proposed regulations introduce the term ''net income tax'' to describe foreign levies described in section 901 and the term ''foreign income tax'' to describe foreign levies described in section 901 or 903. See also Part X.F of this Explanation of Provisions (describing conforming changes made to §§ 1.960–1 and 1.960–2). Conforming changes to the terms and definitions cross-referenced in other regulations will be made when the proposed regulations are finalized.

The proposed regulations specifically address the treatment of surtaxes and the circumstances in which a source-based withholding tax on cross-border income can qualify as a foreign income tax. The proposed regulations also reorganize the existing regulations to address soak-up taxes as part of the determination of the amount of tax paid, rather than as part of the definition of a foreign income tax, and clarify the rules for determining when a foreign tax is a separate levy. The proposed regulations addressing the amount of tax paid also modify the treatment of refundable credits, clarify the interaction between the rules addressing refundable amounts and multiple levies, and clarify the application of the noncompulsory payment rules with respect to foreign tax law elections. Finally, the proposed regulations revise the definition of a tax in lieu of an income tax. These rules are described in more detail in Parts VI.A.3.v, VI.A.4, VI.A.5, VI.B, and VI.C of this Explanation of Provisions.

The proposed regulations do not include proposed amendments to the rules in § 1.901–2A addressing dual

[2] Taxpayers may generally claim a deduction instead of a credit for these foreign taxes, as well as for certain other foreign taxes that do not qualify for the foreign tax credit. See section 164(a).

capacity taxpayers. However, certain proposed changes to §§ 1.901–2 and 1.903–1 may impact § 1.901–2A. For example, when the proposed regulations are finalized, certain terms that are defined in § 1.901–2 and cross-referenced in § 1.901–2A will need to be updated. Comments are requested on whether additional changes to § 1.901–2A are appropriate in light of the proposed revisions to §§ 1.901–2 and 1.903–1.

2. Jurisdictional Nexus Requirement

As a dollar-for-dollar credit against U.S. income tax, the foreign tax credit is intended to mitigate double taxation of foreign source income. This fundamental purpose is served most appropriately if there is substantial conformity in the principles used to calculate the base of the foreign tax and the base of the U.S. income tax. This conformity extends not just to ascertaining whether the foreign tax base approximates U.S. taxable income determined on the basis of realized gross receipts reduced by allocable expenses, but also to whether there is a sufficient nexus between the income that is subject to tax and the foreign jurisdiction imposing the tax. Although prior regulations under section 901 did contain jurisdictional limitations on the definition of an income tax, see § 4.901–2(a)(1)(iii) (1980) (requiring that a foreign tax follow ''reasonable rules regarding source of income, residence, or other bases for taxing jurisdiction''), the existing regulations do not contain such a rule.

In recent years, several foreign countries have adopted or are considering adopting a variety of novel extraterritorial taxes that diverge in significant respects from traditional norms of international taxing jurisdiction as reflected in the Internal Revenue Code. In addition, the Treasury Department and the IRS have received requests for guidance on whether the definition of foreign income tax includes a jurisdictional limitation, and recommending that the regulations adopt a rule requiring that income subject to foreign tax bear an appropriate connection to a foreign country for a foreign tax to be eligible for the foreign tax credit. In light of these developments, the Treasury Department and the IRS have determined that it is appropriate to revisit the regulatory definition of a foreign income tax to ensure that to be creditable, foreign taxes in fact have a predominant character of ''an income tax in the U.S. sense.''

The Treasury Department and the IRS have determined that in order to qualify as a creditable income tax, the foreign tax law must require a sufficient nexus between the foreign country and the taxpayer's activities or investment of capital or other assets that give rise to the income being taxed. For example, a tax imposed by a foreign country on a taxpayer's income that lacks a sufficient nexus to such country (such as the lack of operations, employees, factors of production, or management in that foreign country) is not an income tax in the U.S. sense and should not be eligible for a foreign tax credit if paid or accrued by U.S. taxpayers. Such a nexus is required in order for persons and income to be subject to U.S. income tax, and so a similar nexus reflecting the foreign country's exercise of taxing jurisdiction consistent with Federal income tax principles should be required in order for foreign taxes to be eligible for a dollar-for-dollar credit against U.S. income tax.

The proposed regulations therefore require that for a foreign tax to qualify as an income tax, the tax must conform with established international norms, reflected in the Internal Revenue Code and related guidance, for allocating profit between associated enterprises, for allocating business profits of nonresidents to a taxable presence in the foreign country, and for taxing cross-border income based on source or the situs of property (together, the ''jurisdictional nexus requirement''). Proposed § 1.901–2(c)(1)(i) generally provides that in the case of a foreign country imposing tax on nonresidents, the foreign tax law must determine the amount of income subject to tax based on the nonresident's activities located in the foreign country (including its functions, assets, and risks located in the foreign country). Thus, for example, rules that are consistent with the rules under section 864(c) for taxing income effectively connected with a U.S. trade or business, or with Articles 5 and 7 of the U.S. Model Income Tax Convention for taxing profits attributable to a permanent establishment, will meet this requirement. However, foreign countries that, for example, impose tax by using as a significant factor the location of customers, users, or any other similar destination-based criterion to allocate profit (for example, by deeming a taxable presence based on the existence of customers) will not satisfy the jurisdictional nexus requirement.

If the foreign tax law imposes tax on a nonresident's income based on the income arising from sources in the foreign country (for example, tax imposed on interest, rents, or royalties sourced in the foreign country and paid to a nonresident), proposed § 1.901–2(c)(1)(ii) requires the sourcing rules of the foreign tax law to be reasonably similar to the sourcing rules that apply for Federal income tax purposes. For the avoidance of doubt, the proposed regulations provide that in the case of income from services, the income must be sourced based on the place of performance of the services, not the location of the services recipient.

The jurisdictional nexus requirement for taxing gains from sales or other dispositions of property is separately addressed in proposed § 1.901–2(c)(1)(iii), which provides that income from sales or other dispositions of property by nonresidents that do not meet the activities requirement in proposed § 1.901–2(c)(1)(i) satisfy the jurisdictional nexus requirement only with respect to gains on the disposition of real property in the foreign country or movable property forming part of the business property of a taxable presence in the foreign country (or from interests in certain entities holding such property). This rule is consistent with the fact that Federal income tax law generally does not tax gains of nonresidents that do not have a trade or business in the United States. See, for example, section 865(a)(2) and (e)(2); § 1.871–7(a)(1); see also U.S. Model Income Tax Convention (2016), Art. 13.

A similar rule applies under proposed § 1.901–2(c)(2) with respect to determining the income of a resident taxpayer in cases where income of a related entity may be allocated under transfer pricing rules to the resident taxpayer. For the jurisdictional nexus requirement to be satisfied in such a case, the foreign tax law's transfer pricing rules must be determined under arm's length principles. Thus, for example, foreign tax laws that contain transfer pricing rules that are consistent with the arm's length standard under the section 482 regulations, or with the arm's length principle under the OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations, will satisfy this requirement. However, foreign transfer pricing rules that allocate profits by taking into account as a significant factor the location of customers, users, or any other similar destination-based criterion will not satisfy the jurisdictional nexus requirement. Comments are requested on whether special rules are needed to address foreign transfer pricing rules that allocate profits to a resident on a formulary basis (rather than on the basis of arm's length prices), such as through the use of fixed margins in a manner that is not consistent with arm's length principles. The jurisdictional nexus

requirement is not violated when a foreign country imposes tax on the worldwide income of a resident taxpayer, including under controlled foreign corporation regimes that deem income to be included (or distributed) to a resident shareholder (as opposed to allocated directly to the resident under a transfer pricing adjustment). For this purpose, the terms resident and nonresident are defined in proposed § 1.901–2(g)(6) and in the case of an entity, the classification is generally based on the entity's place of incorporation or management.

As part of its response to the extraterritorial tax measures referred to in this Part VI.A.2 of the Explanation of Provisions, the Treasury Department has been actively engaged in negotiations with other countries, as part of the OECD/G20 Inclusive Framework on BEPS, to explore the possibility of a new international framework for allocating taxing rights.[3] If an agreement is reached that includes the United States, the Treasury Department recognizes that changes to the foreign tax credit system may be required at that time.

No inference is intended as to the application of existing §§ 1.901–2 and 1.903–1 to the treatment of novel extraterritorial foreign taxes such as digital services taxes, diverted profits taxes, or equalization levies. In addition, the proposed regulations, when finalized, would not affect the application of existing income tax treaties to which the United States is a party with respect to covered taxes (including any specifically identified taxes) that are creditable under the treaty. Comments are requested on the extent to which the new jurisdictional nexus requirement may impact the treatment of other types of foreign taxes, and on alternative approaches the Treasury Department and the IRS may consider to modify the rules to achieve the policy objectives described in this Part VI.A.2 of the Explanation of Provisions.

3. Net Gain Requirement

i. Use of Empirical Analysis

The existing regulations provide that the net gain requirement is met if a foreign tax reaches net gain in the ''normal circumstances'' in which it applies. See § 1.901–2(a)(1). As noted in the preamble to the 1983 final regulations, this rule is based on the standard set forth in *Inland Steel Company* v. *United States,* 677 F.2d 72 (Ct. Cl. 1982), *Bank of America Nat'l Trust and Savings Ass'n* v. *United States,* 459 F.2d 513 (Ct. Cl. 1972) (''*Bank of America I*''), and *Bank of America Nat'l Trust and Savings Ass'n* v. *Comm'r,* 61 T.C. 752 (1974), *aff'd,* 538 F.2d 334 (9th Cir.1976) (''*Bank of America II*''). See TD 7918, 48 FR 46272–01 (1983).

The Treasury Department and the IRS have determined that, in some respects, the empirical analysis contemplated by the existing regulations is unnecessary to identify the essential elements of an income tax in the U.S. sense. In addition, in the absence of specific rules and thresholds in the regulations on how to evaluate empirical data (if even available), both taxpayers and the IRS have had difficulties in applying the existing regulations to foreign taxes in a consistent and predictable manner. In some cases, the reliance on empirical data to determine whether the requirements of the existing regulations are met creates uncertainty and undue burdens for taxpayers and the IRS, considering challenges in obtaining the necessary information. Therefore, the proposed regulations limit the relevance of the ''normal circumstances'' in which the tax applies, as well as the role of the predominant character analysis, in determining whether a tax meets the various components of the net gain requirement. These changes will lead to more accurate and consistent outcomes and reduce the compliance and administrative burdens of the existing law requirement that taxpayers and the IRS obtain from the foreign government empirical information, such as tax return information for persons subject to the tax, to determine the normal circumstances in which the tax applies.

Instead, proposed § 1.901–2(b)(1) generally provides that whether a tax is a foreign income tax is determined under the terms of the foreign tax law, taking into account statutes, regulations, case law, and administrative rulings or other official pronouncements, as modified by treaties. Accordingly, whether a tax satisfies the net gain requirement is generally based on whether the terms of the foreign tax law governing the computation of the tax base meet the realization, gross receipts, and cost recovery requirements that make up the net gain requirement under § 1.901–2(a)(3). This approach will better allow taxpayers and the IRS to evaluate the nature of the foreign tax based on objective and readily available information (that is, based on the terms of the foreign tax law, rather than how it is applied in practice), to achieve more consistent and predictable outcomes. Evaluation of the normal circumstances in which the tax applies is still a factor in determining whether specific elements of the net gain requirement are satisfied, but the proposed regulations specifically identify the elements of the requirement for which this type of empirical evidence is relevant.

ii. Realization Requirement

Under the existing regulations, a foreign tax generally satisfies the realization requirement if, judged on the basis of its predominant character, it is imposed upon or after the occurrence of events (''realization events'') that would result in the realization of income under the Code, or in certain cases, it is imposed on the occurrence of a pre-realization event, such as in the case of a foreign law mark-to-market regime. See § 1.901–2(b)(2)(i).

As discussed in Part VI.A.3.i of this Explanation of Provisions, due to the burdens resulting from the requirement to perform an empirical analysis to ascertain the nature of a tax, the proposed regulations provide more specific rules regarding the elements of the requirement for which this type of empirical evidence is relevant. In particular, the Treasury Department and the IRS have determined that the inclusion in the foreign tax base of insignificant amounts of gross receipts that do not meet the realization requirement should not prevent an otherwise-qualifying foreign tax from qualifying as an income tax. Accordingly, proposed § 1.901–2(b)(2) provides that if a foreign tax generally meets the various realization requirements described in proposed § 1.901–2(b)(2)(i)(A) through (C), except with respect to one or more specific and defined classes of nonrealization events, the tax may still be treated as meeting the realization requirement if the incidence and amounts of gross receipts attributable to the nonrealization events are minimal relative to the incidence and amounts of gross receipts attributable to events covered by the foreign tax that do meet the realization requirement. This determination is made based on the application of the foreign tax to all taxpayers subject to the foreign tax (rather than on a taxpayer-by-taxpayer basis). Therefore, for example, if a foreign tax contains all of the same realization requirements as the Code, but also imposes tax on imputed rent with respect to owner-occupied housing, the foreign tax may still qualify as a foreign income tax if, relative to all of the income of all taxpayers that are subject to the tax, imputed rental

[3] See Statement by the OECD/G20 Inclusive Framework on BEPS on the Two-Pillar Approach to Address the Tax Challenges Arising from the Digitalisation of the Economy (January 2020), available at *https://www.oecd.org/tax/beps/statement-by-the-oecd-g20-inclusive-framework-on-beps-january-2020.pdf.*

income comprises a relatively small amount (even if for some taxpayers, all of their income may constitute imputed rent). Comments are requested on whether the regulations could substitute a more objective standard for identifying acceptable deviations from the realization requirement that would avoid the need for empirical analysis.

Proposed § 1.901–2(b)(2)(i)(C) consolidates the rules relating to pre-realization timing differences, including the rule currently in § 1.901–2(b)(2)(ii) that foreign taxes imposed on a shareholder on deemed distributions or inclusions (such as inclusions similar to those imposed by U.S. law under subpart F) of income realized by the distributing entity satisfy the realization requirement, so long as a second tax is not imposed on the shareholder on the same income upon the occurrence of a later event (such as an actual distribution). Under proposed § 1.901–2(b)(2)(i)(C), because a shareholder-level tax on a distribution from a corporation is imposed on a different taxpayer, the shareholder-level tax is not treated as a second tax on the corporation's income (including income arising from a pre-realization event). For this purpose, proposed § 1.901–2(b)(2)(i)(C) provides that a disregarded entity is treated as a taxpayer separate from its owner. Comments are requested on whether there are additional categories of pre-realization timing differences that should be included in the final regulations.

Finally, the Treasury Department and the IRS expect to update the examples illustrating the realization requirement that are contained in § 1.901–2(b)(2)(iv) and include them in the regulations when proposed § 1.901–2(b)(2) is finalized.

iii. Gross Receipts Requirement

Under existing § 1.901–2(b)(3), a foreign tax satisfies the gross receipts requirement if, judged on the basis of its predominant character, it is imposed on the basis of (1) gross receipts; or (2) gross receipts computed under a method that is likely to produce an amount that is not greater than the fair market value of actual arm's length gross receipts (''the alternative gross receipts test''). See § 1.901–2(b)(3)(ii) *Examples 1* and *2.*

The proposed regulations modify the alternative gross receipts test to provide that it is satisfied in the case of tax imposed on deemed gross receipts arising from pre-realization timing difference events described in proposed § 1.901–2(b)(2)(i)(C) (that is, a mark-to-market regime, tax on the physical transfer, processing, or export of readily marketable property, or a deemed distribution or inclusion), or on the basis of gross receipts from a non-realization event that is insignificant and therefore does not cause the foreign tax to fail the realization requirement in proposed § 1.901–2(b)(2). Therefore, taxes on insignificant non-realization events or pre-realization timing difference events that satisfy the realization requirement in proposed § 1.901–2(b)(2)(i)(C) also satisfy the gross receipts test.

However, the proposed regulations remove the provision referring to gross receipts computed under a method that is ''likely'' to produce an amount not greater than gross receipts. This rule purports to allow for foreign taxes to be imposed on an amount greater than the amount of income actually realized, or the value of the property being taxed, and the Treasury Department and the IRS have determined that such a tax should not be considered to be a tax on income, since it can be imposed on amounts in excess of actual gross receipts. In addition, the Treasury Department and the IRS have determined that the test is vague, unduly burdensome, and has given rise to controversies requiring taxpayers and the IRS to conduct an empirical evaluation to determine whether a nonconforming statutory method of determining alternative gross receipts is likely not to exceed the fair market value of actual gross receipts. See, for example, *Phillips Petroleum* v. *Comm'r,* 104 T.C. 256 (1995) (applying the former § 1.901–2T (1980) TD 7739). The Treasury Department and the IRS have determined that, other than in the case of insignificant non-realization events, only a tax base determined with reference to realized gross receipts or, in the case of a pre-realization timing difference event, the value or amount of a deemed inclusion or accrual (and not an approximation of gross receipts), should qualify as an income tax in the U.S. sense. In contrast, a tax based on alternative measurements of gross receipts, such as a foreign tax that requires gross receipts to be calculated by applying a markup to costs, fundamentally diverges from the measurement of realized gross receipts under the Internal Revenue Code, and could result in a taxable base that exceeds the amount of income properly attributable to the taxpayer's activities or investment in the foreign country. The revised rule will also minimize the need for empirical analyses, making it simpler for both taxpayers and the IRS to determine whether a tax satisfies the net gain requirement.

This rule is not intended to implicate the allocation of gross income under transfer pricing or branch profit attribution rules, which are instead addressed under proposed § 1.901–2(c). Proposed § 1.901–2(b)(3)(i) provides that in determining a taxpayer's actual gross receipts, amounts that are properly allocated to such taxpayer under the jurisdictional nexus rules in proposed § 1.901–2(c), such as pursuant to transfer pricing rules that properly allocate income to a taxpayer on the basis of costs incurred by that entity, are treated as the taxpayer's actual gross receipts.

iv. Cost Recovery Requirement

Under the net income requirement in the existing regulations, foreign tax law must permit the recovery of the significant costs and expenses attributable, under reasonable principles, to gross receipts included in the taxable base. A foreign tax law permits the recovery of significant costs and expenses even if such costs and expenses are recovered at a different time than they would be under the Code, unless the time of recovery is such that under the circumstances there is effectively a denial of recovery. Under the ''nonconfiscatory gross basis tax'' rule in § 1.901–2(b)(4) of the existing regulations, which reflects the standard described in *Bank of America I,* a foreign tax whose base is gross receipts or gross income does not satisfy the net income requirement except in the ''rare situation'' when the tax is almost certain to reach some net gain in the normal circumstances in which it applies because costs and expenses will almost never be so high as to offset gross receipts or gross income, respectively, and the rate of the tax is such that after the tax is paid persons subject to the tax are almost certain to have net gain. Thus, a tax on the gross receipts or gross income of businesses can satisfy the net income requirement in the existing regulations if businesses subject to the tax are almost certain never to incur a loss (after payment of the tax).

The Treasury Department and the IRS have determined that to constitute an income tax for U.S. tax purposes, that is, a tax on net gain, the base of a foreign tax should conform in essential respects to the determination of taxable income for Federal income tax purposes. See, for example, *Keasbey & Mattison Co.* v. *Rothensies,* 133 F.2d 894, 895 (3d Cir. 1943) (holding that the criteria prescribed by U.S. revenue laws are determinative of the meaning of the term ''income taxes'' in applying the former version of section 901); and *Comm'r* v. *American Metal Co.,* 221

F.2d 134, 137 (2d Cir. 1955) (providing that ''the determinative question is 'whether the foreign tax is the substantial equivalent of an 'income tax' as that term is understood in the United States' ''). The Treasury Department and the IRS have determined that any foreign tax imposed on a gross basis is by definition not an income tax in the U.S. sense, regardless of the rate at which it is imposed or the extent of the associated costs.

In addition, the Treasury Department and the IRS have determined that the empirical standards contained in *Bank of America I* and that are contemplated by the nonconfiscatory gross basis tax rule in the existing regulations create substantial compliance and administrative burdens for taxpayers and the IRS when evaluating whether a foreign tax is an income tax in the U.S. sense. For example, the IRS and taxpayers must obtain foreign tax return information with respect to all persons subject to the tax to determine if persons subject to the tax are almost certain never to incur an after-tax loss. See, for example, *PPL Corp.* v. *Comm'r,* 135 T.C. 304 (2010), *rev'd,* 665 F.3d 60 (3d Cir. 2011), *rev'd,* 569 U.S. 329 (2013); *Texasgulf, Inc.* v. *Comm'r,* 107 T.C. 51 (1996), *aff'd,* 172 F.3d 209 (2d Cir. 1999); and *Exxon Corp.* v. *Comm'r,* 113 T.C. 338 (1999) (applying the empirical analysis required by the regulations).

Therefore, the proposed regulations remove the nonconfiscatory gross basis tax rule. Instead, the proposed regulations provide that whether a tax meets the net gain requirement is made solely on the basis of the terms of the foreign tax law that define the foreign taxable base, without any consideration of the rate of tax imposed on that base. See proposed § 1.901–2(b)(1). In addition, the cost recovery requirement in proposed § 1.901–2(b)(4) requires the deductions allowed under the foreign tax law to approximate the cost recovery provisions of the Internal Revenue Code in order for the foreign tax to qualify as an income tax in the U.S. sense. Under proposed § 1.901–2(b)(4)(i)(A), a tax that is imposed on gross receipts or gross income, without reduction for any costs or expenses attributable to earning that income, cannot qualify as a net income tax, without regard to whether the empirical impact of the tax is confiscatory, and even if in practice there are no or few costs and expenses attributable to all or particular types of gross receipts included in the foreign tax base. Under this rule, the cost recovery requirement is not satisfied for taxes such as payroll taxes on gross income from wages, but may be satisfied in the case of a personal income tax similar to that imposed under section 1 of the Code on all gross income (including wages), if the foreign country allows taxpayers to reduce such gross income by the substantial costs and expenses that are reasonably attributable to such gross income (taking into account any reasonable deduction disallowance provisions).

Under the ''alternative allowance rule'' in § 1.901–2(b)(4) of the existing regulations, a foreign tax that does not permit recovery of one or more significant costs or expenses, but that provides allowances that effectively compensate for nonrecovery of such significant costs or expenses, is considered to permit recovery of such costs or expenses. The Treasury Department and IRS have determined, however, that the alternative allowance rule fundamentally diverges from the approach to cost recovery in the Internal Revenue Code, and so is inconsistent with an essential element of an income tax in the U.S. sense. Moreover, it is unduly burdensome, and may be impossible as a practical matter, for taxpayers and the IRS to determine whether an alternative allowance under foreign tax law effectively compensates for the nonrecovery of significant costs or expenses attributable to realized gross receipts under that foreign law. The alternative allowance rule in the existing regulations has given rise to controversies between taxpayers and the IRS, and different interpretations by the courts, over whether the rule requires taxpayers to demonstrate that the alternative allowance exceeds disallowed expense deductions for a majority of persons potentially subject to the tax, a majority of persons that actually pay the tax, or for taxpayers in the aggregate, determined by comparing the aggregate amounts of disallowed deductions and alternative allowances reported on the foreign tax returns of all persons subject to the tax. See, for example, *Texasgulf, Inc.* v. *Comm'r,* 107 T.C. 51 (1996), *aff'd,* 172 F3d 209 (2d Cir. 1999); and *Exxon Corp.* v. *Comm'r,* 113 T.C. 338 (1999). Therefore, the proposed regulations at § 1.901–2(b)(4)(i)(A) modify the alternative allowance rule to treat alternative allowances as meeting the cost recovery requirement only if the foreign tax law expressly guarantees that the alternative allowance will equal or exceed actual costs (for example, under a provision identical to percentage depletion allowed under section 613).

The proposed regulations at § 1.901–2(b)(4)(i)(B)(*1*) retain the existing rule that foreign tax law is considered to permit the recovery of significant costs and expenses even if the costs and expenses are recovered at a different time than they would be if the Internal Revenue Code applied, unless the time of recovery is so much later (for example, after the property becomes worthless or is disposed of) as effectively to constitute a denial of such recovery. The regulations clarify that the different time can be either earlier or later than it would be if the Code applied, and that time value of money considerations relating to the economic cost (or value) of accelerating (or deferring) a foreign tax liability are not relevant in determining the amount of recovered costs and expenses.

The proposed regulations also add a new rule to allow a tax to satisfy the cost recovery requirement even if recovery of all or a portion of certain costs or expenses is disallowed, if such disallowance is consistent with the types of disallowances required under the Internal Revenue Code. See proposed § 1.901–2(b)(4)(i)(B)(*2*). For example, foreign tax law is considered to permit the recovery of significant costs and expenses even if such law disallows interest deductions equal to a certain percentage of adjusted taxable income similar to the limitation under section 163(j) or disallows interest and royalty deductions in connection with hybrid transactions similar to those subject to section 267A. This new provision is consistent with the rule that principles of U.S. law apply to determine whether a tax is a creditable income tax. See § 1.901–2(a)(1)(ii); see also, for example, *Keasbey,* 133 F.2d at 897; and *American Metal,* 221 F.2d at 137.

Finally, proposed § 1.901–2(b)(4)(i)(B)(*2*) provides that an empirical analysis of a foreign tax is still pertinent, in part, in determining whether a cost or expense is significant for purposes of the cost recovery requirement. In particular, the significance of a cost or expense is determined based on whether, for all taxpayers to which the foreign tax applies, the item of cost or expense constitutes a significant portion of the total costs or expenses. However, proposed § 1.901–2(b)(4)(i)(B)(*2*) adds certainty by providing that costs or expenses related to capital expenditures, interest, rents, royalties, services, and research and experimentation are always treated as significant costs or expenses. The Treasury Department and the IRS have determined that these types of costs represent a substantial portion of expenses typically deducted in computing taxable income for U.S. tax purposes. Requiring a foreign tax law to allow recovery of these costs will

increase assurances that the income subject to U.S. and foreign tax is actually subject to double taxation. Because interest expense in particular is a significant cost that under section 864(e)(2) is allocable to all of a taxpayer's worldwide income-producing activities regardless of where it is incurred, a foreign levy that allows, for example, no deduction for interest expense is not an income tax in the U.S. sense, even if U.S. taxpayers record minimal interest expense in foreign countries that restrict its deductibility.

v. Qualifying Surtax

The Treasury Department and the IRS have received questions on the appropriate treatment of certain foreign taxes that are computed as a percentage of the tax due under a separate levy that is itself an income tax. To address the treatment of these taxes, proposed § 1.901–2(b)(5) adds a rule providing that a foreign tax satisfies the net gain requirement if the base of the foreign tax is the amount of a foreign income tax.

4. Soak-Up Taxes

The proposed regulations move the soak-up tax rule from the rules that define a creditable levy to the rules for determining the amount of creditable tax that is considered paid. See proposed § 1.901–2(e)(6). Because the rules at existing §§ 1.901–2(a)(3)(ii) and 1.903–1(b)(2) treat an otherwise creditable levy as a soak-up tax only to the extent it would not be imposed but for the availability of a credit, this change is more consistent with the general structure of the regulations that determine whether a separate levy as a whole qualifies as a creditable tax, and then identifies the amount of a particular taxpayer's foreign tax liability that is paid or accrued and can be claimed as a foreign tax credit.

In addition, the proposed regulations omit the special rule in § 1.903–1(b)(2) that limits the portion of a tax in lieu of an income tax that is a soak-up tax to the amount by which the foreign tax exceeds the income tax that would have been paid if the taxpayer had instead been subject to the generally-imposed income tax. The Treasury Department and the IRS have determined that this rule is inconsistent with the rationale for making soak-up taxes not creditable, which is to ensure that the foreign country does not impose a soak-up tax liability that under the existing regulations could be allowed as a foreign tax credit to reduce the taxpayer's U.S. tax liability.

Finally, the Treasury Department and the IRS are reconsidering the examples illustrating the soak-up tax rules that are contained in §§ 1.901–2(c)(2) and 1.903–1(b)(3) (*Examples 6* and *7*) and expect to include updated examples in the regulations when proposed § 1.901–2(e)(6) is finalized. Comments are requested on whether additional issues are presented by currently applicable soak-up taxes that should be addressed in the final regulations.

5. Separate Levy Determination

Whether a foreign levy is an income tax is determined independently for each separate foreign levy. For purposes of sections 901 and 903, whether a single levy or separate levies are imposed by a foreign country depends on U.S. principles and not on whether foreign law imposes the levy or levies in a single or separate statutes. Section § 1.901–2(d)(1) of the existing regulations provides that, where the base of a levy is different in kind, and not merely in degree, for different classes of persons subject to the levy, the levy is considered for purposes of sections 901 and 903 to impose separate levies for such classes of persons.

The proposed regulations revise § 1.901–2(d)(1) to clarify the determination of whether a foreign levy is separate from another foreign levy for purposes of determining if a levy meets the requirements of section 901 or 903. The Treasury Department and the IRS have determined that the standards under the existing regulations for making this determination are unclear. In one place the existing regulations state that the only differentiating factor is if the base of the levy is different in kind, as opposed to degree. See, for example, § 1.901–2(d)(1) (''foreign levies identical to the taxes imposed by sections 11, 541, 881, 882, 1491, and 3111 of the Internal Revenue Code are each separate levies, because the base of each of those levies differs in kind, and not merely in degree''). However, in the same sentence, the regulations suggest that one levy may be separate from another levy if a different class of taxpayers is subject to each levy, regardless of whether the base of the two levies is different in kind. See, for example, id. (''a foreign levy identical to the tax imposed by section 871(b) of the Internal Revenue Code is a separate levy from a foreign levy identical to the tax imposed by section 1 of the Internal Revenue Code *as it applies to persons other than those described in section 871(b)*'' (emphasis added)).

The proposed regulations modify the rules for determining whether a foreign levy is a separate levy to clarify how U.S. principles are relevant in determining whether one foreign levy is separate from another foreign levy. In general, the proposed regulations identify separate levies as those that include different items of income and expense in determining the base of the tax, but in certain circumstances separate levies may result even if the taxable base of each levy is the same. In particular, proposed § 1.901–2(d)(1)(i) provides that a foreign levy is always separate from another foreign levy if the levy is imposed by a different foreign tax authority, even if the base of the tax is the same. Proposed § 1.901–2(d)(1)(ii) provides the general rule that separate levies are imposed on particular classes of taxpayers if the taxable base is different for those taxpayers. For example, the proposed regulations provide that a foreign levy identical to the tax imposed by section 3101 (employee tax on wage income) is a separate levy from the foreign levy identical to the tax imposed by section 3111 (employer tax on wages paid). Proposed § 1.901–2(d)(1)(ii) also provides that income included in the taxable base of a separate levy may also be included in the taxable base of another levy (which may or may not also include other items of income); and separate levies are considered to be imposed if the taxable bases are not combined as a single taxable base. Therefore, a foreign levy identical to the tax imposed by section 1411 is a separate levy from a foreign levy identical to the tax imposed by section 1 because tax is separately imposed on the income included in each taxable base.

Additionally, the proposed regulations at § 1.901–2(d)(1)(iii) provide that a foreign levy imposed on nonresidents is treated as a separate levy from that imposed on residents of the taxing jurisdiction, even if the base is the same for both levies, and even if the levies are treated as a single levy under foreign tax law. These changes are intended to ensure that, in general, if a generally-imposed income tax on residents is also imposed on an extraterritorial basis on some nonresidents, in violation of the jurisdictional nexus requirement, only the portion of the levy that applies to nonresidents will not be treated as a foreign income tax. Otherwise, a foreign country's general income tax regime could fail to qualify as a net income tax if the tax was also imposed on an extraterritorial basis on some nonresidents.

Finally, proposed § 1.901–2(d)(1)(iii) provides that a withholding tax on gross income of nonresidents is treated as a separate levy with respect to each class of gross income (as listed in section 61) to which it applies. This special rule is

provided in order to allow withholding taxes that are imposed on several classes of income, based on sourcing rules that meet the jurisdictional nexus requirement with respect to only some of the classes of income, to be analyzed as separate levies under the covered withholding tax rule in § 1.903–1(c)(2). See Part VI.C.3 of this Explanation of Provisions.

B. Amount of Tax That is Considered Paid

1. Background

As discussed in more detail in Part X of this Explanation of Provisions, section 901 allows a credit for foreign income taxes in either the year the taxes are paid or the year the taxes accrue, according to the taxpayer's method of accounting for such taxes. See section 905(a). Regardless of the year in which the credit is allowed, the taxpayer must both owe and actually remit the foreign income tax to be entitled to a foreign tax credit for such tax. See section 905(b); *Chrysler* v. *Comm'r,* 116 T.C. 465, 469 n.2 (2001), *aff'd,* 436 F.3d. 644 (6th Cir. 2006). The taxpayer's liability for the tax may become fixed and determinable in a different taxable year than that in which the tax is remitted, so that the taxpayer's entitlement to the credit may be perfected in a taxable year after the taxable year in which the credit is allowed.

Section 1.901–2(e) of the existing regulations provides rules for determining the amount of foreign tax that is considered paid and eligible for credit under section 901. The existing regulations at § 1.901–2(g)(1) and proposed § 1.901–2(g)(5) clarify that the word ''paid'' as used in § 1.901–2(e) means ''paid'' or ''accrued,'' depending on whether the taxpayer claims the foreign tax credit for taxes paid (that is, remitted) or accrued (that is, for which the liability becomes fixed) during the taxable year. The proposed regulations clarify in several respects the amount of tax that is considered paid (or accrued, as the case may be) and eligible for credit. These clarifications are explained in Parts VI.B.2 and 3 of this Explanation of Provisions.

2. Refundable Amounts, Credits, and Multiple Levies

Under § 1.901–2(e)(2)(i) of the existing regulations, a payment to a foreign country is not treated as an amount of tax paid to the extent that it is reasonably certain that the amount will be refunded, credited, rebated, abated, or forgiven. That regulation further provides that it is not reasonably certain that an amount will be refunded, credited, rebated, abated, or forgiven if the amount is not greater than a reasonable approximation of the final tax liability to the foreign country.

Current law is unclear whether an amount that is not treated as an amount of tax paid under § 1.901–2(e)(5)(i) because it is reasonably certain to be credited against a taxpayer's tentative liability for a second foreign tax should be treated as a constructive refund of the credited amount from the foreign country, followed by a constructive payment by the taxpayer of the second foreign tax. The law is similarly unclear as to whether credits allowed under foreign tax law that are computed with reference to amounts other than foreign tax payments (such as, for example, investment tax credits) may be treated as a constructive receipt of cash by the taxpayer from the foreign country, followed by a constructive payment by the taxpayer of foreign income tax. The results have sometimes differed depending on whether the credit is refundable under foreign law, that is, whether taxpayers are entitled to receive a cash payment from the foreign country to the extent the credit exceeds the taxpayer's foreign income tax liability. See, for example, Rev. Rul. 86–134, 1986–2 C.B. 104 (investment incentives reduced tentative Dutch income tax liability during period in which such incentives could only be claimed as an offset against the income tax liability, rather than as a refundable credit).

The Treasury Department and the IRS have determined that the current uncertainty as to how to properly account for tax credits leads to varying and inconsistent interpretations and that a single, clear rule regarding the treatment of tax credits would improve the consistency in outcomes for taxpayers. In addition, the Treasury Department and the IRS are concerned that if the use of tax credits can be treated as a means of payment of a foreign income tax for foreign tax credit purposes, then foreign countries, rather than reducing their tax rates, could instead offer tax credits that would have the same economic effect without reducing the amount of foreign income tax that is treated as paid by taxpayers for purposes of the foreign tax credit. The Treasury Department and the IRS have also determined it is too administratively challenging to determine whether a foreign country whose law provides for nominally refundable credits in practice actually issues cash payments to taxpayers that do not have income tax liabilities equal to the credit. In addition, the Treasury Department and the IRS have determined that the rule in § 1.901–2(e)(2)(i) with respect to amounts that will be ''credited'' is ambiguous. Section 1.901–2(e)(4)(i) of the existing regulations provides that if, under foreign law, a taxpayer's tentative liability for one levy (the ''first levy'') is or can be reduced by the amount of the taxpayer's liability for a different levy (the ''second levy''), then the amount considered paid by the taxpayer to the foreign country pursuant to the second levy is an amount equal to its entire liability for that levy, and the remainder of the amount paid is considered paid pursuant to the first levy. However, § 1.901–2(e)(2)(i) suggests that the credited amount of the second levy is not considered paid.

Therefore, proposed § 1.901–2(e)(2)(i) provides certainty on the treatment of credited amounts by eliminating the provision that suggests that an amount of tax is not treated as paid if it is allowed as a credit. Instead, proposed § 1.901–2(e)(2)(ii) provides that foreign income tax is not considered paid if it is reduced by a tax credit, regardless of whether the amount of the tax credit is refundable in cash. Therefore, an amount allowed as a credit (including, but not limited to, an amount paid under one levy that is credited against an amount due under another levy) is not treated as a constructive payment of cash from the foreign country (or a constructive refund of the levy that is paid) followed by a constructive payment of the levy that is reduced by the credit, even if the creditable amount is refundable in cash to the extent it exceeds the taxpayer's liability for the levy that is reduced by the credit. However, proposed § 1.901–2(e)(2)(iii) provides that overpayments of tax (which exceed the taxpayer's liability and so are not treated as an amount of tax paid) that are refundable in cash at the taxpayer's option and that are applied in satisfaction of the taxpayer's liability for foreign income tax may qualify as an amount of such foreign income tax paid.

Comments are requested on whether additional rules should be provided for government grants that are provided outside of the foreign tax system, and the circumstances in which such grants should also be treated as a reduction in the amount of tax paid.

Finally, as noted in this Part VI.B.2, the multiple levy rule in § 1.901–2(e)(4) of the existing regulations provides that when an amount of a second levy is applied as a credit to reduce the taxpayer's liability for a first levy, the full amount of the second levy (and not the amount of the first levy that is offset by the credit) is considered paid. The proposed regulations clarify the

multiple levy rule by referring to the first levy as the ''reduced levy'' and to the second levy as the ''applied levy.'' The proposed regulations also modify an existing example and add a new example to illustrate the application of proposed § 1.901–2(e)(2) and (4). See proposed § 1.901–2(e)(4)(ii).

3. Noncompulsory Payments

i. Background

Section 1.901–2(e)(5) provides that an amount paid is not a compulsory payment, and thus is not an amount of tax paid, to the extent that the amount paid exceeds the amount of the taxpayer's liability under foreign law for tax (the ''noncompulsory payment rule''). Section 1.901–2(e)(5) further provides that if foreign tax law includes options or elections whereby a taxpayer's liability may be shifted, in whole or part, to a different year, the taxpayer's use or failure to use such options or elections does not result in a noncompulsory payment, and that a settlement by a taxpayer of two or more issues will be evaluated on an overall basis, not on an issue-by-issue basis, in determining whether an amount is a compulsory amount. In addition, it provides that a taxpayer is not required to alter its form of doing business, its business conduct, or the form of any transaction in order to reduce its liability for tax under foreign law.

On March 30, 2007, proposed regulations (REG–156779–06) were published in the **Federal Register** at 72 FR 15081 that, in part, would amend § 1.901–2(e)(5) to treat as a single taxpayer all foreign entities in which the same United States person has a direct or indirect interest of 80 percent or more (a ''U.S.-owned foreign group''). The proposed rule (the ''2007 proposed regulations'') would apply for purposes of determining whether amounts paid are compulsory payments of foreign tax, for example, when one member of a U.S.-owned foreign group surrenders a loss to another member of the group that reduces the foreign tax due from the second member in that year but increases the amount of foreign tax owed by the loss member in a subsequent year. In Notice 2007–95, 2007–2 C.B. 1091, the Treasury Department and the IRS announced that, in reviewing comments received, it was determined that the proposed change may lead to inappropriate results in certain cases and that the proposed change would be effective for taxable years beginning after the publication of final regulations, but that taxpayers may rely on that portion of the proposed regulations for taxable years ending on or after March 29, 2007, and beginning on or before the date on which final regulations are published.

Section 1.909–2 provides an exclusive list of foreign tax credit splitter arrangements, including a loss-sharing splitter arrangement, which exists under a foreign group relief or other loss-sharing regime to the extent a ''usable shared loss'' of a ''U.S. combined income group'' (that is, an individual or corporation and all the entities with which it combines income and expense under Federal income tax law) is used to offset foreign taxable income of another U.S. combined income group. See § 1.909–1(b)(2).

ii. Treatment of Elections and Other Clarifications

Section 1.901–2(e)(5) currently applies on a taxpayer-by-taxpayer basis, obligating each taxpayer to minimize its liability for foreign taxes over time. The 2007 proposed regulations were intended to create a limited exception to the taxpayer-by-taxpayer approach, recognizing that the net effect of a loss surrender in the case of a group relief regime may be to minimize the amount of foreign taxes paid in the aggregate by the group over time. However, the 2007 proposed regulations were both overinclusive and underinclusive. Comments criticized the approach taken, including how the U.S.-owned foreign group was defined, and noted that the proposal had created uncertainty over the extent to which noncompulsory payment issues arise in situations not addressed by the proposed regulations. In addition, as noted in Notice 2007–95, the Treasury Department and the IRS have determined that the 2007 proposed regulations would lead to inappropriate results in certain cases. Furthermore, a comment received in connection with 2012 temporary regulations issued under section 909 (TD 9597, 77 FR 8127) recommended that the 2007 proposed regulations be withdrawn in light of the coverage of loss-sharing splitter arrangements under the section 909 regulations.

The Treasury Department and the IRS agree that the 2007 proposed regulations should be withdrawn. However, withdrawing the 2007 proposed regulations (which taxpayers were permitted to rely on under Notice 2007–95) without providing additional guidance could result in a disallowance of all foreign tax credits related to loss-sharing arrangements because under § 1.901–2(e)(5) the requirement to minimize foreign income tax liability applies on a taxpayer-by-taxpayer basis. To address this issue, proposed § 1.901–2(e)(5)(ii)(B)(*2*) provides that when foreign law permits one foreign entity to join a consolidated group, or to surrender its loss to offset the income of another foreign entity pursuant to a foreign group relief or other loss-sharing regime, a taxpayer's decision to file as a consolidated group, to surrender or not to surrender a loss, or to use or not to use a surrendered loss, will not give rise to a noncompulsory payment.

Although the proposed regulations will generally exempt loss surrender under group relief or other loss-sharing regimes from the noncompulsory payment regulations, the Treasury Department and the IRS remain concerned that in certain cases loss sharing arrangements, particularly when combined with hybrid arrangements, may be used to separate foreign taxes from the related income. For example, if passive category income of a CFC is offset for U.S. tax purposes by a loss recognized by a disregarded entity owned by that CFC, but that loss is surrendered to reduce general category tested income of an affiliated CFC for foreign tax purposes, under § 1.909–3(a) the split taxes of the loss CFC may be eligible to be deemed paid if the affiliated CFC's related income is included in the U.S. shareholder's income in the same taxable year, but such taxes may not be properly associated with the related income. Therefore, the Treasury Department and the IRS are considering whether additional guidance on loss sharing arrangements, including for example under § 1.861–20, is needed. Comments are requested on this and other aspects of the treatment of loss sharing arrangements.

The existing regulations at § 1.901–2(e)(5) provide that where foreign tax law includes options or elections whereby a taxpayer's foreign income tax liability may be shifted to a different year, the taxpayer's use or failure to use such options or elections does not result in a noncompulsory payment. However, the regulations are not clear as to whether the use or failure to use options or elections that result in an overall change in foreign income tax liability over time would result in a noncompulsory payment. For example, a taxpayer's choice to capitalize and amortize capital expenditures over time, rather than to claim a current expense deduction, does not result in a noncompulsory payment; in contrast, a taxpayer's election to compute its tax liability under one of two alternative regimes, one of which qualifies as an income tax and one of which qualifies as a tax in lieu of an income tax, may result in a noncompulsory payment if

the taxpayer does not choose the option that is reasonably calculated to minimize its liability for creditable foreign tax over time. Accordingly, proposed § 1.901–2(e)(5)(ii) provides that the use or failure to use such an option or election is relevant to whether a taxpayer has minimized its liability for foreign income taxes. However, an exception is provided for elections to surrender losses under a foreign consolidation, group relief or other loss-surrender regime, as well as for an option or election to treat an entity as fiscally transparent or non-fiscally transparent for foreign tax purposes. Because these elections and options generally have the effect of shifting to another entity, rather than reducing in the aggregate, a taxpayer group's foreign income tax liability, the Treasury Department and the IRS have determined that foreign tax credit concerns related to the use or failure to use such an election or option are more appropriately addressed under other rules. The Treasury Department and IRS request comments on whether there are other foreign options or elections that should be excepted from the general rule.

The Treasury Department and IRS are aware that some taxpayers have taken the position that because § 1.901–2(e)(5) refers to payments of ''foreign taxes,'' rather than ''foreign income taxes,'' the noncompulsory payment regulations only require taxpayers to minimize their total liability for all foreign taxes in the aggregate (including non-income taxes such as excise taxes), as opposed to minimizing foreign income tax. The Treasury Department and IRS disagree with this interpretation, since § 1.901–2(e) defines the amount of ''taxes paid'' for purposes of section 901, which only applies to creditable foreign income taxes. Accordingly, proposed § 1.901–2(e)(5)(i) clarifies that taxpayers are obligated to minimize their foreign income tax liabilities. For example, if a taxpayer may choose to apply a tax credit to reduce either the amount of a creditable income tax or the amount of a non-creditable excise tax, then the proposed regulations require that the taxpayer choose to minimize its liability for the creditable income tax; if instead the taxpayer chooses to apply the credit against the excise tax, income tax in the amount of the applied credit is considered a noncompulsory payment.

Finally, proposed § 1.901–2(e)(5)(i) clarifies that the time value of money is not relevant in determining whether a taxpayer has met its obligation to minimize the amount of its foreign income tax liabilities over time. This rule is consistent with the rule in § 1.901–2(b)(4), providing that the amount of costs that are treated as recovered in computing the base of a foreign tax is the same, regardless of whether a taxpayer chooses to deduct currently, or to capitalize and amortize, a particular expense. Therefore, for example, if a taxpayer subject to foreign income tax at a rate of 20 percent chooses to capitalize a $100x cost and deduct it ratably over five years rather than to deduct the entire $100x cost in the first year, the full $100x cost is considered recovered under either option, and is not affected by the fact that as an economic matter the present value of the $20x reduction in tax liability by reason of the $100x deduction in the first year exceeds the discounted present value of the same $20x reduction in tax spread over five years. Similarly, under proposed § 1.901–2(e)(5)(i), the taxpayer will be treated as paying the same amount of foreign income tax regardless of whether it chooses to pay that amount in the current tax year or in a later year.

Although the Treasury Department and the IRS understand that time value of money considerations have economic effects, for Federal income tax purposes income and expenses (including taxes) generally are neither discounted nor indexed by reference to time value of money considerations. A regime that required taxpayers to minimize the discounted present value, rather than the nominal amount, of foreign income tax liabilities would be complex, requiring assumptions about future tax rates and appropriate discount rates. Similarly, a regime that required taxpayers to compare the discounted present value of a foreign tax credit for a foreign income tax to the discounted present value of a deduction for an alternative payment of non-creditable tax that would be incurred in a different year and select the option that minimized the cost to the U.S. fisc would be comparably complex and burdensome for taxpayers to apply and for the IRS to administer. Accordingly, the proposed regulations provide that economic considerations related to the discounted present value of U.S. and foreign tax benefits are not taken into account for purposes of determining the amount of cost recovery or the amount of foreign income tax that is, or would be under foreign tax law options available to the taxpayer, paid or accrued over time.

C. Tax in Lieu of Income Tax

1. In General

Section 903 provides that, for purposes of the foreign tax credit, the term ''income, war profits, and excess profits taxes'' includes a tax paid in lieu of an income tax otherwise generally imposed by any foreign country or by any possession of the United States (an ''in lieu of tax''). The existing regulations clarify that the foreign country's purpose in imposing the foreign tax (for example, whether it imposes the foreign tax because of administrative difficulty in determining the base of the income tax otherwise generally imposed) is immaterial. See § 1.903–1(a). The existing regulations further provide that it is immaterial whether the base of the foreign tax bears any relation to realized net income and that the base may, for example, be gross income, gross receipts or sales, or the number of units produced or sold. See § 1.903–1(b)(1). The existing regulations also require that the foreign tax meet a substitution requirement, which is satisfied if the tax in fact operates as a tax imposed in substitution for, and not in addition to, an income tax or a series of income taxes otherwise generally imposed. See id.

The proposed regulations revise the substitution requirement by more specifically defining the circumstances in which a foreign tax is considered ''in lieu of'' a generally-imposed income tax, consistent with the interpretation of the substitution requirement in prior judicial decisions. See, for example, *Metro. Life Ins. Co.* v. *United States,* 375 F.2d 835, 838–40 (Ct. Cl. 1967). In addition, the proposed regulations provide that an in lieu of tax under section 903, by virtue of the substitution requirement, must also satisfy the jurisdictional nexus requirement described in proposed § 1.901–2(c). Although prior regulations under section 903 did contain a jurisdictional limitation with respect to in lieu of taxes, see § 4.903–1(a)(4) (1980) (requiring that an in lieu of tax follow ''reasonable rules of taxing jurisdiction within the meaning of § 4.901–2(a)(1)(iii)''), the existing regulations do not contain such a rule. The reasons for adopting a jurisdictional nexus requirement under § 1.901–2, as described in Part VI.A.2 of this Explanation of Provisions, apply equally to in lieu of taxes described in section 903. In addition, this rule is necessary to ensure that a foreign tax that is imposed on net gain but that fails the jurisdictional nexus requirement in § 1.901–2 cannot be converted into a creditable tax under section 903 simply by being imposed on a taxable base other than income (such as a tax on gross receipts).

Furthermore, the proposed regulations include a special rule for

certain cross-border source-based withholding taxes in order to clarify the application of the substitution requirement to such taxes. The rules in proposed § 1.903–1 apply independently to each separate levy. Therefore, if a separate levy is an in lieu of tax, and a second levy is later enacted by the same foreign country, such second levy may also qualify as an in lieu of tax if the requirements in proposed § 1.903–1 are met.

2. Substitution Requirement

The foreign tax that is being analyzed under section 903 (the ''tested foreign tax'') satisfies the substitution requirement only if, based on the foreign tax law, four tests are met. First, as under the existing regulations, a separate levy that is a foreign income tax described in § 1.901–2(a)(3) (a ''foreign net income tax'') must be generally imposed by the same foreign country (a ''generally-imposed net income tax''). See proposed § 1.903–1(c)(1)(i).

Second, proposed § 1.903–1(c)(1)(ii) requires that neither the generally-imposed net income tax nor any other separate levy that is a foreign net income tax imposed by the same foreign country that imposes the tested foreign tax is imposed with respect to any portion of the income to which the amounts (such as sales or units of production) that form the base of the tested foreign tax relate (the ''excluded income''). For example, if a tonnage tax regime applies with respect to a taxpayer engaged in shipping, income from shipping must be excluded from the foreign country's regular net income tax for the tonnage tax to qualify as an in lieu of tax. This requirement is not met if, under the foreign tax law, a net income tax imposed by the same foreign country applies to the excluded income of any persons that are subject to the tested foreign tax, even if not all of the persons subject to the tested foreign tax are subject to the net income tax.

Third, proposed § 1.903–1(c)(1)(iii) requires that, but for the existence of the tested foreign tax, the generally-imposed net income tax would be imposed on the excluded income. For example, if a tonnage tax regime applies with respect to a taxpayer engaged in shipping, it must be shown that, but for the existence of such regime, the regular income tax would apply to income from shipping. This ''but for'' requirement is met only if the imposition of the tested foreign tax bears a ''close connection'' to the failure to impose the generally-imposed net income tax on the excluded income. See *Metro. Life Ins. Co,* 375 F.2d at 840.

The proposed regulations provide that the close connection requirement is satisfied if the generally-imposed net income tax would apply by its terms to the excluded income but for the fact that it is expressly excluded. For example, if a corporate income tax regime would, by its terms, apply to all corporations, but income of insurance companies is expressly excluded by law under such regime and taxed under a separate regime, then the close connection requirement is met.

Otherwise, a close connection must be established with proof that the foreign country made a ''cognizant and deliberate choice'' to impose the tested foreign tax instead of the generally-imposed net income tax. Id. Such proof may take into account the legislative history of either the tested foreign tax or the generally-imposed net income tax for purposes of ascertaining the intent and purpose of the two taxes in order to determine the relationship between them.

Not all income derived by persons subject to the tested foreign tax need be excluded income, as long as the tested foreign tax applies only to amounts that relate to the excluded income. For example, if a taxpayer that earns income from operating restaurants and hotels is subject to a generally-imposed net income tax except that, pursuant to an agreement with the foreign country, the taxpayer's income from restaurants is subject to a tax based on number of tables and not to the income tax, the table tax can meet the substitution requirement notwithstanding that the hotel income is subject to the generally-imposed net income tax.

Fourth, proposed § 1.903–1(c)(1)(iv) requires that, if the generally-imposed net income tax were applied to the excluded income, the generally-imposed net income tax would either continue to qualify as a foreign net income tax, or would itself constitute a separate levy that is a foreign net income tax. This rule is intended to ensure that a foreign tax can qualify as an in lieu of tax only if the foreign country imposing the tax could instead have subjected the excluded income to a tax on net gain that would satisfy the jurisdictional nexus requirement in § 1.901–2(c).

Finally, proposed § 1.861–20(h) provides a rule for allocating and apportioning foreign taxes described in section 903 (other than withholding taxes) to statutory and residual groupings. In general, the rule provides that the in lieu of tax is allocated and apportioned in the same proportions as the excluded income.

3. Covered Withholding Tax

Gross-basis taxes, such as withholding taxes, do not satisfy the net gain requirement under proposed § 1.901–2(b). While such withholding taxes may be treated as in lieu of taxes under section 903, the analysis under section 903 and existing § 1.903–1 is unclear. Therefore, proposed § 1.903–1(c)(2) provides a special rule for applying the substitution requirement to certain ''covered withholding taxes'' imposed by a foreign country that also has a generally-imposed net income tax.

First, the tax must be a withholding tax (as defined in section 901(k)(1)(B)) that is imposed on gross income of persons who are nonresidents of the foreign country imposing the tax. See proposed § 1.903–1(c)(2)(i).

Second, the tax cannot be in addition to a net income tax that is imposed by the foreign country on any portion of the income subject to the withholding tax. See proposed § 1.903–1(c)(2)(ii). Thus, for example, if a withholding tax applies by its terms to certain gross income of nonresidents that is also subject to the generally-imposed net income tax if it is attributable to a taxable presence of the nonresident in the foreign country imposing the tax, the withholding tax cannot meet the substitution requirement, including as to nonresidents that do not have a taxable presence in that country.

Third, the withholding tax must meet the source-based jurisdictional nexus requirement in proposed § 1.901–2(c)(1)(ii), requiring that rules for sourcing income to the foreign country are reasonably similar to the sourcing rules that apply for Federal income tax purposes (including that services income is sourced to the place of performance). Similar to the rule in proposed § 1.903–1(c)(1)(iv) requiring that the generally-imposed net income tax, if expanded to cover the excluded income, would continue to qualify as a net income tax under § 1.901–2, proposed § 1.903–1(c)(2)(iii) requires that the income subject to the withholding tax satisfies the source requirement described in § 1.901–2(c)(1)(ii).

VII. Rules for Allocating Taxes After Certain Ownership and Entity Classification Changes

A. Background

On February 14, 2012, the **Federal Register** published final regulations (77 FR 8124, TD 9576) under section 901 concerning the determination of the person who pays a tax for foreign tax credit purposes (the ''2012 final regulations''). The 2012 final regulations

address the inappropriate separation of foreign income taxes from the income on which the tax was imposed in certain circumstances. The 2012 final regulations provide rules for allocating foreign tax imposed on the combined income of multiple persons, as well as rules for allocating entity-level foreign tax imposed on partnerships and disregarded entities that undergo ownership or certain entity classification changes that do not cause the foreign taxable year of the partnership or disregarded entity (the ''continuing foreign taxable year'') to close.

Section 1.901–2(f)(4)(i) of the 2012 final regulations addresses partnership terminations under section 708(b)(1) that do not cause the foreign taxable year to close. Under this provision, foreign tax paid or accrued with respect to the continuing foreign taxable year (for example, in the case of a section 708(b)(1) termination, foreign tax paid or accrued by a successor corporation or owner of a disregarded entity) is allocated between each terminating partnership and successor entity (or, in the case of a partnership that becomes a disregarded entity, the owner of the disregarded entity). The allocation is based upon the respective portions of the foreign tax base that are attributable under the principles of § 1.1502–76(b) to the period of existence of the terminating partnership and successor entity or the period of ownership by a disregarded entity owner during the continuing foreign taxable year. Section 1.901–2(f)(4)(i) also provides similar rules for allocating foreign tax paid or accrued by a partnership among the respective portions of the partnership's U.S. taxable year that end with, and begin after, a change in a partner's interest in the partnership that does not result in a partnership termination (a variance).

Section 1.901–2(f)(4)(ii) of the 2012 final regulations addresses a change in the ownership of a disregarded entity that does not cause the foreign taxable year of the entity to close. Under this rule, foreign tax paid or accrued with respect to the foreign taxable year is allocated between the transferor and transferee of the disregarded entity. The allocation is made based on the respective portions of the foreign tax base that are attributable under the principles of § 1.1502–76(b) to the period of ownership of each transferor and transferee.

B. Covered Events

The proposed regulations move the § 1.901–2(f)(4) allocation rules that apply in the case of partnership terminations and variances and other ownership and entity classification changes to new § 1.901–2(f)(5), and modify those rules to ensure that they cover any entity classification change under U.S. tax law that does not cause the entity's foreign taxable year to close. The proposed regulations also clarify certain aspects of the 2012 final regulations. The general legal liability rules for taxes imposed on partnerships and disregarded entities are now contained in proposed § 1.901–2(f)(4) and are generally unchanged from the 2012 final regulations.

Proposed § 1.901–2(f)(5)(i) provides a single allocation rule that applies to a partnership, disregarded entity, or corporation that undergoes one or more ''covered events'' during its foreign taxable year that do not result in a closing of the foreign taxable year. Under proposed § 1.901–2(f)(5)(ii), a covered event is a partnership termination under section 708(b)(1), a transfer of a disregarded entity, or a change in the entity classification of a disregarded entity or a corporation. These proposed regulations therefore apply to allocate foreign tax paid or accrued with respect to the continuing foreign taxable year of a partnership that terminates under section 708(b)(1), a disregarded entity that becomes a partnership or a corporation, and a corporation that becomes a partnership or a disregarded entity. In addition, proposed § 1.901–2(f)(5)(iv) allocates foreign tax paid or accrued with respect to certain changes in a partner's interest in a partnership (a ''variance'') by treating the variance as a covered event.

These proposed regulations also ensure that the allocation rules apply not just in the case of one or more covered events of the same type within a continuing foreign taxable year, but also in the case of any combination of covered events. For example, proposed § 1.901–2(f)(5) applies to foreign tax that is paid or accrued with respect to a continuing foreign taxable year in which a corporation elects to be treated as a disregarded entity and the disregarded entity subsequently becomes a partnership. A portion of foreign tax is allocated among all persons that were predecessor entities (namely, a terminating partnership or corporation undergoing an entity classification change) or prior owners (namely, the owner of a disregarded entity that is transferred or undergoes an entity classification change) during the continuing foreign taxable year. Like the rules provided in the 2012 final regulations, the allocation is made based on the respective portions of the foreign tax base for the continuing foreign taxable year that are attributable under the principles of § 1.1502–76(b) to the period of existence or ownership of each predecessor entity or prior owner during such year.

C. Timing of the Payment or Accrual of an Allocated Tax

These proposed regulations also provide consistent rules for when allocated tax is treated as paid or accrued. Proposed § 1.901–2(f)(5)(i) provides that tax allocated to a predecessor entity is treated as paid or accrued as of the close of the last day of its last U.S. taxable year, and that tax allocated to the prior owner of a disregarded entity is treated as paid or accrued as of the close of the last day of its U.S. taxable year in which the change in ownership occurs.

D. Treatment of Withholding Taxes

The 2012 final regulations do not clearly state whether foreign withholding taxes are subject to the allocation rules. As explained in Part VI.A of this Explanation of Provisions, foreign taxes are allocated based on the portion of the foreign tax base that is attributed to the period of existence or ownership of each predecessor or prior owner during the foreign taxable year, applying the principles of § 1.1502–76(b). The principles of § 1.1502–76(b) allow taxpayers to use either a closing of the books method or a ratable allocation method in attributing the foreign tax base to these periods.

If the ratable allocation method is used, foreign tax is generally allocated to a predecessor entity or prior owner based on its ratable share of the foreign tax base for the continuing foreign taxable year. In the case of net basis foreign tax paid or accrued by a new owner or successor entity with respect to a continuing foreign taxable year, the resulting allocation of a portion of the tax to a predecessor entity or prior owner is appropriate because the predecessor entity or prior owner generally took into account for U.S. tax purposes a portion of the related income on which the net basis tax was imposed. However, in the case of withholding tax that is imposed on an amount that accrues for U.S. tax purposes when it is paid, such as a dividend, an allocation of a portion of the withholding tax based on ratably allocating the dividend income over the foreign taxable year to a predecessor entity or prior owner is not appropriate because the predecessor entity or prior owner will not have taken any of the related dividend income into account for U.S. tax purposes. Even if withholding tax is imposed on income, such as interest,

that accrues for U.S. tax purposes ratably over a period, an allocation of a portion of the withholding tax to a predecessor entity or prior owner based on ratably allocating the interest income over the foreign taxable year may not be appropriate if the foreign taxable year is not the same period as the accrual period under the terms of the instrument that generated the interest.

Because applying the ratable allocation method under proposed § 1.901–2(f)(5) to allocate withholding taxes to a predecessor entity or prior owner may separate withholding taxes from income that accrues when paid, and may not achieve appropriate matching of withholding taxes and related income in the case of withholding tax imposed on income that accrues over a period, these proposed regulations provide that withholding taxes paid in the foreign taxable year of a covered event are not subject to allocation under proposed § 1.901–2(f)(5).

E. Elections Under Sections 336(e) and 338

Sections 1.336–2(g)(3)(ii) and 1.338–9(d) provide rules for allocating foreign tax between old target and new target where a section 336(e) election or 338 election, respectively, is in effect with respect to the sale, exchange, or distribution of the target and the transaction does not cause old target's foreign taxable year to close. The proposed regulations clarify that, in the case of a section 338 election, the allocation is made with respect to the portions of the foreign tax base that are attributable under § 1.1502–76(b) principles to old target and new target, and clarify how the allocation is made if there are multiple transfers of the stock of target that are each subject to a separate section 338 election during the foreign taxable year. The proposed regulations also provide that if a section 338 election is made for target and target holds an interest in a disregarded entity or partnership, the rules of § 1.901–2(f)(4) and (5) apply to determine the person who is considered for Federal income tax purposes to pay foreign income tax imposed at the entity level on the income of the disregarded entity or partnership. In addition, the proposed regulations clarify that withholding tax is not subject to allocation. Finally, the proposed regulations make a conforming change to the allocation rules that apply where a section 336(e) election is in effect by providing that withholding taxes are not subject to allocation.

VIII. Transition Rules Accounting for NOL Carrybacks

A. Background

The 2019 FTC final regulations provide transition rules for assigning any separate limitation loss (''SLL'') or overall foreign loss (''OFL'') accounts in a pre-2018 separate category to a post-2017 separate category. The regulations also provide transition rules for how an SLL or OFL that reduced pre-2018 general category income is recaptured in post-2017 years, and for how to treat foreign losses that are part of general category net operating losses (''NOLs'') incurred in pre-2018 taxable years that are carried forward to post-2017 taxable years. See § 1.904(f)–12(j).

The transition rules included in the 2019 FTC final regulations did not address post-2017 NOL carrybacks to pre-2018 taxable years because section 172 generally did not allow for NOL carrybacks when the 2019 FTC final regulations were issued. However, on March 27, 2020, Congress enacted the Coronavirus Aid, Relief, and Economic Security Act, Pub. L. 116–136, 134 Stat. 281 (2020) (the ''CARES Act''), which revised section 172(b) to allow taxpayers to carry back, for five years, NOLs incurred in 2018 through 2020.

B. Rule for Post-2017 NOL Carrybacks

The proposed regulations provide rules analogous to the existing transition rules in § 1.904(f)–12(j) to situations involving an NOL arising in a post-2017 taxable year that is carried back to a pre-2018 taxable year. In particular, proposed § 1.904(f)–12(j)(5)(i) confirms that the rules of § 1.904(g)–3(b) apply to the NOL carryback, and provides that income in a pre-2018 separate category in the taxable year to which the NOL is carried back is generally treated as if it included only income that would be assigned to the same separate category in post-2017 taxable years. Therefore, any SLL created by reason of a passive category component of a post-2017 NOL that is carried back to offset pre-2018 general category income will be recaptured in post-2017 taxable years as general category income, and not as a combination of post-2017 general, foreign branch, or section 951A category income.

However, in order to reduce the potential for creating SLLs by reason of the carryback of a post-2017 NOL component in the foreign branch category or section 951A category to a pre-2018 taxable year, the proposed regulations provide that such losses will first ratably offset a taxpayer's general category income in the carryback year, to the extent thereof, and that no SLL account will be created as a result of that offset. The amount of income in the general category available to be offset under this rule is determined after first offsetting the general category income in the carryback year by a post-2017 NOL component in the general category that is carried back to the same year.

IX. Foreign Tax Credit Limitation Under Section 904

A. Revisions to Definition of Foreign Branch Category Income

The proposed regulations revise certain aspects of the foreign branch category income rules in § 1.904–4(f) to account for a broader range of disregarded payments, as well as to better coordinate with the rules in § 1.861–20 and the elective high-tax exception rules in proposed § 1.954–1(d) of the 2020 HTE proposed regulations (85 FR 44650).

Section 904(d)(2)(J)(i) defines foreign branch category income as business profits of a United States person that are attributable to qualified business units in foreign countries. Section 1.904–4(f)(2)(ii) and (iii) of the 2019 FTC final regulations provide that income attributable to a foreign branch does not include income arising from activities carried out in the United States or income arising from stock that is not dealer property. Section 1.904–4(f)(1)(ii) of the 2019 FTC final regulations, reflecting section 904(d)(2)(J)(ii), provides that passive category income is excluded from foreign branch category income. These rules exclude from foreign branch category income for purposes of section 904 income generated by assets that may be owned through the foreign branch and reflected on its books and records, but that is not properly characterized as business profits attributable to foreign branch activities.

In contrast, in the different context of applying the disregarded payment rules in proposed § 1.861–20(d)(3)(v) or proposed § 1.954–1(d), which rely on the rules in § 1.904–4(f), such income is properly attributed to a taxable unit or a tested unit, respectively, for purposes of those provisions. In order to facilitate the incorporation by cross-reference of the rules and principles in § 1.904–4(f) for attributing income to taxable units for purposes of other provisions, the proposed regulations move the exclusions for income arising from U.S. activities and stock to § 1.904–4(f)(1)(iii) and (iv), respectively, and modify the language to provide that such income may be attributable to a foreign branch but is always excluded from foreign branch category income. See also Part

V.F.4 of this Explanation of Provisions (discussing the rules in proposed § 1.861–20(d)(3)(v)(B)(*2*) for attributing income to taxable units). This technical change does not reflect any reconsideration by the Treasury Department and the IRS of the determination in the 2019 FTC final regulations that income arising from U.S. activities and stock do not constitute business profits that are attributable to foreign branches within the meaning of section 904(d)(2)(J).

Proposed § 1.904–4(f)(2)(vi)(G) provides that the disregarded reallocation payment rules generally apply in the case of disregarded payments made to and from a ''non-branch taxable unit'' (as defined in proposed §§ 1.904–4(f)(3) and 1.904–6(b)(2)(i)(B)), which includes certain persons and interests that do not meet the definition of a foreign branch or foreign branch owner. This change accounts for the fact that disregarded payments may occur among, for example, foreign branches, foreign branch owners, and disregarded entities that have no trade or business (and are therefore not foreign branches). In order to attribute gross income to a foreign branch or a foreign branch owner, disregarded payments to and from non-branch taxable units must cause the reattribution of current gross income to the same extent as disregarded payments to and from foreign branches and foreign branch owners. The gross income attributed to a non-branch taxable unit after taking into account all the disregarded payments that it makes and receives must then be further attributed to a foreign branch (if it is part of a ''foreign branch group''), or foreign branch owner (if it is part of a ''foreign branch owner group''), to the extent of its ownership of the non-branch taxable unit. For this purpose, a non-branch taxable unit is part of either a foreign branch group or a foreign branch owner group to the extent it is owned, including indirectly through other non-branch taxable units, by a foreign branch or a foreign branch owner, respectively. The gross income that is attributed to the members of a foreign branch group is attributed to the foreign branch that owns the group, and the gross income that is attributed to the members of a foreign branch owner group is attributed to the foreign branch owner that owns the group.

The proposed regulations also clarify that the reattribution of gross income by reason of disregarded payments is capped at the amount of current gross income in the payor foreign branch or foreign branch owner. See proposed § 1.904–4(f)(2)(vi)(A).

Finally, the proposed regulations include more detailed rules on the treatment of payments between foreign branches, and provide an example illustrating the application of the matching rule in § 1.1502–13 to the rules in § 1.904–4(f)(2)(vi) in response to a comment received with respect to the 2019 FTC proposed regulations. See proposed § 1.904–4(f)(4)(xiii) through (xv) (*Examples 13* through *15*).

B. Financial Services Entities

Section 904(d)(2)(D)(i) provides that financial services income can only be received or accrued by a person ''predominantly engaged in the active conduct of a banking, insurance, financing, or similar business.'' The 2019 FTC proposed regulations modified the definition of a financial services entity (''FSE'') by adopting a definition of ''predominantly engaged in the active conduct of a banking, insurance, financing, or similar business'' and ''income derived in the active conduct of a banking, insurance, financing, or similar business.'' As discussed in the preamble to the 2020 FTC final regulations, in response to comments made in response to the 2019 FTC proposed regulations, the Treasury Department and the IRS determined that these provisions of the 2019 FTC proposed regulations should be revised and reproposed to provide an additional opportunity for comment.

The proposed regulations retain the general approach of the existing § 1.904–4(e) final regulations by providing a numerical test whereby an entity is a financial services entity if more than a threshold percentage of its gross income is derived directly from active financing income, and the regulations continue to contain a list of income that qualifies as active financing income. However, the proposed regulations lower the threshold from 80 percent to 70 percent, and further provide that active financing income must generally be earned from customers or other counterparties that are not related parties. These changes will promote simplification and greater consistency between Code provisions that have complementary policy objectives, while still taking into account the differences between sections 954 and 904. The modified rule also makes clear that internal financing companies do not qualify as financial services entities if 70 percent or less of their gross income meets the unrelated customer requirement. In addition, the proposed regulations modify § 1.904–5(b)(2) to provide that the look-through rules in § 1.904–5 apply in all cases to assign related party payments attributable to passive category income to the passive category, including in the case of related party payments made to a financial services entity. Comments are requested on the treatment of related party payments in the numerator and denominator of the 70-percent gross income test, and whether related party payments should in some cases constitute active financing income.

In the case of an insurance company's income from investments, the Treasury Department and the IRS recognize that an insurance company must hold passive investment assets to support its insurance obligations, including capital and surplus in addition to insurance reserves, to ensure the company's ability to satisfy insurance liabilities if claims are greater than anticipated or investment returns are less than anticipated. However, the Treasury Department and the IRS have determined that limits on the amount of an insurance company's investment income that may be treated as active financing income are appropriate in cases where an insurance company holds substantially more investment assets and earns substantially more passive investment income than necessary to support its insurance business. Thus, proposed § 1.904–4(e)(2)(ii) imposes a cap on the amount of an insurance company's income from investments that may be treated as active financing income. The cap is determined based on an applicable percentage of the insurance company's total insurance liabilities. If investment income exceeds the insurance company's investment income limitation, investment income in excess of the limitation is not considered ordinary and necessary to the proper conduct of the company's insurance business and will not qualify as active financing income.

The Treasury Department and the IRS request comments on the investment income limitation rule and in particular on whether the applicable percentages selected for life and nonlife insurance companies are reasonable.

X. Sections 901(a) and 905(a)—Rules Regarding When the Foreign Tax Credit Can Be Claimed

A. Background

Section 901(a) provides that a taxpayer has the option, for each taxable year, to claim a credit for foreign income taxes paid or accrued to a foreign country in such taxable year, subject to the limitations under section 904. Alternatively, a taxpayer may deduct the foreign income taxes under section 164(a)(3). The deduction and credit for

foreign income taxes are mutually exclusive; section 275(a)(4) provides that no deduction shall be allowed for foreign income taxes if the taxpayer chooses to take to any extent the benefits of section 901. Section 1.901–1(c) of the existing regulations, which clarifies the application of section 275(a)(4), provides that if a taxpayer chooses with respect to any taxable year to claim a credit for taxes to any extent, such choice will be considered to apply to all taxes paid or accrued in such taxable year to all foreign countries, and no portion shall be allowed as a deduction in such taxable year or any succeeding taxable year.

Section 901(a) further provides that the choice to claim the foreign tax credit for any taxable year ''may be made or changed at any time before the expiration of the period prescribed for making a claim for credit or refund of the tax imposed by this chapter for such taxable year.'' Section 6511 prescribes the periods for making a claim for credit or refund of U.S. tax. The default period under section 6511(a) is three years from the time the taxpayer filed the relevant return or two years from when the tax is paid, whichever is later. Section 6511(d) sets forth special periods of limitation for making a claim of credit or refund of U.S. tax that is attributable to particular attributes. Under section 6511(d)(3), if the refund relates to an overpayment attributable to any taxes paid or accrued to any foreign country for which credit is allowed under section 901, the taxpayer has 10 years from the un-extended due date of the return for the taxable year in which the foreign taxes are paid or accrued to file the claim. See § 301.6511(d)–3. Section 6511(d)(2) sets out a special limitations period for refund claims ''attributable to a net operating loss carryback'' of three years from the due date of the return for the year in which the net operating loss originated. The existing regulations at § 1.901–1(d) provide that a taxpayer can claim the benefits of section 901 (or claim a deduction in lieu of a foreign tax credit) at any time before the expiration of the period prescribed by section 6511(d)(3)(A).

Section 905(a) and § 1.905–1(a) of the existing regulations provide that a taxpayer may claim a credit for foreign income taxes either in the year the taxes accrue or in the year the taxes are paid, depending on the taxpayer's method of accounting. Sections 1.446–1(c) and 1.461–1 provide rules for when income and liabilities are taken into account for taxpayers using the cash receipts and disbursement method of accounting (cash method) and for taxpayers using the accrual method of accounting. Under § 1.461–1(a)(1), cash method taxpayers generally take into account allowable deductions in the taxable year in which paid. For accrual method taxpayers, § 1.461–1(a)(2) provides that liabilities are taken into account in the taxable year in which all the events have occurred that establish the fact of the liability, the amount of the liability can be determined with reasonable accuracy, and economic performance has occurred with respect to the liability. If the liability of a taxpayer is to pay a tax, economic performance occurs as the tax is paid to the governmental authority that imposed the tax. See § 1.461–4(g)(6)(i). However, in the case of foreign income taxes, economic performance occurs when the requirements of the all events test, other than economic performance, are met, whether or not the taxpayer elects to credit such taxes under section 901. See § 1.461–4(g)(6)(iii)(B). In the case of foreign income taxes imposed on the basis of a taxable period, because all of the events that fix the fact and amount of liability for the foreign tax with reasonable accuracy do not occur until the end of the foreign taxable year, such foreign income taxes accrue and are creditable in the U.S. tax year within which the taxpayer's foreign taxable year ends. See § 1.960–1(b)(4); Revenue Ruling 61–93, 1961–1 C.B. 390.

Section 905(a) also provides that, regardless of the taxpayer's method of accounting, a taxpayer can elect to claim the foreign tax credit in the year in which the taxes accrue. Once made, this election is irrevocable and must be followed in all subsequent years. In addition, courts have held that the election to claim the foreign tax credit on the accrual basis cannot be made on an amended return. See *Strong* v. *Willcuts,* 17 AFTR 1027 (D. Minn.) (1935) (holding that taxpayer may not change to accrual basis on an amended return because when the taxpayer made an election that the Government has accepted, the rights of the parties became fixed); see also Rev. Rul. 59–101, 1959–1 C.B. 189 (holding that a taxpayer who elected on his original return to claim credit for foreign income tax accrued may not change this election and file amended returns to claim credit for foreign taxes in the year paid). However, for the year the election is made, a taxpayer can claim a credit both for taxes that accrue in that year as well as taxes paid in such year that had accrued in prior years. See *Ferrer* v. *Comm'r,* 35 T.C. 617 (1961) (holding that a cash method taxpayer is entitled, in the year he elects pursuant to section 905(a) to claim foreign tax credits on the accrual basis, to claim a credit for prior years' foreign income taxes paid as well as foreign income taxes accrued in that year), *rev'd on other grounds,* 304 F.2d 125 (2d Cir. 1962).

With respect to the accrual of a contested tax, the Supreme Court held in *Dixie Pine Products Co.* v. *Comm'r,* 320 U.S. 516 (1944), that a state income tax that is contested is not fixed, and so does not accrue, until the contest is resolved. See also section 461(f) (rule permitting taxpayers to deduct contested taxes in the year in which they are paid does not apply to foreign income taxes). The contested tax doctrine, however, does not apply in determining when foreign taxes accrue for purposes of the foreign tax credit. See *Cuba Railroad Co.* v. *United States,* 124 F. Supp. 182, 185 (S.D.N.Y. 1954) (holding that taxes with respect to taxpayer's 1943 income accrued for purposes of the foreign tax credit in 1943 even though the tax was contested and paid in a later year). In Revenue Ruling 58–55, 1958–1 C.B. 266, the IRS examined *Dixie Pine* and *Cuba Railroad,* as well as the legislative history and purpose of the foreign tax credit provisions, and concluded that a contested foreign tax does not accrue until the contest is resolved and the liability becomes finally determined, but for foreign tax credit purposes, the foreign tax, once finally determined, is considered to accrue in the taxable year to which it relates. The revenue ruling further clarified that this ''relation back'' rule does not apply for purposes of determining the taxable year in which foreign taxes may be deducted under section 164, which is governed by the contested tax doctrine.

The relation back rule has since been consistently applied by courts. See, for example, *United States* v. *Campbell,* 351 F.2d 336, 338 (2d Cir. 1965) (explaining that if a taxpayer contests his liability for a foreign tax imposed on income in 1960, and the liability is finally adjudicated in 1965, the taxpayer may not claim the credit until 1965, but at that time the credit relates back to offset U.S. tax imposed on taxpayer's 1960 income); *Albemarle Corp. & Subsidiaries* v. *United States,* 797 F.3d 1011, 1019 (Fed. Cir. 2015) (holding that in the context of determining in what year a taxpayer is eligible to claim a foreign tax credit, the relation back doctrine applies, and thus the 10-year limitations period for filing a refund claim started to run from the un-extended due date for the return for the year to which the tax relates, not the later year in which the contest was resolved). In Revenue Ruling 70–290,

1970–1 C.B. 160, the IRS held that contested taxes that have been paid to the foreign country may be provisionally accrued and claimed as a foreign tax credit, even if the liability has not actually accrued because the taxpayer continues to contest its liability for the tax in the foreign country. The revenue ruling reasons that this is permissible because section 905(c) would require a redetermination of U.S. tax liability if the taxpayer's contest is successful, and the foreign tax is refunded to the taxpayer by the foreign government. Revenue Ruling 84–125, 1984–2 C.B. 125, similarly held that a taxpayer is eligible to claim a credit for the portion of contested taxes that have actually been paid for the taxable year in which the contested liability relates because such taxes are accruable at the time of payment, even though the amount of the liability is not finally determined.

The Treasury Department and the IRS received comments in response to the 2019 FTC proposed regulations asking for clarification on when contested taxes accrue for purposes of the foreign tax credit and for clarification regarding whether the special period of limitations in section 6511(d)(3)(A) applies in the case of a refund claim relating to foreign income taxes that a taxpayer chose to deduct. Questions have also arisen regarding whether taxpayers can make an election to claim the foreign tax credit or revoke such an election (in order to deduct the foreign taxes) on an amended return when making or revoking such election results in a time-barred U.S. tax deficiency in one or more intervening years because the assessment statute under section 6501 does not align with the time for making or changing the election under § 1.901–1(d).

These proposed regulations provide rules clarifying when a foreign tax credit may be taken for both cash method taxpayers and for accrual method taxpayers, and in the case of accrual method taxpayers, clarify the application of the relation-back doctrine. The proposed regulations also modify the period during which a taxpayer can change the choice to claim a credit or a deduction for foreign income taxes on an amended return to align with the different refund periods under section 6511. The proposed regulations also clarify that a change from claiming a deduction to claiming a credit, or vice versa, for foreign income taxes results in a foreign tax redetermination under section 905(c). In addition, the proposed regulations address mismatch and time-barred deficiency issues resulting from the application of the relation-back doctrine for the accrual of foreign income taxes for purposes of the foreign tax credit, and the application of the contested tax doctrine for purposes of determining when foreign income taxes can be deducted.

B. Rules for Choosing To Deduct or Credit Foreign Income Taxes

1. Application of Section 275(a)(4)

Section 1.901–1(c) of the existing regulations, interpreting section 275(a)(4), provides that if a taxpayer chooses to claim a foreign tax credit to any extent with respect to the taxable year, such choice applies to all creditable taxes and no deduction for any such taxes is allowed in such taxable year or in any succeeding taxable year. Questions have arisen as to whether this rule prevents taxpayers from claiming either the benefit of a credit or a deduction with respect to additional taxes that are paid in a taxable year in which a taxpayer claims a foreign tax credit if those additional taxes relate (under the relation-back doctrine) to an earlier year in which taxpayer claimed a deduction. As described in Part X.A of this Explanation of Provisions, additional tax paid by an accrual method taxpayer (or a cash method taxpayer that has elected to claim foreign tax credits using the accrual method) as a result of a foreign tax audit or at the end of a contest relate back and are considered to accrue in the taxable year to which the taxes relate. Thus, the additional taxes are not creditable in the year they are paid and would only be creditable in the relation-back year. However, if a taxpayer deducted foreign income taxes in the relation-back year, the taxpayer cannot claim an additional deduction in the earlier year because the additional taxes accrue for deduction purposes in the year the additional taxes are paid.

The Treasury Department and the IRS have determined that this result is not intended by section 275(a)(4), the purpose of which is to prevent taxpayers from claiming the benefits of both a credit and a deduction with respect to the same taxes. Thus, the proposed regulations provide an exception which allows a taxpayer that is claiming credits on an accrual basis to claim, in a year in which it has elected to claim a credit for foreign income taxes that accrue in that year, also to deduct additional taxes paid in that year that, for foreign tax credit purposes, relate back and are considered to accrue in a prior year in which the taxpayer deducted foreign income taxes. See proposed § 1.901–1(c)(3).

2. Period Within Which an Election To Claim a Foreign Tax Credit Can Be Made or Changed

The proposed regulations also modify § 1.901–1(d), which sets forth the period during which a taxpayer can make or change its election to claim a foreign tax credit. Existing § 1.901–1(d), which was amended in 1987 under TD 8160 (52 FR 33930–02), provides that a taxpayer can, for a particular taxable year, claim the benefits of section 901 or claim a deduction in lieu of a foreign tax credit at any time before the expiration of the period prescribed by section 6511(d)(3)(A) (or section 6511(c) if the period is extended by agreement). The 1987 amendment was preceded by cases in which courts determined that the applicable period of limitations for making an initial election to claim a foreign tax credit under section 901 is the special 10-year period in section 6511(d)(3)(A). See *Woodmansee* v. *United States,* 578 F.2d 1302 (9th Cir. 1978); *Hart* v. *United States,* 585 F.2d 1025 (Ct. Cl. 1978) (also holding that prior regulations, which required taxpayers to make the election to claim a foreign tax credit within the three-year period prescribed by 6511(a), were invalid).

However, as recent court decisions have made clear, the 10-year statute of limitations in section 6511(d)(3)(A) applies only to claims for credit or refund of U.S. taxes attributable to foreign income taxes for which the taxpayer was allowed a credit; it does not apply in the case of a claim for credit or refund of U.S. taxes attributable to foreign income taxes for which a taxpayer claimed a deduction under section 164(a)(3). See, for example, *Trusted Media Brands, Inc.* v. *United States,* 899 F.3d 175 (2d Cir. 2018). In addition, the reason for the special period of limitations provided by section 6511(d)(3) is to allow taxpayers to seek a refund of U.S. tax if foreign taxes were assessed or increased after the regular three-year statute of limitations period has run, and to better align with the IRS' ability to assess additional U.S. tax under section 905(c) when a taxpayer receives a refund of the foreign income tax claimed as a credit. The special period of limitations is not needed when a taxpayer instead claims a deduction, because accrued foreign income taxes do not relate back for deduction purposes, and the additional tax paid as a result of the foreign assessment can be claimed as a deduction in the year the contest is resolved.

Therefore, the Treasury Department and the IRS have determined that the

better interpretation of section 901(a) is that the period for choosing or changing the election to claim a credit or a deduction is based on the applicable refund period, depending on the choice made. Thus, an election to claim a credit, or to change from claiming a deduction to claiming a credit, for taxes paid or accrued in a particular year must be made before the expiration of the 10-year period prescribed by section 6511(d)(3)(A) within which a claim for refund attributable to foreign tax credits may be made, but a choice to claim a deduction, or to change from claiming a credit to claiming a deduction, for taxes paid or accrued in a particular year must be made before the expiration of the three-year period prescribed by section 6511(a) within which a claim for refund attributable to a section 164 deduction may be made. See proposed § 1.901–1(d). This proposed rule eliminates the mismatch between the election and refund periods that exists under the existing regulations, whereby a taxpayer who makes a timely election to change from claiming a credit to claiming a deduction within a 10-year period may in some cases be time-barred from obtaining a refund of U.S. taxes attributable to the resulting decrease in taxable income for the deduction year. In addition, the proposed rule is consistent with the court's decision in each of *Hart* and *Woodmansee,* since it allows taxpayers to elect to claim a credit within the 10-year period provided by section 6511(d)(3)(A).

3. Change in Election Treated as a Foreign Tax Redetermination Under Section 905(c)

As part of the 2019 FTC final regulations, the Treasury Department and the IRS issued final regulations under § 1.905–3 to provide guidance on when foreign tax redeterminations occur. Section 1.905–3(a) provides that a foreign tax redetermination means a change in the liability for a foreign income tax or certain other changes that affect a taxpayer's foreign tax credit. Consistent with section 905(c), this includes when foreign income taxes for which a taxpayer claimed a credit are refunded, foreign income taxes when paid or later adjusted differ from amounts a taxpayer claimed as a credit or added to PTEP group taxes, and when accrued taxes are not paid within 24 months of the close of the taxable year to which the taxes relate. The 2020 FTC final regulations further modify the definition of foreign tax redetermination to include changes to foreign income tax liability that affect a taxpayer's U.S. tax liability even when there is no change to the amount of foreign tax credits claimed, such as when a change to foreign taxes affects subpart F and GILTI inclusion amounts or affects whether or not a CFC's subpart F income and tested income is eligible for the high-tax exception under section 954(b)(4) in the year to which the redetermined foreign tax relates.

These proposed regulations further amend § 1.905–3 to provide that a foreign tax redetermination includes a change by a taxpayer in its decision to claim a credit or a deduction for foreign income taxes that may affect a taxpayer's U.S. tax liability. Section 905(c)(1)(A) provides that a foreign tax redetermination is required ''if accrued taxes when paid differ from the amounts claimed as credits by the taxpayer.'' When a taxpayer changes its election from claiming a credit to claiming a deduction, or vice versa, with respect to foreign income taxes paid or accrued in a particular year, the amount of tax that was accrued and paid differs from the amount that has been claimed as a credit by the taxpayer. Accordingly, a change in a taxpayer's election to claim a credit or a deduction for foreign income taxes is described in section 905(c)(1)(A) even if the foreign income tax liability remains unchanged.

This interpretation is consistent with the purpose of section 905(c) and within the constraints courts have placed in interpreting the provision. As noted by the court in *Texas Co. (Caribbean) Ltd.* v. *Comm'r,* 12 T.C. 925 (1949), section 905(c) addresses problems for which the relevant information might not be available within the general period of limitations or ones where the taxpayer has exclusive control of the information, which justify removing these situations from the generally-applicable period of limitations on assessment. The court in *Texas Co.* held that a U.S. tax deficiency that results from a computational error, which was discoverable by the IRS within the normal assessment period, is not within the scope of section 905(c). A taxpayer's decision to change its election can occur outside the normal assessment period under section 6501(a) and is information that is under the exclusive control of the taxpayer. Thus, the Treasury Department and the IRS have determined that it is appropriate to treat a change in election as a foreign tax redetermination that requires a redetermination of U.S. tax liability for the affected years and notification of the IRS to the extent required under § 1.905–4.

The effect of treating a change in a taxpayer's decision to claim a credit or a deduction for foreign income taxes as a foreign tax redetermination is that the IRS may assess and collect any U.S. tax deficiencies in intervening years that result from the taxpayer's change in election, even if the generally-applicable three-year assessment period under section 6501(a) has expired. See section 6501(c)(5). This can occur, for example, if a timely change to switch from deductions originally claimed in a loss year (to increase a net operating loss) to credits (in order to claim a carryforward of excess foreign taxes in a later year) would result in a time-barred deficiency in a year to which the net operating loss that was increased by the deductions for foreign taxes was originally carried. Currently, the law is unclear how section 274(a)(4), equitable doctrines such as the duty of consistency, or the mitigation provisions under sections 1311 through 1314 operate to prevent taxpayers from obtaining a double benefit (through both a deduction and a credit) for a single amount of foreign income tax paid. These uncertainties have led taxpayers to request guidance from the IRS to clarify the effect of a timely change in election on their U.S. tax liabilities. The proposed regulations provide a clear and efficient process by which taxpayers can eliminate uncertainty with respect to the tax consequences of changing from claiming a credit to claiming a deduction, or vice versa, for foreign income taxes, within the time period allowed.

C. Rules for When a Cash Method Taxpayer Can Claim the Foreign Tax Credit

Proposed § 1.905–1(c) provides rules on when foreign income taxes are creditable for taxpayers using the cash method of accounting. Consistent with § 1.461–1(a)(1), which provides that for taxpayers using the cash method, amounts representing allowable deductions are taken into account in the taxable year in which they are paid, proposed § 1.905–1(c)(1) provides that foreign income taxes are creditable in the taxable year in which they are paid. Foreign income taxes are generally considered paid in the year the taxes are remitted to the foreign country. However, foreign income taxes that are withheld from gross income by the payor are considered paid in the year withheld. See proposed § 1.905–1(c)(1). As discussed in Part VI.B of this Explanation of Provisions, taxes that are not paid within the meaning of § 1.901–2(e) because they exceed a reasonable approximation of the taxpayer's final foreign income tax liability are not eligible for a foreign tax credit.

The regulations at § 1.905–3(a) further provide that a refund of foreign income taxes that have been claimed as a credit

in the year paid, or a subsequent determination that the amount paid exceeds the taxpayer's liability for foreign income tax, is a foreign tax redetermination under section 905(c), and the taxpayer must file an amended return and redetermine its U.S. tax liability for the affected years. However, additional taxes that are paid by a cash method taxpayer in a later year with respect to a prior year do not relate back to the prior year, nor do they result in a redetermination of foreign income taxes paid and U.S. tax lability under section 905(c) for the prior year; instead, those additional taxes are creditable in the year in which they are paid.

Proposed 1.905–1(e) sets forth rules for cash method taxpayers electing to claim foreign tax credits on an accrual basis. As provided by section 905(a), this election is irrevocable, and once made, must be followed in all subsequent years, and consistent with the holding in *Strong* v. *Willcuts,* the election generally cannot be made on an amended return. See proposed § 1.905–1(e)(1). However, the proposed regulations provide exceptions to these general rules in order to ensure that a taxpayer who makes this election to switch from claiming credits on a cash basis to an accrual basis is not double taxed in certain situations. First, proposed § 1.905–1(e)(2) provides that a taxpayer who has previously never claimed a foreign tax credit may make the election to claim the foreign tax credit on an accrual basis when the taxpayer claims the credit, even if such initial claim for credit is made on an amended return. In addition, following the decision in *Ferrer* v. *CIR,* proposed § 1.905–1(e)(3) provides that, for the taxable year in which the accrual election is made and for the subsequent years in which a taxpayer claims a foreign tax credit on an accrual basis, that taxpayer can claim a foreign tax credit for taxes paid in the year, if pursuant to the rules for accrual method taxpayers that are described in Part X.D of this Explanation of Provisions, those taxes paid relate to a taxable year before the taxpayer elected to claim credits on an accrual basis. The Treasury Department and the IRS have determined that this result is appropriate because otherwise taxpayers that make the accrual election would, in effect, have to forego a credit for prior year taxes, unless the election is made for the very first year in which a credit is claimed.

D. Rules for Accrual Method Taxpayers

1. In General

Proposed § 1.905–1(d)(1) provides general rules for when taxpayers using the accrual method of accounting can claim a foreign tax credit. This determination requires applying the all events test contained in § 1.461–1. In accordance with § 1.461–1(a)(2)(i), foreign income taxes accrue in the taxable year in which all the events have occurred that establish the fact of liability, and the amount of the liability can be determined with reasonable accuracy. See also § 1.461–4(g)(6)(iii)(B) (economic performance with respect to foreign income taxes occurs when the requirements of the all events test, other than the payment prong of the economic performance requirement, are met). The proposed regulations confirm that where the all events test has not been met with respect to a foreign income tax liability, such as in the case where the tax liability is contingent upon a distribution of earnings, such taxes have not accrued and may not be claimed as a credit. See proposed § 1.905–1(d)(1)(i).

Proposed § 1.905–1(d)(1)(ii) incorporates the relation-back doctrine, and provides that, for foreign tax credit purposes, once the all events test is met, the foreign income taxes relate back and are considered to accrue in the year to which the taxes relate, the ''relation-back year.'' For example, additional taxes paid as a result of a foreign adjustment relate back and are considered to accrue at the end of the foreign taxable year(s) with respect to which the taxes were adjusted. Thus, the additional taxes paid in the later year are creditable in the relation-back year, not in the year in which the additional taxes are paid. See proposed § 1.905–1(d)(6)(iii) (*Example 3*); see also § 1.905–3(b)(1)(ii)(A) (*Example 1*). Moreover, in the case of foreign income taxes which are treated as refunded pursuant to § 1.905–3(a) because they were not paid within 24 months of the close of the taxable year in which they first accrued, proposed § 1.905–1(d)(1)(ii) provides that when payment is later made, the taxes are considered to accrue in the relation-back year.

2. Special Rule for 52–53 Week Taxable Years

Consistent with Revenue Ruling 61–93, the proposed regulations provide that the liability for a foreign tax becomes fixed on the last day of the taxpayer's foreign taxable year; thus, foreign income taxes generally accrue and are creditable in the taxpayer's U.S. taxable year with or within which its foreign taxable year ends. However, the Treasury Department and the IRS have determined that it is appropriate to provide a limited exception to this rule in order to address mismatches that occur for taxpayers that elect to use a 52–53 week taxable year for U.S. tax purposes under § 1.441–2. Section 1.441–2 permits certain eligible taxpayers to elect to use a fiscal year that (i) varies from 52 to 53 weeks in length, (ii) always ends on the same day of the week, and (iii) ends either on the same day of the week that last occurs in a calendar month or on whatever date the same day of the week falls that is nearest to the last day of the calendar month.

A taxpayer that adopts a 52–53 week year, or that changes from a 52–53 week year to another fiscal year, without changing its foreign taxable year, will often have a short taxable year that does not include the foreign year-end. That short U.S. taxable year would include substantially all of the foreign income but none of the related foreign taxes. Similarly, a taxpayer that uses a 52–53 week year for U.S. tax purposes but that uses a foreign tax year that ends on a fixed month-end will in some years have a U.S. taxable year that does not include a foreign year-end and in other years have a U.S. taxable year that includes two foreign year-ends. For example, a taxpayer who uses a 52–53 week year that ends on the last Friday of December for U.S. tax purposes would have a tax year that begins Saturday, December 26, 2020, and that ends Friday, December 31, 2021, which includes two calendar year-ends. The following taxable year, which begins on Saturday, January 1, 2022, and ends on Friday, December 30, 2022, would not include a calendar year-end.

Proposed § 1.905–1(d)(2) addresses these mismatches by providing that where a U.S. taxpayer uses a 52–53 week taxable year that ends by reference to the same calendar month as its foreign taxable year, and the U.S taxable year closes within 6 days of the close of the foreign taxable year, then for purposes of determining the amount of foreign income tax that accrues during the U.S. taxable year, the U.S. taxable year will be deemed to end on the last day of its foreign taxable year.

3. Accrual of Contested Foreign Income Taxes

The Treasury Department and IRS have determined that the administrative rulings that allow an accrual method taxpayer to claim a foreign tax credit for a contested tax that has been remitted to a foreign country, notwithstanding the fact that the contest is ongoing, are inconsistent with the all events test

(specifically, the test's requirement that all the events must have occurred that establish the fact and amount of the liability with reasonable accuracy).[4] In addition, permitting taxpayers to claim a credit for contested taxes before the contest is resolved reduces the incentive for taxpayers to continue to pursue the contest and exhaust all effective and practical remedies, as required under § 1.901–2(e)(5)(i), if the period of assessment for the year to which the taxes relate has closed and the IRS would be time-barred from disallowing the foreign tax credit claimed with respect to the contested tax paid on noncompulsory payment grounds. The Treasury Department and the IRS have determined that this is an inappropriate result that undermines the longstanding policy for requiring an amount of foreign income tax to be a compulsory payment in order to be creditable.

Therefore, the proposed regulations provide new rules for when a credit for contested foreign income taxes can be claimed. Following the Supreme Court's holding in *Dixie Pine,* and consistent with the exception to section 461(f) and § 1.461–2(a)(2)(i) for foreign income taxes, proposed § 1.905–1(d)(3) provides that contested foreign income taxes do not accrue until the contest is resolved, because only then is the amount of the foreign income tax liability finally determined. Thus, contested foreign income taxes accrue and are creditable only when resolution of the contest establishes the fact and the amount of a liability with reasonable accuracy, even if the taxpayer remits the contested taxes to the foreign country in an earlier year. When the contest is resolved, the liability accrues and, for foreign tax credit purposes, relates back and is considered to accrue in the earlier year to which the liability relates. Once the finally determined liability has been paid, as required by section 905(c)(2)(B) and § 1.905–3(a), the taxpayer can claim a foreign tax credit in the relation-back year.

However, the Treasury Department and the IRS recognize that a taxpayer may be placed in a difficult position if it pays the contested tax to the foreign country (which it may do, for example, to toll the accrual of interest owed to the foreign country) but cannot be made whole until the contest is resolved, possibly years later. Thus, the proposed regulations provide that a taxpayer may elect to claim a provisional credit for the portion of the taxes paid, even though the contest is not resolved and the amount of the liability is not yet fixed. See proposed § 1.905–1(d)(4). As a condition for making this election, a taxpayer must agree to give the IRS an opportunity to examine whether the taxpayer exhausted all effective and practical remedies when the contest is concluded by agreeing to notify the IRS when the contest concludes and by agreeing to not assert the statute of limitations as a defense to the assessment of additional taxes and interest if the IRS determines that the tax was not a compulsory payment. The proposed regulations require taxpayers making this election to file with their amended return (for the year in which the credit is claimed) a provisional foreign tax credit agreement meeting the conditions under proposed § 1.905–1(d)(4)(ii) through (iv) and to file annual certifications notifying the IRS of the status of the contest.

The Treasury Department and the IRS intend to withdraw Revenue Ruling 70–290 and Revenue Ruling 84–125 when the proposed regulations are finalized. Taxpayers can make the election under proposed § 1.905–1(d)(4) for contested taxes remitted in taxable years beginning on or after the date the proposed regulations are finalized but that relate to an earlier taxable year. See proposed § 1.905–1(h).

4. Correction of Improper Accruals

The proposed regulations address issues that arise when an accrual method taxpayer, including a foreign corporation or a partnership or other pass-through entity, has established an improper method of accounting for accruing foreign income taxes. A taxpayer generally establishes an improper method of accounting for an item once it has treated the item consistently in two consecutive tax years (see Rev. Rul. 90–38, 1990–1 CB 57). Proposed § 1.905–1(d)(5)(i) provides that the time at which a taxpayer accrues a foreign income tax expense generally is treated as a method of accounting, regardless of whether the taxpayer or the owners of the foreign corporation, partnership or other pass-through entity claim credits or deductions for those taxes. Therefore, taxpayers must comply with the procedures set forth in Revenue Procedure 2015–13, 2015–5 I.R.B. 419, or successor administrative procedures, to obtain the Commissioner's consent before changing from an improper method to a proper method of accruing foreign income taxes.

The proposed regulations provide specific rules, under a ''modified cut-off'' approach, for adjusting the amount of foreign income taxes that can be claimed as a credit or deduction in the year that a taxpayer changes from an improper to a proper method of accruing foreign income taxes (and in subsequent years, if applicable) in order to prevent a duplication or omission of any amount of foreign income tax paid. Proposed § 1.905–1(d)(5)(ii) requires taxpayers to adjust the amount of foreign income tax that is assigned under § 1.861–20 to each statutory or residual grouping (such as separate categories) and that properly accrues in the year of change, accounted for in the currency in which the foreign tax liability is denominated, (1) downward by the amount of foreign income tax in the same grouping that was improperly accrued and claimed as a credit or a deduction in a taxable year before the year of change (''pre-change year'') and that did not properly accrue in any pre-change year, and (2) upward by the amount of foreign income tax in the same grouping that properly accrued in a pre-change year but which the taxpayer, under its improper method of accounting, failed to accrue and claim as either a credit or a deduction in any pre-change year. To the extent that the required amount of the downward adjustment exceeds the amount of properly-accrued foreign income tax in the year of change, the balance carries forward to offset properly-accrued taxes in subsequent years.

Proposed § 1.905–1(d)(5)(iii) provides rules coordinating the application of the rules under section 905(c) with the rules in proposed § 1.905–1(d)(5). Under proposed § 1.905–1(d)(5)(iii), the determination of whether an improperly-accrued foreign income tax was paid within 24 months of the close of the taxable year to which the taxes relate for purposes of section 905(c)(2) will be measured from the close of the taxable year(s) in which the taxpayer accrued the tax. Any payment of properly-accrued tax in and after the year of change that is offset by the downward adjustment required by proposed § 1.905–1(d)(5)(ii) and so not allowed as a foreign tax credit or deduction in that year is treated as a payment of the foreign income tax improperly accrued in pre-change years, in order, based on the most recently-accrued amounts.

Finally, proposed § 1.905–1(d)(5)(iv) provides that when a foreign corporation, partnership, or other pass-through entity changes from an improper method of accruing foreign income taxes, the rules in § 1.905–1(d)(5) apply as if the foreign corporation, partnership or other pass-through entity were eligible to, and did, claim foreign tax credits. Comments are

[4] See Rev. Rul. 70–290, 1970–1 C.B. 160, and Rev. Rul. 84–125, 1984–2 C.B. 125, discussed in Part X.A of this Explanation of Provisions.

requested on additional adjustments that may be required to prevent an omission or duplication of a tax benefit for foreign income taxes that have been improperly accrued (or which the taxpayer has improperly failed to accrue) under the taxpayer's improper method of accounting. Comments are also requested on alternative methods for implementing a method change involving the improper accrual of foreign income taxes.

E. Creditable Foreign Tax Expenditures of Partnerships and Other Pass-Through Entities

The proposed regulations provide rules that clarify when foreign income taxes paid or accrued by a partnership or other pass-through entity (that is, foreign income taxes for which the pass-through entity is considered to be legally liable under § 1.901–2(f)) can be claimed as a credit or deduction by such entity's partners, shareholders, or beneficiaries. Consistent with the rules in §§ 1.702–1(a)(6) and 1.703–1(b)(2), proposed § 1.905–1(f) provides that a partner that elects to claim a foreign tax credit in a taxable year may claim its distributive share of foreign income taxes that the partnership paid or accrued (as determined under the partnership's method of accounting) during the partnership's taxable year that ends with or within the partner's taxable year. Thus, the pass-through entity's method of accounting for foreign income taxes generally controls for purposes of determining the taxable year in which a partner is considered to pay or accrue its distributive share of those taxes. Therefore, a cash method taxpayer may claim a credit for its distributive share of an accrual method partnership's foreign income taxes even if the partnership has not paid (that is, remitted) the taxes to the foreign country during the partner's taxable year with or within which the partnership's tax expense accrued, so long as those taxes otherwise qualify for the credit, and subject to the rules of section 905(c)(2)(A) (treating accrued foreign taxes as refunded if not paid within 24 months). The rules in proposed § 1.905–1(f) also apply in the case of shareholders of a S corporation, beneficiaries of an estate or trust, or other owners of a pass-through entity with respect to foreign income taxes paid or accrued by such entities.

With respect to a contested foreign tax liability of a pass-through entity, the proposed regulations provide that the entity takes into account and reports a contested foreign income tax to its partners, shareholders, beneficiaries, or other owners only when the contest concludes and the finally determined amount of the liability has been paid by the entity. This rule takes into account the requirement in section 905(c)(2)(B) and § 1.905–3(a) that a foreign tax that first accrues more than 24 months after the close of the taxable year to which the tax relates can only be claimed as a credit once the tax has been paid. See proposed § 1.905–1(f)(1). However, proposed § 1.905–1(f)(2) allows a partner or other owner of a pass-through entity to claim a provisional foreign tax credit for its share of a contested foreign income tax liability that the entity has paid to the foreign country pursuant to the procedures in proposed § 1.905–1(d)(4). As required by §§ 1.905–3(a) and 1.905–4(b), a pass-through entity is required to notify the IRS and its partners, shareholders, or beneficiaries if there is a foreign tax redetermination with respect to foreign income tax previously reported to its partners, shareholders, or beneficiaries.

F. Conforming Changes to Regulations Under Section 960

Existing regulations under section 960 provide a definition of a current year tax that includes language regarding the timing of accrual of a foreign income tax, including the timing of accrual of additional payments of foreign income tax resulting from a foreign tax redetermination. These proposed regulations revise this definition to cross-reference the proposed rules in § 1.905–1 regarding when foreign income taxes are considered to be paid or accrued for foreign tax credit purposes.

In addition, existing rules exclude from the definition of a foreign income tax a levy for which a credit is disallowed at the level of a controlled foreign corporation. The proposed regulations revise the definition of a foreign income tax in § 1.960–1(b) to include a levy that is a foreign income tax within the meaning of proposed § 1.901–2(a), including a levy for which a credit is disallowed at the level of the controlled foreign corporation. These changes are necessary to clarify that a foreign income tax for which a credit is disallowed is nonetheless an item of expense that must be allocated and apportioned to an income group under the rules of § 1.960–1(d) in order to determine the amount of net income in each income group.

Finally, proposed § 1.960–1(b)(5) introduces a new defined term, ''eligible current year taxes,'' that refers to current year taxes for which a foreign tax credit may be allowed. This change is necessary to ensure that the current year taxes that are deemed paid under sections 960(a) and (d) comprise only current year taxes that are eligible for a foreign tax credit. Conforming changes to § 1.960–2 are proposed to provide that deemed paid computations are made only with respect to eligible current year taxes. Additional conforming changes will be proposed to § 1.960–3 to address the computation of deemed paid taxes under section 960(b) as part of future proposed regulations under section 959.

XI. Applicability Dates

The rules in §§ 1.164–2(d), 1.336–2(g)(3)(ii) and (iii), 1.338–9(d), 1.368(b)–10(c)(1), 1.861–9(k), 1.861–10(f) and (g), 1.861–14(h), 1.861–20(h), 1.901–1, 1.901–2, 1.903–1, 1.904–4(e)(1)(ii) and (e)(2) and (3), 1.904–5(b)(2), 1.905–1, 1.905–3(a) and (b)(4), 1.960–1(b)(4) through (6), and 1.960–1(c)(1)(ii) through (iv) and (d)(3)(ii)(B) generally apply to taxable years beginning on or after the date final regulations adopting these rules are filed with the **Federal Register**.

Consistent with the prospective applicability date in the section 250 regulations, the revisions to §§ 1.250(b)–1(c)(7) and 1.250(b)–5(c)(5) apply to taxable years beginning on or after January 1, 2021. See § 1.250–1(b).

The rules in proposed §§ 1.367(b)–4(b)(2)(i)(B), 1.367(b)–7(g), 1.367(b)–10(c)(1), 1.861–3(d), 1.861–8(e)(4)(i), and 1.861–10(e)(8)(v) generally apply to taxable years ending on or after November 2, 2020.

Proposed §§ 1.245A(d)–1, 1.861–20 (other than proposed § 1.861–20(h)), 1.904–4(f), and 1.904–6(b)(2) apply to taxable years that begin after December 31, 2019, and end on or after November 2, 2020.

Finally, proposed § 1.904(f)–12(j)(5) applies to carrybacks of net operating losses incurred in taxable years beginning after December 31, 2017, which is consistent with the applicability date in the CARES Act with respect to net operating loss carrybacks. See Public Law 116–136, 134 Stat. 355, section 2303(d), (2020); see also section 7805(b)(2).

Special Analyses

I. Regulatory Planning and Review

Executive Orders 13771, 13563 and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563

emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Executive Order 13771 designation for any final rule resulting from these proposed regulations will be informed by comments received.

The proposed regulations have been designated by the Office of Information and Regulatory Affairs (OIRA) as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (MOA, April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations. The Office of Information and Regulatory Affairs has designated these regulations as economically significant under section 1(c) of the MOA. Accordingly, the OMB has reviewed these regulations.

A. Background and Need for the Proposed Regulations

The U.S. foreign tax credit (FTC) regime alleviates potential double taxation by allowing a non-refundable credit for foreign income taxes paid or accrued that could be applied to reduce the U.S. tax on foreign source income. Although the Tax Cuts and Jobs Act (TCJA) eliminated the U.S. tax on some foreign source income by enacting a dividends received deduction, the United States continues to tax other foreign source income, and to provide foreign tax credits against this U.S. tax. The calculation of how foreign taxes can be credited against U.S. tax operates by defining different categories of foreign source income (a ''separate category'') based on the type of income.[5] Foreign taxes paid or accrued, as well as deductions for expenses borne by U.S. parents and domestic affiliates that support foreign operations, are allocated to the separate categories based on the income to which such taxes or deductions relate. These allocations of deductions reduce foreign source taxable income and therefore reduce the allowable FTCs for the separate category, since FTCs are limited to the U.S. income tax on the foreign source taxable income (that is, foreign source gross income less allocated expenses) in that separate category. Therefore, these expense allocations help to determine how much foreign tax credit is allowable, and the taxpayer can then use allowable foreign tax credits allocated to each separate category against the U.S. tax owed on income in that category.

The Code and existing regulations further provide definitions of the foreign taxes that constitute creditable foreign taxes. Section 901 allows a credit for foreign income taxes, war profits taxes, and excess profits taxes. The existing regulations under section 901 define these ''foreign income taxes'' such that a foreign levy is an income tax if it is a tax whose predominant character is that of an income tax in the U.S. sense. Under the existing regulations, this requires that the foreign tax is likely to reach net gain in the normal circumstances in which it applies (the ''net gain requirement''), and that it is not a so-called soak-up tax.

The ''net gain requirement'' is made up of the realization, gross receipts, and net income requirements, and the existing regulations define in detail their meaning. Generally, the creditability of the foreign tax under the existing regulations relies on the definition of an income tax under U.S. principles, and on several aggregate empirical tests designed to determine if in practice the tax base upon which the tax is levied is an income tax base. However, compliance and administrative challenges faced by taxpayers and the IRS in implementing the existing definition of an income tax under these regulations necessitate changes to the existing structure. These proposed regulations set forth such changes.

Additionally, as a dollar-for-dollar credit against United States income tax, the foreign tax credit is intended to mitigate double taxation of foreign source income. This fundamental purpose is most appropriately served if there is substantial conformity in the principles used to calculate the base of the foreign tax and the base of the U.S. income tax, not only with respect to the definition of the income tax base, but also with respect to the jurisdictional nexus upon which the tax is levied. The Treasury Department and the IRS have received requests for guidance with respect to a jurisdictional limitation, and recommending that the regulations adopt a rule necessitating some form of nexus rule for creditable taxes. Further, countries, including the United States, have traditionally adhered to consensus-based norms governing jurisdictional nexus for the imposition of tax. However, the adoption or potential adoption by foreign countries of novel extraterritorial foreign taxes that diverge in significant respects from these norms of taxing jurisdiction now suggests that further guidance is appropriate to ensure that creditable foreign taxes in fact have a predominant character of ''an income tax in the U.S. sense.''

Finally, these regulations are necessary in order to respond to outstanding comments raised with respect to other regulations and in order to address a variety of issues arising from the interaction of provisions in other regulations.

The Treasury Department and the IRS issued final regulations in 2019 (84 FR 69022) (2019 FTC final regulations) and proposed regulations (84 FR 69124) (2019 FTC proposed regulations), which are being finalized in this issue of the **Federal Register** as part of the 2020 FTC final regulations. The Treasury Department and the IRS received comments with respect to the 2019 FTC proposed regulations, some of which are addressed in these proposed regulations (instead of the 2020 FTC final regulations) in order to allow further opportunity for notice and comment.

The following analysis provides an overview of the regulations, discussion of the costs and benefits of these regulations as compared with the baseline, and a discussion of alternative policy choices that were considered.

B. Overview of the Structure of and Need for Proposed Regulations

These proposed regulations address a variety of outstanding issues, most importantly with respect to the existing definition of an income tax. Section 901 allows a credit for foreign income taxes, and the existing regulations define the conditions under which foreign taxes will be considered income taxes. These proposed regulations revise aspects of this definition in light of challenges that taxpayers and the IRS have faced in applying the rules. In particular, the requirements in the existing regulations presuppose conclusions based on country-level or other aggregated data that can be difficult for taxpayers and the IRS to analyze for purposes of determining net gain, causing both administrative and compliance burdens and difficulties resolving disputes. Therefore, the proposed regulations revise the net gain requirements such that, in cases where data-driven conclusions have been difficult to establish historically, the requirements rely less on data of the effects of the foreign tax, and instead rely more on the terms of the foreign tax law (See Part VI.A.3 of the Explanation of Provisions for additional detail, and Part I.C.3.i. of this Special Analyses for alternatives considered and affected taxpayers). For example, a foreign tax, to be creditable, must generally be levied on gross receipts (and certain deemed gross receipts) net of deductions. Under these

[5] Before the TCJA, these categories were primarily the passive income and general income categories. The TCJA added new separate categories for global intangible low-taxed income (the section 951A category) and foreign branch income.

proposed regulations, the use of data to demonstrate that an alternative receipts base upon which the tax is levied is in practice a gross receipts equivalent cannot be used to satisfy the gross receipts portion of the net gain requirement.

In addition to these changes, the proposed regulations introduce a jurisdictional limitation for purposes of determining whether a foreign tax is an income tax in the U.S. sense; that is, the foreign tax law must require a sufficient nexus between the foreign country and the taxpayer's activities or investment of capital or other assets that give rise to the income being taxed. Therefore, a tax imposed by a foreign country on income that lacks sufficient nexus to activity in the foreign country (such as operations, employees, factors of production) in a country is not creditable. This limitation is designed to ensure that the foreign tax is an income tax in the U.S. sense by requiring that there is an appropriate nexus between the taxable amount and the taxing foreign jurisdiction (see Part VI.A.2 of the Explanation of Provisions for additional detail, and Part I.C.3.ii of this Special Analyses for discussion of alternatives considered and taxpayers affected). Together, the clarifications and changes introduced in the net gain requirement and the jurisdictional nexus requirement will tighten the rules governing the creditability of foreign taxes and will likely restrict creditability of foreign taxes to some extent relative to the existing regulations.

Finally, these proposed regulations address other issues raised in comments or resulting from other legislation. For example, comments asked for clarification of uncertainty regarding the appropriate level of aggregation (affiliated group versus subgroup) at which expenses of life insurance companies should be allocated to foreign source income, and comments asked for clarification on when contested taxes (that is, taxes owed to a foreign government which a taxpayer disputes) accrue for purposes of the foreign tax credit. With respect to the life insurance issue, the 2019 FTC proposed regulations specified an allocation method, but requested comments regarding whether another method might be superior. Subsequent comments supported both methods for different reasons, and the Treasury Department and the IRS found both methods to have merit. Therefore, the proposed regulations allow taxpayers to choose the most appropriate method for their circumstances. (See Part V.E of the Explanation of Provisions for additional detail, and Part I.C.3.iii of this Special Analyses for alternatives considered and affected taxpayers).

With respect to the contested tax issue, the proposed regulations establish that contested taxes do not accrue (and therefore cannot be claimed as a credit) until the contest is resolved; however, the proposed regulations will allow taxpayers to claim a provisional credit for the portion of taxes already paid to the foreign government, if the taxpayer agrees to notify the IRS when the contest concludes and agrees not to assert the statute of limitations as a defense to assessment of U.S. tax if the IRS determines that the taxpayer failed to take appropriate steps to secure a refund of the foreign tax. (See Part X.D of the Explanation of Provisions for additional detail, and Part I.C.3.iv of this Special Analyses for alternatives considered and affected taxpayers). In this way, the proposed regulations alleviate taxpayer cash flow constraints that could result from temporary double taxation during the period of dispute resolution, while still providing the taxpayer with the incentive to resolve the tax dispute and providing the IRS with the ability to ensure that appropriate action was taken regarding dispute resolution.

The guidance and specificity provided by these regulations clarify which foreign taxes are creditable as income taxes, and (with respect to contested taxes) when they are creditable. The guidance also helps to resolve uncertainty and more generally to address issues raised in comments.

C. Economic Analysis

1. Baseline

In this analysis, the Treasury Department and the IRS assess the benefits and costs of these proposed regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these regulations.

2. Summary of Economic Effects

The proposed regulations provide certainty and clarity to taxpayers regarding the creditability of foreign taxes. In the absence of the enhanced specificity provided by these regulations, similarly situated taxpayers might interpret the creditability of taxes differently, particularly with respect to new extraterritorial taxes, potentially resulting in inefficient patterns of economic activity. For example, some taxpayers may forego specific economic projects, foreign or domestic, that other taxpayers deem worthwhile based on different interpretations of the tax consequences alone. The guidance provided in these regulations helps to ensure that taxpayers face more uniform incentives when making economic decisions. In general, economic performance is enhanced when businesses face more uniform signals about tax treatment.

In addition, these regulations generally reduce the compliance and administrative burdens associated with information collection and analysis required to claim foreign tax credits, relative to the no-action baseline. The regulations achieve this reduction because they rely to a significantly lesser extent on data-driven conclusions than the regulatory approach provided in the existing regulations and instead rely more on the terms and structure of the foreign tax law.

To the extent that taxpayers, in the absence of further guidance, would generally interpret the existing foreign tax credit rules as being more favorable to the taxpayer than the proposed regulations provide, the proposed regulations may result in reduced international activity relative to the no-action baseline. This reduced activity may have included both activities that could have been beneficial to the U.S. economy (perhaps because the activities would have represented enhanced international opportunities for businesses with U.S. owners) and activities that may not have been beneficial (perhaps because the activities would have been accompanied by reduced activity in the United States). Thus, the Treasury Department and the IRS recognize that foreign economic activity by U.S. taxpayers may be a complement or substitute to activity within the United States and that to the extent these regulations lead to a reduction in foreign economic activity relative to the no-action baseline, a mix of results may occur. To the extent that foreign governments, in response to these proposed regulations, alter their tax regimes to reduce their reliance on taxes that are not income taxes in the U.S. sense, any such reduction in foreign economic activity by U.S. taxpayers as a result of these proposed regulations, relative to the no-action baseline, will be mitigated.

The Treasury Department and the IRS project that the regulations will have economic effects greater than $100 million per year ($2020) relative to the no-action baseline. This determination is based on the substantial size of many of the businesses potentially affected by these regulations and the general responsiveness of business activity to

effective tax rates,[6] one component of which is the creditability of foreign taxes. Based on these two magnitudes, even modest changes in the treatment of foreign taxes, relative to the no-action baseline, can be expected to have annual effects greater than $100 million ($2020).

The Treasury Department and the IRS have not undertaken quantitative estimates of the economic effects of these regulations. The Treasury Department and the IRS do not have readily available data or models to estimate with reasonable precision (i) the tax stances that taxpayers would likely take in the absence of the proposed regulations or under alternative regulatory approaches; (ii) the difference in business decisions that taxpayers might make between the proposed regulations and the no-action baseline or alternative regulatory approaches; or (iii) how this difference in those business decisions will affect measures of U.S. economic performance.

In the absence of such quantitative estimates, the Treasury Department and the IRS have undertaken a qualitative analysis of the economic effects of the proposed regulations relative to the no-action baseline and relative to alternative regulatory approaches. This analysis is presented in Part I.C.3 of this Special Analyses.

The Treasury Department and the IRS solicit comments on this economic analysis and particularly solicit data, models, or other evidence that may be used to enhance the rigor with which the final regulations might be developed.

3. Options Considered and Number of Affected Taxpayers, by Specific Provisions

i. ''Net Gain Requirement'' for Determining a Creditable Foreign Tax

a. Summary

Under existing rules, a foreign tax is creditable if it reaches ''net gain,'' which is determined based in part on data-driven analysis. Therefore, under the existing rules, a gross basis tax can in certain cases be creditable if it can be shown that the tax as applied does not result in taxing more than the taxpayer's profit. In certain cases, in order to determine creditability, the IRS requests country-level or other aggregate data to analyze whether the tax reaches net gain. The creditability determination is made based on data with respect to a foreign tax in its entirety, as it is applied for all taxpayers. In other words, the tax is creditable or not creditable based on its application to all taxpayers rather than on a taxpayer-by-taxpayer basis. However, different taxpayers can and do take different positions with respect to what the language of the existing regulations and the empirical tests imply about creditability.

b. Options Considered for the Proposed Regulations

The Treasury Department and the IRS considered three options to address concerns with the ''net gain'' test. The first option is not to implement any changes and to continue to determine the definition of a foreign income tax based in part on conclusions based on country-level or other aggregate data. This option would mean that the determination of whether a tax satisfies the definition of foreign income tax would continue to be administratively difficult for taxpayers and the IRS, in part because it requires the IRS and the taxpayer to obtain information from the foreign country to determine how the tax applies in practice to taxpayers subject to the tax. The existing regulations apply a ''predominant character'' analysis such that deviations from the net gain requirement do not cause a tax to fail this requirement if the predominant character of the tax is that of an income tax in the U.S. sense. For example, the existing regulations allow a credit for a foreign tax whose base, judged on its predominant character, is computed by reducing gross receipts by significant costs and expenses, even if gross receipts are not reduced by all allocable costs and expenses. This requires some judgment in determining whether the exclusion of some costs and expenses causes the tax to fail the net gain requirement.

The second option considered is not to use data-driven conclusions for any portion of the net gain requirement and rely only on foreign tax law to make the determination. This rule would be easier to apply compared with the first option because it requires looking only at foreign law, regulations, and rulings. However, this option could result in an overly harsh outcome, to the extent the rules determine whether a levy is an income tax in its entirety (that is, not on a taxpayer-by-taxpayer basis). For example, if a country had a personal income tax that satisfied all the requirements, except that the country also included imputed rental income in the tax base, the Treasury Department and the IRS would not necessarily want to disallow as a credit the entire personal income tax system of that country due to the one deviation from U.S. tax law definitions of income tax. As part of this option, the Treasury Department and the IRS therefore considered also allowing a parsing of each tax for conforming and non-conforming parts. For example, in the prior example, only a portion of the income tax could be disallowed (that is, the portion attributable to imputed rental income). However, this approach would be extremely complicated to administer since there would need to be special rules for determining which portion of the tax relates to the non-conforming parts and which do not. It would also imply that taxpayers could not know from the outset whether a particular levy is an income tax but would instead have to analyze the tax in each fact and circumstances in which it applied to a particular taxpayer.

The third option considered is to use data-driven conclusions only for portions of the net gain requirement. The net gain requirement consists of three requirements: The realization requirement, the gross receipts requirement, and the cost recovery requirement. The Treasury Department and the IRS considered retaining data-based conclusions in portions of the realization requirement and the cost-recovery requirement but removing them in the gross receipts requirement. This is the approach taken in these regulations. In these regulations, the cost recovery requirement retains the rule that the tax base must allow for recovery of significant costs and expenses. Data are still used in the cost recovery analysis to determine whether a cost or expense is significant with respect to all taxpayers.

Because these options differ in terms of the creditability of foreign taxes, they may increase or decrease foreign activity by U.S. taxpayers. The Treasury Department and the IRS have not projected the differences in economic activity across the three alternatives because they do not have readily available data or models that capture these effects. It is anticipated that the proposed regulations will reduce taxpayer compliance costs relative to the baseline by significantly reducing the circumstances in which taxpayers must incur costs to obtain data (which may or may not be readily available) in order to evaluate the creditability of a tax.

The Treasury Department and the IRS do not have data or models that would allow them to quantify the reduced administrative burden resulting from these final regulations relative to alternative regulatory approaches. The Treasury Department and the IRS expect

[6] See E. Zwick and J. Mahon, ''Tax Policy and Heterogeneous Investment Behavior,'' at *American Economic Review* 2017, 107(1): 217–48 and articles cited therein.

that the regulations will reduce administrative burden and compliance burdens because the collection and analysis of empirical data is time consuming for taxpayers and the IRS, and the existing regulations have resulted in a variety of disputes. Hence a reduction in required data collection should reduce burdens. Further, greater reliance on legal definitions rather than empirical review of available data has the potential to reduce the number of disputes, which also should reduce burdens.

c. Number of Affected Taxpayers

The Treasury Department and the IRS have determined that the population of taxpayers potentially affected by the net gain provisions of the proposed regulations includes any taxpayer with foreign operations claiming foreign tax credits (or with the potential to claim foreign tax credits). Based on currently available tax filings for tax year 2018, there were about 9.3 million Form 1116s filed by U.S. individuals to claim foreign tax credits with respect to foreign taxes paid on individual, partnership, or S corporation income. There were 17,500 Form 1118s filed by C corporations to claim foreign tax credits with respect to foreign taxes paid. In addition, there were about 16,500 C corporations with CFCs that filed at least one Form 5471 with their Form 1120 return, indicating a potential to claim a foreign tax credit even if no credit was claimed in 2018. Similarly, in these data there were about 41,000 individuals with CFCs that e-filed at least one Form 5471 with their Form 1040 return. In 2018, there were about 3,250 S corporations with CFCs that filed at least one Form 5471 with their Form 1120S return. The identified S corporations had an estimated 23,000 shareholders. Finally, the Treasury Department and the IRS estimate that there were approximately 7,500 U.S. partnerships with CFCs that e-filed at least one Form 5741 in 2018. The identified partnerships had approximately 1.7 million partners, as indicated by the number of Schedules K–1 filed by the partnerships; however, this number includes both domestic and foreign partners. Furthermore, there is, likely to be some overlap between the Form 5471 and the Form 1116 and/or 1118 filers.

These numbers suggest that between 9.3 million (under the assumption that all Form 5471 filers or shareholders of filers also filed Form 1116 or 1118) and 11 million (under the assumption that filers or shareholders of filers of Form 5471 are a separate pool from Form 1116 and 1118 filers) taxpayers will potentially be affected by these regulations. Based on Treasury tabulations of Statistics of Income data, the total volume of foreign tax credits reported on Form 1118 in 2016 was about 90 billion dollars. Data do not exist that would allow the Treasury Department or the IRS to identify how this total volume might change as a result of these regulations; however, the Treasury Department and the IRS anticipate that only a small fraction of existing FTCs would be impacted by these regulations.

ii. Jurisdictional Nexus

a. Summary

Rules under existing § 1.901–2 do not explicitly require, for purposes of determining whether a foreign tax is a creditable foreign income tax, the tax to be imposed only on income that has a jurisdictional nexus (or adequate connection) to the country imposing the tax. In order ensure that creditable taxes under section 901 conform to traditional international norms of taxing jurisdiction and therefore are income taxes in the U.S. sense, these regulations add a jurisdictional nexus requirement.

b. Options Considered for the Proposed Regulations

The Treasury Department and the IRS considered the following three options for designing a nexus requirement. The first option considered is to create a jurisdictional nexus requirement based on Articles 5 (Permanent Establishment) and 7 (Business Profits) in the U.S. Model Income Tax Convention (the ''U.S. Convention''). The U.S. Convention includes widely accepted and understood standards with respect to a country's right to tax a nonresident's income. The relevant articles of the U.S. Convention generally require a certain presence or level of activity before the country can impose tax on business income, and the tax can only be imposed on income that is attributable to the business activity. This option was rejected due to concerns that this standard would be too rigid and prescriptive, and such a rigid standard is not necessary; there are numerous departures from the U.S. Convention in both domestic laws and bilateral treaties, which are not considered problematic because they are not considered significant deviations from international norms.

The second option considered was to create a jurisdictional nexus requirement based on Code section 864, which contains a standard for income effectively connected with the conduct of a U.S. trade or business (ECI). The Code does not provide a definition of U.S. trade or business; it is instead defined in case law, and the definition is therefore not strictly delineated. This option was therefore rejected as potentially being too broad, and not necessarily targeting the primary concern with respect to the new extraterritorial taxes, which is that, in contrast to traditional international income tax norms governing the creditability of taxes, they are imposed based on the location of customers or users, or other destination-based criteria.

The third option considered was to require that foreign tax imposed on a nonresident must be based on the nonresident's activities located in the foreign country (including its functions, assets, and risks located in the foreign country) without taking into account as a significant factor the location of customers, users, or similar destination-based criteria. This more narrowly tailored approach better addresses the concern that extraterritorial taxes that are imposed on the basis of location of customers, users, or similar criteria should not be creditable under traditional norms reflected in the Internal Revenue Code that govern nexus and taxing rights and therefore should be excluded from creditable income taxes. Taxes imposed on nonresidents that would meet the Code-based ECI requirement could qualify, as well as taxes that would meet the permanent establishment and business profit standard under the U.S. Convention. This is the option adopted by the Treasury Department and the IRS.

This approach is consistent with the fact that under traditional norms reflected in the Internal Revenue Code, income tax is generally imposed taking into account the location of the operations, employees, factors of production, residence, or management of the taxpayer. In contrast, consumption taxes such as sales taxes, value-added taxes, or so-called destination based income taxes are generally imposed on the basis of location of customers, users, or similar destination-based criteria. Although the tax incidence of these two groups of taxes may vary, tax incidence does not play a role in the definition of an income tax in general, or an income tax in the U.S. sense. Therefore, the choice among regulatory options was based on which option most closely aligned the definition of foreign income taxes to taxes that are income taxes in the U.S. sense.

The Treasury Department and the IRS have not attempted to estimate the

differences in economic activity that might result under each of these regulatory options because they do not have readily available data or models that capture (i) the jurisdictional nexus of taxpayers' activities under the different regulatory approaches and (ii) the economic activities that taxpayers might undertake under different jurisdictional nexus criteria. The Treasury Department and the IRS further have not attempted to estimate the difference in compliance costs under each of these regulatory options.

c. Number of Affected Taxpayers

The Treasury Department and the IRS have determined that the population of taxpayers potentially affected by the jurisdictional nexus provisions of the proposed regulations includes any taxpayer with foreign operations claiming foreign tax credits (or with the potential to claim foreign tax credits). Based on currently available tax filings for tax year 2018, there were about 9.3 million Form 1116s filed by U.S. individuals to claim foreign tax credits with respect to foreign taxes paid on individual, partnership, or S corporation income. There were 17,500 Form 1118s filed by C corporations to claim foreign tax credits with respect to foreign taxes paid. In addition, there were about 16,500 C corporations with CFCs that filed at least one Form 5471 with their Form 1120 return, indicating a potential to claim a foreign tax credit, even if no credit was claimed in these years. Similarly, for the same period, there were about 41,000 individuals with CFCs that e-filed at least one Form 5471 with their Form 1040 return. In 2018, there were about 3,250 S corporations with CFCs that filed at least one Form 5471 with their Form 1120S return. The identified S corporations had an estimated 23,000 shareholders. Finally, the Treasury Department and the IRS estimate that there were approximately 7,500 U.S. partnerships with CFCs that e-filed at least one Form 5471 in 2018. The identified partnerships had approximately 1.7 million partners, as indicated by the number of Schedules K–1 filed by the partnerships; however, this number includes both domestic and foreign partners. Furthermore, there is likely to be overlap between the Form 5471 and the Form 1116 and/or 1118 filers.

These numbers suggest that between 9.3 million (under the assumption that all Form 5471 filers or shareholders of filers also filed Form 1116 or 1118) and 11 million (under the assumption that filers or shareholders of filers of Form 5471 are a separate pool from Form 1116 and 1118 filers) taxpayers will potentially be affected by these regulations. Based on Treasury Department tabulations of Statistics of Income data, the total volume of foreign tax credits reported on Form 1118 in 2016 was about 90 billion dollars. Data do not exist that would allow us to identify how this total volume might change as a result of these regulations; however, the Treasury Department and the IRS anticipate that only a small fraction of existing FTCs would be impacted by these regulations.

iii. Allocation and Apportionment of Expenses for Insurance Companies

a. Summary

Section 818(f) provides that for purposes of applying the expense allocation rules to a life insurance company, the deduction for policyholder dividends, reserve adjustments, death benefits, and certain other amounts (''section 818(f) expenses'') are treated as items that cannot be definitely allocated to an item or class of gross income. That means, in general, that the expenses are apportioned ratably across all of the life insurance company's gross income.

Under the expense allocation rules, for most purposes, affiliated groups are treated as a single entity, although there are exceptions for certain expenses. The statute is unclear, however, about how affiliated groups are to be treated with respect to the allocation of section 818(f) expenses of life insurance companies. Depending on how section 818(f) expenses are allocated across an affiliated group, the results could be different because the gross income categories across the affiliated group could be calculated in multiple ways. The Treasury Department and the IRS received comments and are aware that in the absence of further guidance taxpayers are taking differing positions on this treatment. Some taxpayers argue that the expenses described in section 818(f) should be apportioned based on the gross income of the entire affiliated group, while others argue that expenses should be apportioned on a separate company or life subgroup basis taking into account only the gross income of life insurance companies.

b. Options Considered for the Proposed Regulations

The Treasury Department and the IRS are aware of at least five potential methods for allocating section 818(f) expenses in a life-nonlife consolidated group. First, the expenses might be allocated solely among items of the life insurance company that has the reserves (''separate entity method''). Second, to the extent the life insurance company has engaged in a reinsurance arrangement that constitutes an intercompany transaction (as defined in § 1.1502–13(b)(1)), the expenses might be allocated in a manner that achieves single entity treatment between the ceding member and the assuming member (''limited single entity method''). Third, the expenses might be allocated among items of all life insurance members (''life subgroup method''). Fourth, the expenses might be allocated among items of all members of the consolidated group (including both life and non-life members) (''single entity method''). Fifth, the expenses might be allocated based on a facts and circumstances analysis (''facts and circumstances method'').

The 2019 FTC proposed regulations proposed adopting the separate entity method because it is consistent with section 818(f) and with the separate entity treatment of reserves under § 1.1502–13(e)(2). The Treasury Department and the IRS recognized, however, that this method may create opportunities for consolidated groups to use intercompany transactions to shift their section 818(f) expenses and achieve a more advantageous foreign tax credit result. Accordingly, the Treasury Department and the IRS requested comments on whether a life subgroup method more accurately reflects the relationship between section 818(f) expenses and the income producing activities of the life subgroup as a whole, and whether the life subgroup method is less susceptible to abuse because it might prevent a consolidated group from inflating its foreign tax credit limitation through intercompany transfers of assets, reinsurance transactions, or transfers of section 818(f) expenses. Comments received supported both methods and the Treasury Department and the IRS have concluded that the life subgroup method should generally be used, because it minimizes opportunities for abuse and is more consistent with the general rules allocating expenses among affiliated group members. However, recognizing that the single entity method also has merit, the proposed regulations permit a taxpayer to make a one-time election to use the separate entity method for all life insurance members in the affiliated group. This election is binding for all future years and may not be revoked without the consent of the Commissioner. Because the election is binding and applies to all members of the group, taxpayers will not be able to change allocation

methods from year to year depending on which is most advantageous. The Treasury Department and the IRS may consider future proposed regulations to address any additional anti-abuse concerns (such as under section 845), if needed.

The Treasury Department and the IRS have not attempted to assess the differences in economic activity that might result under each of these regulatory options because they do not have readily available data or models that capture activities at this level of specificity. The Treasury Department and the IRS further have not estimated the difference in compliance costs under each of these regulatory options because they lack adequate data.

c. Number of Affected Taxpayers

The Treasury Department and the IRS have determined that the population of taxpayers potentially affected by these insurance expense allocation rules consists of life insurance companies that are members of an affiliated group. The Treasury Department and the IRS have established that there are approximately 60 such taxpayers.

iv. Creditability of Contested Foreign Income Taxes

a. Summary

Section 901 allows a taxpayer to claim a foreign tax credit for foreign income taxes paid or accrued (depending on the taxpayer's method of accounting) in a taxable year. Foreign income taxes accrue in the taxable year in which all the events have occurred that establish the fact of the liability and the amount of the liability can be determined with reasonable accuracy (''all events test''). When a taxpayer disputes or contests a foreign tax liability with a foreign country, that contested tax does not accrue until the contest concludes because only then can the amount of the liability be finally determined. However, under two IRS revenue rulings (Rev. Ruls. 70–290 and 84–125), a taxpayer is allowed to claim a credit for the portion of a contested tax that the taxpayer has actually paid to the foreign country, even though the taxpayer continues to dispute the liability. While this alleviates taxpayer cash flow constraints associated with temporary double taxation, it is not fully consistent with the all events test. In addition, it potentially disincentivizes the taxpayer from continuing to contest the foreign tax, since the tax is already credited and the dispute could be time-consuming and costly, which could result in U.S. tax being reduced by foreign tax in excess of amounts properly due.

b. Options Considered for the Proposed Regulations

The Treasury Department and the IRS considered three options for the treatment of contested foreign taxes. The first option considered is to not make any changes to the existing rule and to continue to allow taxpayers to claim a credit for a foreign tax that is contested but that has been paid to the foreign country. The Treasury Department and the IRS determined that this option is inconsistent with the all events test. It would also result in a taxpayer potentially having two foreign tax redeterminations (FTRs) with respect to one contested liability: One FTR at the time the taxpayer pays the contested tax to the foreign country, and a second FTR when the contest concludes (if the finally determined liability differs from the amount that was paid and claimed as a credit). Furthermore, this option impinges on the IRS's ability to enforce the requirement in existing § 1.902–1(e) that a tax has to be a compulsory payment in order to be creditable—if a taxpayer claims a credit for a contested tax, then surrenders the contest once the assessment statute closes, the IRS would be time-barred from challenging that the tax was not creditable on the grounds that the taxpayer failed to exhaust all practical remedies.

The second option considered is to only allow taxpayers to claim a credit when the contest concludes. In some cases, the taxpayer must pay the tax to the foreign country in order to contest the tax or in order to stop the running of interest in the foreign country. This option would leave the taxpayer out of pocket to two countries (potentially giving rise to cash flow issues for the taxpayer) while the contest is pending, which could take several years. The Treasury Department and the IRS determined that this outcome is unduly harsh.

The third option considered is to allow taxpayers the option to claim a provisional credit for an amount of contested tax that is actually paid, even though in general, taxpayers can only claim a credit when the contest resolves. This is the option adopted in proposed § 1.905–1(d)(3) and (4). As a condition for making this election, the taxpayer must enter into a provisional foreign tax credit agreement in which it agrees to notify the IRS when the contest concludes and agrees to not assert the expiration of the assessment statute (for a period of three years from the time the contest resolves) as a defense to assessment, so that the IRS is able to challenge the foreign tax credit claimed with respect to the contested tax if the IRS determines that the taxpayer failed to exhaust all practical remedies.

The Treasury Department and the IRS have not attempted to assess the differences in economic activity that might result under each of these regulatory options because they do not have readily available data or models that capture taxpayers' activities under the different treatments of contested taxes. The Treasury Department and the IRS further have not attempted to estimate the difference in compliance costs under each of these regulatory options.

c. Number of Affected Taxpayers

The Treasury Department and the IRS have determined that the proposed regulations potentially affect U.S. taxpayers that claim foreign tax credits on an accrual basis and that contest a foreign income tax liability with a foreign country. Although data reporting the number of taxpayers that claim a credit for contested foreign income tax in a given year are not readily available, the potentially affected population of taxpayers would, under existing § 1.905–3, have a foreign tax redetermination for the year to which the contested tax relates. Data reporting the number of taxpayers subject to a foreign tax redetermination in a given year are not readily available, however some taxpayers currently subject to such redetermination will file amended returns. Based on currently available tax filings for tax year 2018, the Treasury Department and the IRS have determined that approximately 1,500 filers would be affected by these proposed regulations. This estimate is based on the number of U.S. corporations that filed an amended return that had a Form 1118 attached to the Form 1120; S corporations that filed an amended return with a Form 5471 attached to the Form 1120S or that reported an amount of foreign tax accrued on the Form 1120S, Schedule K; partnerships that filed an amended return with a Form 5471 attached to Form 1065 or that reported an amount of foreign tax accrued on Schedule K; U.S. individuals that filed an amended return and had a Form 1116 attached to the Form 1040. Because only taxpayers that claim foreign tax credits on an accrual basis could potentially be subject to the proposed regulations, only taxpayers that checked the accrual box on the Form 1116 or Form 1118, or that indicated on Schedule K that an amount of foreign income tax accrued, were taken into account for the estimate.

II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (''Paperwork Reduction Act'') requires that a federal agency obtain the approval of the OMB before collecting information from the public, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit.

A. Overview

The proposed regulations include new collection of information requirements in proposed §§ 1.905–1(d)(4) and (5), 1.901–1(d)(2), and 1.905–3. The collections of information in proposed § 1.905–1(d)(4) apply to taxpayers that elect to claim a provisional credit for contested foreign income taxes before the contest resolves. Taxpayers making this election are required to file an agreement described in proposed § 1.905–1(d)(4)(ii) as well as an annual certification described in proposed § 1.905–1(d)(4)(iii). The collection of information in § 1.905–1(d)(5) requires taxpayers that are correcting an improper method of accruing foreign income tax expense to file a Form 3115, Application for Change in Accounting Method, with their return. Proposed §§ 1.901–1(d)(2) and 1.905–3 require taxpayers that make a change between claiming a credit and a deduction for foreign income taxes to comply with the notification and reporting requirements in § 1.905–4, which is being finalized in a Treasury Decision published concurrently with this notice of proposed rulemaking. The collection of information in § 1.905–4 generally requires taxpayers to file an amended return for the year or years affected by a foreign tax redetermination (FTR), along with an updated Form 1116 or Form 1118, and a written statement providing specific information relating to the FTR. The burdens associated with collections of information in proposed §§ 1.905–1(d)(4)(iii) and (d)(5), 1.901–1(d)(2), and 1.905–3, which will be conducted through existing IRS forms, is described in Part II.B of this Special Analyses. The burden for a new collection of information in proposed § 1.905–1(d)(4)(ii), which will be conducted on a new IRS form, is described in Part II.C of this Special Analyses.

B. Collections of Information—Proposed §§ 1.905–1(d)(4)(iii), 1.905–1(d)(5), 1.901–1(d)(2), and 1.905–3

The Treasury Department and the IRS intend that the information collection requirements described in this Part II.B will be set forth in the forms and instructions identified in Table 1.

TABLE 1—TABLE OF TAX FORMS IMPACTED

Tax forms impacted		
Collection of information	Number of respondents (estimated)	Forms to which the information may be attached
§ 1.905–1(d)(4)(iii)	1,500	Form 1116, Form 1118.
§ 1.905–1(d)(5)	465,500–514,500	Form 3115.
§ 1.901–1(d)(2), § 1.905–3	10,400–13,500	Form 1065 series, Form 1040 series, Form 1041 series, and Form 1120 series.

Source: [MeF, DCS, and IRS's Compliance Data Warehouse].

As indicated in Table 1, the Treasury Department and the IRS intend the annual certification requirement in proposed § 1.905–1(d)(4)(iii), which applies to taxpayers that elect to claim a provisional credit for contested taxes, will be conducted through amendment of existing Form 1116, Foreign Tax Credit (Individual, Estate, or Trust) (covered under OMB control numbers 1545–0074 for individuals, and 1545–0121 for estates and trusts) and existing Form 1118, Foreign Tax Credit (Corporations) (covered under OMB control number 1545–0123). The collection of information in proposed § 1.905–1(d)(4)(iii) will be reflected in the Paperwork Reduction Act submission that the Treasury Department and the IRS will submit to OMB for these forms. The current status of the Paperwork Reduction Act submissions related to these forms is summarized in Table 2. The estimate for the number of impacted filers with respect to the collection of information in proposed § 1.905–1(d)(4)(iii), as well as with respect to the collection of information in proposed § 1.905–1(d)(4)(ii) (described in Part II.C), is based on the number of U.S. corporations that filed an amended return that had a Form 1118 attached to the Form 1120; S corporations that filed an amended return with a Form 5471 attached to the Form 1120S or that reported an amount of foreign tax accrued on the Form 1120S, Schedule K; partnerships that filed an amended return with a Form 5471 attached to Form 1065 or that reported an amount of foreign tax accrued on Schedule K; and U.S. individuals that filed an amended return and had a Form 1116 attached to the Form 1040.

The Treasury Department and the IRS expect that the collection of information in proposed § 1.905–1(d)(5) will be reflected in the Paperwork Reduction Act submission that the Treasury Department and the IRS will submit to OMB for Form 3115 (covered under OMB control numbers 1545–0123 and 1545–0074). See Table 2 for current status of the Paperwork Reduction Act submission for Form 3115. Exact data is not available to estimate the number of taxpayers that have used an incorrect method of accounting for accruing foreign income taxes, and that are potentially subject to the collection of information in proposed § 1.905–1(d)(5). The estimate in Table 1 of number of taxpayers potentially affected by this collection of information is based on the total number of filers in the Form 1040, Form 1041, Form 1120, Form 1120S, and Form 1065 series that indicated on their return that they use an accrual method of accounting, and that either claimed a foreign tax credit or claimed a deduction for taxes (which could include foreign income taxes). This represents an upper bound of potentially affected taxpayers. The Treasury Department and the IRS expect that only a small percentage of this population of taxpayers will be subject to the collection of information in proposed § 1.905–1(d)(5), because only taxpayers that have used an improper method of accounting are subject to proposed § 1.905–1(d)(5).

The collection of information resulting from proposed §§ 1.901–1(d)(2) and 1.905–3, which is contained in § 1.905–4, will be reflected in the Paperwork Reduction Act submission that the Treasury Department and the IRS will submit for OMB control numbers 1545–0123, 1545–0074 (which cover the reporting burden for filing an amended return and amended Form

1116 and Form 1118 for individual and business filers), OMB control number 1545–0092 (which covers the reporting burden for filing an amended return for estate and trust filers), OMB control number 1545–0121 (which covers the reporting burden for filing a Form 1116 for estate and trust filers), and OMB control number 1545–1056 (which covers the reporting burden for the written statement for FTRs). Exact data are not available to estimate the additional burden imposed by proposed §§ 1.901–1(d)(2) and 1.905–3, which propose to amend the definition of foreign tax redetermination in § 1.905–3 to include a taxpayer's change from claiming a deduction to claiming a credit, or vice versa, for foreign income taxes. Taxpayers making or changing their election to claim a foreign tax credit, under existing regulations, must already file amended returns and, if applicable, a Form 1116 or Form 1118, for the affected years. The Treasury Department and the IRS do not anticipate that proposed regulations, which would require taxpayers making this change to comply with the collection of information and reporting burden in § 1.905–4, will substantially change the reporting requirement. Exact data are not available to estimate the number of taxpayers potentially subject to proposed §§ 1.901–1(d)(2) and 1.905–3. The estimate in Table 1 is based upon the total number of filers in the Form 1040, Form 1041, and Form 1120 series that either claimed a foreign tax credit or claimed a deduction for taxes (which could include foreign income taxes), and filed an amended return. This estimate represents an upper bound of potentially affected taxpayers.

OMB control number 1545–0123 represents a total estimated burden time for all forms and schedules for corporations of 3.344 billion hours and total estimated monetized costs of $61.558 billion ($2019). OMB control number 1545–0074 represents a total estimated burden time, including all other related forms and schedules for individuals, of 1.717 billion hours and total estimated monetized costs of $33.267 billion ($2019). OMB control number 1545–0092 represents a total estimated burden time, including related forms and schedules, but not including Form 1116, for trusts and estates, of 307,844,800 hours and total estimated monetized costs of $14.077 billion ($2018). OMB control number 1545–0121 represents a total estimated burden time for all estate and trust filers of Form 1116, of 25,066,693 hours and total estimated monetized costs of $1.744 billion ($2018). OMB control number 1545–1056 has an estimated number of respondents in a range from 8,900 to 13,500 and total estimated burden time of 56,000 hours and total estimated monetized costs of $2,583,840 ($2017).

The overall burden estimates provided for OMB control numbers 1545–0123, 1545–0074, and 1545–0092 are aggregate amounts that relate to the entire package of forms associated with these OMB control numbers and will in the future include but not isolate the estimated burden of the tax forms that will be revised as a result of the information collections in the proposed regulations. The difference between the burden estimates reported here and those future burden estimates will therefore not provide an estimate of the burden imposed by the proposed regulations. The burden estimates reported here have been reported for other regulations related to the taxation of cross-border income. The Treasury Department and IRS urge readers to recognize that many of the burden estimates reported for regulations related to taxation of cross-border income are duplicates and to guard against overcounting the burden that international tax provisions impose. The Treasury Department and the IRS have not identified the estimated burdens for the collections of information in proposed §§ 1.905–1(d)(4)(iii) and (d)(5), 1.901–1(d)(2), and 1.905–3 because no burden estimates specific to proposed §§ 1.905–1(d)(4)(iii) and (d)(5), 1.901–1(d)(2), and 1.905–3 are currently available. The Treasury Department and the IRS estimate burdens on a taxpayer-type basis rather than a provision-specific basis.

The Treasury Department and the IRS request comments on all aspects of information collection burdens related to the proposed regulations, including estimates for how much time it would take to comply with the paperwork burdens described above for each relevant form and ways for the IRS to minimize the paperwork burden. Any proposed revisions to these forms that reflect the information collections contained in proposed §§ 1.905–1(d)(4)(iii) and (d)(5), 1.901–1(d)(2), and 1.905–3 will be made available for public comment at *https://apps.irs.gov/app/picklist/list/draftTaxForms.html* and will not be finalized until after these forms have been approved by OMB under the Paperwork Reduction Act.

TABLE 2—STATUS OF CURRENT PAPERWORK REDUCTION SUBMISSIONS

Form	Type of filer	OMB No.(s)	Status
Form 1116	Trusts & estates (NEW Model)	1545–0121	Approved by OMB through 10/31/2020.
	https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201704-1545-023		
	Individual (NEW Model)	1545–0074	Approved by OMB through 1/31/2021.
	https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201909-1545-021		
Form 1118	Business (NEW Model)	1545–0123	Approved by OMB through 1/31/2021.
	https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201907-1545-001		
Form 3115	Business (NEW Model)	1545–0123	Approved by OMB through 1/31/2021.
	https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201907-1545-001		
	Individual (NEW Model)	1545–0074	Approved by OMB through 1/31/2021.
	https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201909-1545-021		
Notification of FTRs		1545–1056	Approved by OMB through 12/31/2020.

TABLE 2—STATUS OF CURRENT PAPERWORK REDUCTION SUBMISSIONS—Continued

Form	Type of filer	OMB No.(s)	Status
	https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201703-1545-008		
Amended returns	Business (NEW Model)	1545–0123	Approved by OMB through 1/31/2021.
	https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201907-1545-001		
	Individual (NEW Model)	1545–0074	Approved by OMB through 1/31/2021.
	https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201909-1545-021		
	Trusts & estates	1545–0092	Approved by OMB through 5/31/2022.
	https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201806-1545-014		

C. Collections of Information—Proposed § 1.905–1(d)(4)(ii)

The collection of information contained in § 1.905–1(d)(4)(ii) have been submitted to the Office of Management and Budget (OMB) for review in accordance with the Paperwork Reduction Act. Commenters are strongly encouraged to submit public comments electronically. Comments and recommendations for the proposed information collection should be sent to *http://www.reginfo.gov/public/do/PRAMain*, with electronic copies emailed to the IRS at *omb.unit@irs.gov* (indicate REG–101657–20 on the subject line). This particular information collection can be found by selecting ''Currently under Review—Open for Public Comments'' then by using the search function. Comments can also be mailed to OMB, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies mailed to the IRS, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collections of information should be received by January 11, 2021.

The likely respondents are: U.S. persons who pay or accrue foreign income taxes:

Estimated total annual reporting burden: 3,000 hours.

Estimated average annual burden per respondent: 2 hours.

Estimated number of respondents: 1,500.

Estimated frequency of responses: Annually.

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that the proposed regulations will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act.

The proposed regulations provide guidance needed to comply with statutory changes and affect individuals and corporations claiming foreign tax credits. The domestic small business entities that are subject to the foreign tax credit rules in the Code and in the proposed regulations are generally those domestic small business entities that are at least 10 percent corporate shareholders of foreign corporations, and so are eligible to claim dividends received deductions or compute foreign taxes deemed paid under section 960 with respect to inclusions under subpart F and section 951A from CFCs. Other provisions of these proposed regulations might also affect domestic small business entities that operate in foreign jurisdictions or that have income from sources outside of the United States.

Based on 2018 Statistics of Income data, the Treasury Department and the IRS computed the fraction of taxpayers owning a CFC by gross receipts size class. The smaller size classes have a relatively small fraction of taxpayers that own CFCs, which suggests that many domestic small business entities would be unaffected by these regulations. Many of the important aspects of the proposed regulations, including the rules in proposed §§ 1.245A(d)–1(a), 1.367(b)–4, 1.367(b)–7, 1.367(b)–10, 1.861–3, and 1.960–1 apply only to U.S. persons that operate a foreign business in corporate form, and, in most cases, only if the foreign corporation is a CFC.

Other provisions in the proposed regulations, specifically the rules in proposed §§ 1.861–14 and 1.904–4, generally apply only to members of an affiliated group and insurance companies or other members of the financial services industry earning income from sources outside of the United States. It is infrequent for domestic small entities to operate as part of an affiliated group, to be taxed as an insurance company, or to constitute a financial services entity, and also earn income from sources outside of the United States. Consequently, the Treasury Department and the IRS expect that the proposed regulations are unlikely to affect a substantial number of domestic small business entities. However, adequate data are not available at this time to certify that a substantial number of small entities would be unaffected.

The Treasury Department and the IRS have determined that the proposed regulations will not have a significant economic impact on domestic small business entities. Based on information from the Statistics of Income 2017 Corporate File, foreign tax credits as a percentage of three different tax-related measures of annual receipts (see Table for variables) by corporations are substantially less than the 3 to 5 percent threshold for significant economic impact.

Size (by business receipts)	Under $500,000	$500,000 under $1,000,000	$1,000,000 under $5,000,000	$5,000,000 under $10,000,000	$10,000,000 under $50,000,000	$50,000,000 under $100,000,000	$100,000,000 under $250,000,000	$250,000,000 or more
FTC/Total Receipts	0.12%	0.00%	0.00%	0.00%	0.01%	0.01%	0.02%	0.28%
FTC/(Total Receipts-Total Deductions)	0.61%	0.03%	0.09%	0.05%	0.35%	0.71%	1.38%	9.89%

Size (by business receipts)	Under $500,000	$500,000 under $1,000,000	$1,000,000 under $5,000,000	$5,000,000 under $10,000,000	$10,000,000 under $50,000,000	$50,000,000 under $100,000,000	$100,000,000 under $250,000,000	$250,000,000 or more
FTC/Business Receipts ...	0.84%	0.00%	0.00%	0.00%	0.01%	0.01%	0.02%	0.05%

Source: Statistics of Income (2017) Form 1120.

Although proposed §§ 1.905–1(d)(4) and (5), 1.901–1(d)(2), and 1.905–3 contain a collection of information requirement, the small businesses that are subject to these requirements are domestic small entities with significant foreign operations. The data to assess precise counts of small entities affected by proposed §§ 1.905–1(d)(4) and (5), 1.901–1(d)(2), and 1.905–3 are not readily available. As demonstrated in the table in this Part III of the Special Analyses, foreign tax credits do not have a significant economic impact for any gross-receipts class of business entities.[7] Therefore, the proposed regulations do not have a significant economic impact on small business entities. Accordingly, it is hereby certified that the requirements of proposed §§ 1.905–1(d)(4) and (5), 1.901–1(d)(2), and 1.905–3 will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 7805(f), these proposed regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses. The Treasury Department and the IRS also request comments from the public on the certifications in this Part III of the Special Analyses.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. This proposed rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

[7] Although proposed §§ 1.905–1(d)(5), 1.901–1(d)(2), and 1.905–3 also impact taxpayers that claim a deduction, instead of a credit, for foreign income taxes, the Treasury Department and the IRS expect that the vast majority of taxpayers that have creditable foreign income taxes would choose a dollar-for-dollar credit instead of a deduction; thus, the data in this table measuring foreign tax credit against various variables is a reasonable estimate of the economic impact of these proposed regulations.

V. Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive order.

Comments and Request for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed rules. See also the specific requests for comments in the following Parts of the Explanation of Provisions: I (on potential revisions to § 1.861–20(d) to address concerns regarding foreign law transactions that may circumvent the purpose of section 245A(d)), III (on the proposed revisions to § 1.367(b)–4(b)(2) and on whether further changes to regulations issued under section 367 are appropriate in order to clarify their application after the repeal of section 902), V.A (on the definition of advertising expenditures and the method of cost recovery for purposes of the election in proposed § 1.861–9(k)), V.D (regarding the rules on direct allocation of interest expense incurred by foreign banking branches), V.F.2 (regarding the assignment of foreign tax on a U.S. return of capital amount resulting from a disposition of stock), V.F.3 (regarding the assignment of foreign tax on partnership distributions and sales of partnership interests), V.F.4.ii (regarding ordering rules for assignment of foreign taxes with respect to multiple disregarded payments and regarding the assignment of foreign gross basis taxes paid by taxable units that make disregarded payments), V.F.4.iii (regarding the method of determining the statutory and residual groupings to which a remittance is assigned), V.F.5 (regarding the appropriate treatment of foreign income taxes paid or accrued in connection with the sharing of losses and foreign law group-relief regimes), VI.A.1 (on whether additional revisions to § 1.901–2A are needed in light of the proposed revisions to §§ 1.901–2 and 1.903–1), VI.A.2 (regarding the jurisdictional nexus requirement in proposed § 1.901–2(c), including whether special rules are needed to address foreign transfer pricing rules that allocate profits to a resident on a formulary basis), VI.A.3.ii (on whether a more objective standard for identifying acceptable deviations from the realization requirement should be adopted in the final regulations and on whether additional categories of pre-realization timing differences are needed), VI.A.4 (regarding additional issues related to soak-up taxes), VI.B.2 (regarding additional rules for government grants that are provided outside the foreign tax system), VI.B.3.ii (on the treatment of loss sharing arrangements and on other foreign options and elections that should be excepted from the general rule in § 1.901–2(e)(5)(ii)), IX.B (on the treatment of related party payments in the 70-percent gross income test, on whether related party payments should in some cases constitute active financing income, and on the investment income limitation rule), and X.D.4 (on alternative methods and additional adjustments for implementing a method change involving the improper accrual of foreign income taxes).

Any electronic comments submitted, and to the extent practicable any paper comments submitted, will be made available at *www.regulations.gov* or upon request.

A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments. Requests for a public hearing are also encouraged to be made electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**. Announcement 2020–4, 2020–17 IRB 1, provides that until further notice, public hearings conducted by the IRS will be held telephonically. Any telephonic hearing

will be made accessible to people with disabilities.

Drafting Information

The principal authors of the proposed regulations are Corina Braun, Karen J. Cate, Jeffrey P. Cowan, Logan M. Kincheloe, Brad McCormack, Jeffrey L. Parry, Tianlin (Laura) Shi, and Suzanne M. Walsh of the Office of Associate Chief Counsel (International), as well as Sarah K. Hoyt and Brian R. Loss of Associate Chief Counsel (Corporate). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

■ **Paragraph 1.** The authority citation for part 1 is amended by adding an entry for § 1.245A(d)–1 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805.

* * * * *

Section 1.245A(d)–1 also issued under 26 U.S.C. 245A(g).

* * * * *

■ **Par. 2.** Section 1.164–2 is amended by revising paragraph (d) and adding paragraph (i) to read as follows:

§ 1.164–2 Deduction denied in case of certain taxes.

* * * * *

(d) *Foreign income taxes.* Except as provided in § 1.901–1(c)(2) and (3), all foreign income taxes as defined in § 1.901–2(a) paid or accrued (as the case may be, depending on the taxpayer's method of accounting for such taxes) in such taxable year, if the taxpayer chooses to take to any extent the benefits of section 901, relating to the credit for taxes of foreign countries and possessions of the United States, for taxes that are paid or accrued (according to the taxpayer's method of accounting for such taxes) in such taxable year.

* * * * *

(i) *Applicability dates.* Paragraph (d) of this section applies to foreign taxes paid or accrued in taxable years beginning on or after [date final regulations are filed with the **Federal Register**].

■ **Par. 3.** Section 1.245A(d)–1 is added to read as follows:

§ 1.245A(d)–1 Disallowance of foreign tax credit or deduction.

(a) *In general.* With respect to a domestic corporation for which a deduction under section 245A(a) is allowable, neither a foreign tax credit under section 901 nor a deduction is allowed for foreign income taxes that are attributable to a specified distribution or specified earnings and profits of a foreign corporation. In addition, if a domestic corporation is a United States shareholder of a foreign corporation (''upper-tier foreign corporation'') that itself owns (including indirectly through a pass-through entity) stock of another foreign corporation (''lower-tier foreign corporation''), no foreign tax credit under section 901 (including by reason of section 960) is allowed to the domestic corporation, and no deduction is allowed to the upper-tier foreign corporation, for foreign income taxes paid or accrued by the upper-tier foreign corporation that are attributable to a specified distribution or specified earnings and profits of the lower-tier foreign corporation. Moreover, neither a foreign tax credit under section 901 nor a deduction is allowed to a successor (including an individual who is a citizen or resident of the United States) of a corporation described in this paragraph (a) for foreign income taxes that are attributable to the portion of a foreign corporation's specified earnings and profits that constitute section 245A(d) PTEP.

(b) *Attribution of foreign income taxes to specified distributions and specified earnings and profits*—(1) *In general.* Foreign income taxes are attributable to a specified distribution from a foreign corporation to the extent such taxes are allocated and apportioned under § 1.861–20 to foreign taxable income arising from the specified distribution. Foreign income taxes are attributable to specified earnings and profits of a foreign corporation to the extent such taxes are allocated and apportioned under § 1.860–20 to foreign taxable income arising from a distribution or inclusion under foreign law of specified earnings and profits if the event giving rise to such distribution or inclusion does not give rise to a specified distribution. See, for example, §§ 1.861–20(d)(2)(ii)(B), (C), or (D) (foreign law distribution or disposition and certain foreign law transfers between taxable units), 1.861–20(d)(3)(i)(C) (income from a reverse hybrid), 1.861–20(d)(3)(iii) (foreign law inclusion regime), and 1.861–20(d)(3)(v)(C)(*1*)(*i*) (disregarded payment treated as a remittance). For purposes of this paragraph (b), § 1.861–20 is applied by treating foreign gross income in an amount equal to the amount of a distribution (under Federal income tax law) that is a specified distribution, or the amount of a distribution or inclusion under foreign law that would if recognized for Federal income tax purposes be a distribution out of, or inclusion with respect to, specified earnings and profits, as a statutory grouping, and any remaining portion of the foreign gross income arising from the distribution or inclusion under foreign law as the residual grouping. See also § 1.960–1(e) (foreign income tax paid or accrued by a controlled foreign corporation that is assigned to the residual grouping cannot be deemed paid under section 960).

(2) *Anti-avoidance rule.* Foreign income taxes are treated as attributable to a specified distribution from, or the specified earnings and profits of, a foreign corporation if a transaction, series of related transactions, or arrangement is undertaken with a principal purpose of avoiding the purposes of section 245A(d) and this section, including, for example, by separating foreign income taxes from the income, or earnings and profits, to which such foreign income taxes relate or by making distributions (or causing inclusions) under foreign law in multiple years that give rise to foreign income taxes that are allocated and apportioned with reference to the same previously taxed earnings and profits. See paragraph (e)(4) of this section (*Example 3*).

(c) *Definitions.* The following definitions apply for purposes of this section.

(1) *Foreign income tax.* The term *foreign income tax* has the meaning set forth in § 1.901–2(a).

(2) *Hybrid dividend.* The term *hybrid dividend* has the meaning set forth in § 1.245A(e)–1(b)(2).

(3) *Pass-through entity.* The term *pass-through entity* has the meaning set forth in § 1.904–5(a)(4).

(4) *Section 245A(d) PTEP.* The term *section 245A(d) PTEP* means previously taxed earnings and profits described in § 1.960–3(c)(2)(v) or (ix) to the extent such previously taxed earnings and profits arose as a result of a sale or exchange that by reason of section 964(e)(4) or 1248 gave rise to a deduction under section 245A(a) or as a result of a tiered hybrid dividend that by reason of section 245A(e)(2) and § 1.245A(e)–1(c)(1) gave rise to an inclusion in the gross income of a United States shareholder.

(5) *Specified distribution.* With respect to a domestic corporation, the term *specified distribution* means, in the case of a distribution to the domestic corporation (including indirectly through a pass-through entity), the portion of the distribution that is a

dividend for which a deduction under section 245A(a) is allowed or that is a hybrid dividend or that is attributable to section 245A(d) PTEP. In addition, the term specified distribution means, in the case of a distribution from a foreign corporation to another foreign corporation (including indirectly through a pass-through entity), the portion of the distribution that is attributable to section 245A(d) PTEP or that is a tiered hybrid dividend that gives rise to an inclusion in the gross income of a United States shareholder of the second foreign corporation by reason of section 245A(e)(2) and § 1.245A(e)–1(c)(1).

(6) *Specified earnings and profits.* With respect to a domestic corporation, the term *specified earnings and profits* means the portion of earnings and profits of the foreign corporation that would give rise to a specified distribution (determined without regard to section 246 or § 1.245A–5) if an amount of money equal to all of the foreign corporation's earnings and profits were distributed with respect to the stock of the foreign corporation owned by all the shareholders on any date on which the domestic corporation has an item of foreign gross income as the result of a distribution from or inclusion with respect to the foreign corporation under foreign law. In addition, for purposes of applying § 1.861–20(d)(3)(i)(B) or (D) to assign foreign gross income arising from a distribution with respect to, or a disposition of, stock of the foreign corporation, earnings and profits in the amount of the U.S. return of capital amount (as defined in § 1.861–20(b)) that are deemed to arise in a section 245A subgroup (after applying the asset method in § 1.861–9) are also treated as specified earnings and profits.

(7) *Tiered hybrid dividend.* The term *tiered hybrid dividend* has the meaning set forth in § 1.245A(e)–1(c)(2).

(d) *Effect on earnings and profits.* The disallowance of a credit or deduction for foreign income taxes under paragraph (a) of this section does not affect whether the foreign income taxes reduce earnings and profits of a corporation.

(e) *Examples.* The following examples illustrate the application of this section.

(1) *Presumed facts.* Except as otherwise provided, the following facts are presumed for purposes of the examples:

(i) USP is a domestic corporation;

(ii) CFC is a controlled foreign corporation organized in Country A, and is not a reverse hybrid (as defined in § 1.861–20(b));

(iii) USP would be allowed a deduction under section 245A(a) to the extent of dividends received from CFC;

(iv) All parties have a U.S. dollar functional currency and a U.S. taxable year and foreign taxable year that correspond to the calendar year;

(v) No party has deductions for Country A tax purposes or deductions for Federal income tax purposes (other than foreign income tax expense); and

(vi) Section 245A(d) is the operative section.

(2) *Example 1: Distribution for foreign and Federal income tax purposes*—(i) *Facts.* USP owns all of the outstanding stock of CFC. As of December 31, Year 1, CFC has $800x of section 951A PTEP (as defined in § 1.960–3(c)(2)(viii)) in a single annual PTEP account (as defined in § 1.960–3(c)(1)), and $500x of earnings and profits described in section 959(c)(3). On December 31, Year 1, CFC distributes $1,000x of cash to USP. For Country A tax purposes, the distribution is treated entirely as a dividend to USP, and Country A imposes a withholding tax on USP of $150x with respect to the $1,000x of foreign gross income. For Federal income tax purposes, $800x of the distribution is excluded from USP's gross income and not treated as a dividend under section 959(a) and (d), respectively; the remaining $200x of the distribution gives rise to a dividend to USP.

(ii) *Analysis*—(A) *Identification of specified distribution.* With respect to USP, $200x of the distribution gives rise to a dividend for which a deduction under section 245A(a) is allowed. Accordingly, the distribution results in a $200x specified distribution. See paragraph (c)(5) of this section.

(B) *Foreign income taxes attributable to specified distribution.* For purposes of allocating and apportioning the $150x of Country A foreign income tax, § 1.861–20 is applied by first assigning the $1,000x of Country A gross income to the relevant statutory and residual groupings for purposes of applying section 245A(d) as the operative section. Under paragraph (b)(1) of this section, the statutory grouping is foreign gross income in the amount of the specified distribution and the residual grouping is the remaining amount of foreign gross income. Under § 1.861–20(d)(3)(i)(B)(*2*), the foreign dividend amount ($1,000x) is, to the extent of the U.S. dividend amount ($1,000x), assigned to the same statutory or residual groupings to which the distribution of the U.S. dividend amount is assigned under Federal income tax law. Thus, $200x of the foreign dividend amount is assigned to the statutory grouping, and the remaining $800x is assigned to the residual grouping. Under § 1.861–20(f), $30x ($150x × $200x/$1,000x) of the Country A foreign income tax is apportioned to the statutory grouping, and $120x ($150x × $800x/$1,000x) of the Country A foreign income tax is apportioned to the residual grouping.

(C) *Disallowance.* USP is allowed neither a foreign tax credit nor a deduction for the $30x of Country A foreign income tax that is allocated and apportioned to, and therefore attributable to, the $200x specified distribution. See paragraphs (a) and (b) of this section.

(3) *Example 2: Distribution for foreign law purposes*—(i) *Facts.* USP owns all of the outstanding stock of CFC. On December 31, Year 1, CFC distributes $1,000x of its stock to USP. For Country A tax purposes, the stock distribution is treated entirely as a dividend to USP, and Country A imposes a withholding tax on USP of $150x with respect to the $1,000x of foreign gross income. For Federal income tax purposes, USP recognizes no U.S. gross income as a result of the stock distribution pursuant to section 305(a). As of December 31, Year 1, the date of the stock distribution, CFC has $800x of section 951A PTEP (as defined in § 1.960–3(c)(2)(viii)) in a single annual PTEP account (as defined in § 1.960–3(c)(1)), and $500x of earnings and profits described in section 959(c)(3).

(ii) *Analysis*—(A) *Identification of specified earnings and profits.* With respect to USP, CFC has $500x of specified earnings and profits because if, on December 31, Year 1, CFC were to distribute $1,300x of money (an amount equal to all of CFC's earnings and profits) with respect to its stock to USP, $500x of the distribution would be a dividend for which USP would be allowed a deduction under section 245A(a) and, therefore, would give rise to a specified distribution. See paragraphs (c)(5) and (6) of this section. The remaining $800x of the distribution would not be included in USP's gross income or treated as a dividend and, thus, would not give rise to a deduction under section 245A(a). See section 959(a) and (d), respectively.

(B) *Foreign income taxes attributable to specified earnings and profits.* For purposes of allocating and apportioning the $150x of Country A foreign income tax, § 1.861–20 is applied by first assigning the $1,000x of Country A gross income to the relevant statutory and residual groupings for purposes of applying section 245A(d) as the operative section. Under paragraph (b)(1) of this section, the statutory grouping is the amount of foreign gross income arising from the foreign law

distribution that would if recognized for Federal income tax purposes be a distribution out of CFC's specified earnings and profits, and the residual grouping is the remaining amount of the foreign gross income. There is no corresponding U.S. item because under section 305(a) USP recognizes no U.S. gross income with respect to the stock distribution. Under § 1.861–20(d)(2)(ii)(B), the item of foreign gross income (the $1,000x dividend) is assigned under the rules of § 1.861–20(d)(3)(i)(B) to the same statutory or residual groupings to which the foreign gross income would be assigned if a distribution of the same amount were made for Federal income tax purposes on December 31, Year 1, the date the stock distribution occurs for Country A tax purposes. If recognized for Federal income tax purposes, a $1,000x distribution on December 31, Year 1, would result in a U.S. dividend amount (which as defined in § 1.861–20(b) includes distributions of previously taxed earnings and profits) of $1,000x. Under § 1.861–20(d)(3)(i)(B)(*2*), the foreign dividend amount ($1,000x) is, to the extent of the U.S. dividend amount ($1,000x), assigned to the same statutory or residual groupings from which a distribution of the U.S. dividend amount would be made under Federal income tax law. Thus, $200x of foreign gross income related to the foreign dividend amount is assigned to the statutory grouping for the gross income that would arise from a distribution of CFC's specified earnings and profits, and $800x is assigned to the residual grouping. Under § 1.861–20(f), $30x ($150x × $200x/$1,000x) of the Country A foreign income tax is apportioned to the statutory grouping, and $120x ($150x × $800x/$1,000x) of the Country A foreign income tax is apportioned to the residual grouping.

(C) *Disallowance.* USP is allowed neither a foreign tax credit nor a deduction for the $30x of Country A foreign income tax that is allocated and apportioned to, and therefore attributable to, the $500x of specified earnings and profits of CFC. See paragraphs (a) and (b) of this section.

(4) *Example 3: Successive foreign law distributions subject to anti-abuse rule*—(i) *Facts.* During Year 1, CFC generates $500x of subpart F income that is included in USP's income under section 951(a), and $500x of foreign oil and gas extraction income (as defined in section 907(c)(1)) in Country A. As of December 31, Year 1, CFC has $500x of earnings and profits described in section 959(c)(3) and $500x of section 951(a)(1)(A) PTEP (as defined in § 1.960–3(c)(2)(x)). CFC generates no income in Years 2 through 4. In each of Years 2 and 3, USP makes a consent dividend election under Country A law that, for Country A tax purposes, deems CFC to distribute to USP, and USP immediately to contribute to CFC, $500x on December 31 of each year. For Country A tax purposes, each deemed distribution and contribution is treated as a dividend of $500x to USP, followed immediately by a contribution to CFC of $500x, and Country A imposes a withholding tax on USP of $150x with respect to $500x of foreign gross income in each of Years 2 and 3. For Federal income tax purposes, the Country A consent dividend is disregarded, and USP recognizes no U.S. gross income. In Year 4, CFC distributes $1,000x to USP, which for Country A tax purposes is treated as a return of contributed capital on which no withholding tax is imposed. For Federal income tax purposes, $500x of the $1,000x distribution is excluded from USP's gross income and not treated as a dividend under section 959(a) and (d), respectively; the remaining $500x of the distribution gives rise to a dividend to USP for which USP is allowed a deduction under section 245A(a). The Country A consent dividend elections in Years 2 and 3 are made with a principal purpose of avoiding the application of section 245A(d) and this section to disallow a credit or deduction for Country X withholding tax incurred with respect to CFC's specified earnings and profits.

(ii) *Analysis*—(A) *Identification of specified earnings and profits.* With respect to USP, CFC has $500x of specified earnings and profits in Years 2 and 3 because if, on the date of each foreign law distribution, CFC were to distribute $1,000x of money (an amount equal to all of CFC's earnings and profits) with respect to its stock owned by USP, $500x of the distribution would be a dividend for which USP would be allowed a deduction under section 245A(a) and, therefore, would give rise to a specified distribution. See paragraphs (c)(5) and (6) of this section.

(B) *Foreign income taxes attributable to specified earnings and profits.* For purposes of allocating and apportioning the $150x of Country A foreign income tax incurred by USP in each of Years 2 and 3, § 1.861–20 is applied by first assigning the $500x of Country A gross income to the relevant statutory and residual groupings for purposes of applying section 245A(d) as the operative section. Under paragraph (b)(1) of this section, the statutory grouping is the amount of foreign gross income arising from the foreign law distribution that would if recognized for Federal income tax purposes be a distribution out of CFC's specified earnings and profits, and the residual grouping is the remaining amount of the foreign gross income. The $500x of foreign gross income is not included in the U.S. gross income of USP, and thus, there is no corresponding U.S. item. The Country A consent dividends in Years 2 and 3 meet the definition of a foreign law distribution in § 1.861–20(b) because Country A treats them as a taxable distribution but Federal income tax law does not. Under § 1.861–20(d)(2)(ii)(B), the $500x item of foreign law dividend income is assigned to a statutory or residual grouping by treating CFC as making an actual distribution (for Federal income tax purposes) of $500x on December 31 of each of Years 2 and 3. Accordingly, in each of Years 2 and 3, the $500x of foreign gross income arising from the foreign law distribution is assigned to the residual grouping because the hypothetical distribution is treated as distributed out of section 951(a)(1)(A) PTEP, which are not characterized as specified earnings and profits. Under § 1.861–20(f), none of the $150x of Country A foreign income tax incurred by USP in each of Years 2 and 3 is apportioned to the statutory grouping relating to specified earnings and profits.

(C) *Disallowance pursuant to anti-avoidance rule.* By electing to make two successive foreign law distributions in Years 2 and 3 that were subject to Country A withholding tax and that did not individually exceed, but in the aggregate did exceed, the section 951(a)(1)(A) PTEP of CFC, and then making an actual distribution of property equal to all of the earnings and profits of CFC in Year 4 that was not subject to Country A withholding tax (because the previous consent dividends converted CFC's earnings and profits to capital for Country A tax purposes), USP would have avoided the disallowance under section 245A(d) (but for the application of the anti-avoidance rule in paragraph (b)(2) of this section) despite having received a $500x dividend that gave rise to a deduction under section 245A(a), and incurring withholding tax related to the earnings and profits that gave rise to that dividend. However, the Country A consent dividend elections in Years 2 and 3 were made with a principal purpose of avoiding the purposes of section 245A(d) and this section. Therefore, USP is allowed neither a foreign tax credit nor a deduction for $150x of Country A foreign income tax, which is treated as being attributable to

the $500x of specified earnings and profits of CFC. See paragraphs (a) and (b)(2) of this section.

(f) *Applicability date.* This section applies to taxable years of a foreign corporation that begin after December 31, 2019, and end on or after November 2, 2020, and with respect to a United States person, taxable years in which or with which such taxable years of the foreign corporation end.

§ 1.245A(e)–1 [Amended]

■ **Par. 4.** Section 1.245A(e)–1 is amended by adding the language ''and § 1.245A(d)–1'' after the language ''rules of section 245A(d)'' in paragraphs (b)(1)(ii), (c)(1)(iii), (g)(1)(ii) introductory text, (g)(1)(iii) introductory text, and (g)(2)(ii) introductory text.

■ **Par. 5.** Section 1.250(b)–1 is amended by adding two sentences to the end of paragraph (c)(7) to read as follows:

§ 1.250(b)–1 Computation of foreign-derived intangible income (FDII).

* * * * *

(c) * * *

(7) * * * A taxpayer must use a consistent method to determine the amount of its domestic oil and gas extraction income (''DOGEI'') and its foreign oil and gas extraction income (''FOGEI'') from the sale of oil or gas that has been transported or processed. For example, a taxpayer must use a consistent method to determine the amount of FOGEI from the sale of gasoline from foreign crude oil sources in computing the exclusion from gross tested income under § 1.951A–2(c)(1)(v) and the amount of DOGEI from the sale of gasoline from domestic crude oil sources in computing its section 250 deduction.

* * * * *

■ **Par. 6.** Section 1.250(b)–5 is amended by revising paragraph (c)(5) to read as follows:

§ 1.250(b)–5 Foreign-derived deduction eligible income (FDDEI) services.

* * * * *

(c) * * *

(5) *Electronically supplied service.* The term *electronically supplied service* means, with respect to a general service other than an advertising service, a service that is delivered primarily over the internet or an electronic network and for which value of the service to the end user is derived primarily from automation or electronic delivery. Electronically supplied services include the provision of access to digital content (as defined in § 1.250(b)–3), such as streaming content; on-demand network access to computing resources, such as networks, servers, storage, and software; the provision or support of a business or personal presence on a network, such as a website or a web page; online intermediation platform services; services automatically generated from a computer via the internet or other network in response to data input by the recipient; and similar services. Electronically supplied services do not include services that primarily involve the application of human effort by the renderer (not considering the human effort involved in the development or maintenance of the technology enabling the electronically supplied services). Accordingly, electronically supplied services do not include, for example certain services (such as legal, accounting, medical, or teaching services) provided electronically and synchronously.

* * * * *

■ **Par. 7.** Section 1.336–2 is amended:

■ 1. By revising the heading of paragraph (g)(3)(ii).

■ 2. In paragraph (g)(3)(ii)(A), by revising the first sentence and removing the language ''foreign tax'' and adding in its place the language ''foreign income tax'' in the second sentence.

■ 3. By revising paragraphs (g)(3)(ii)(B) and (g)(3)(iii).

■ 4. By removing both occurrences of paragraph (h) at the end of the section.

The revisions read as follows:

§ 1.336–2 Availability, mechanics, and consequences of section 336(e) election.

* * * * *

(g) * * *

(3) * * *

(ii) *Allocation of foreign income taxes*—(A) * * * Except as provided in paragraph (g)(3)(ii)(B) of this section, if a section 336(e) election is made for target and target's taxable year under foreign law (if any) does not close at the end of the disposition date, foreign income tax as defined in § 1.960–1(b)(5) (other than a withholding tax as defined in section 901(k)(1)(B)) paid or accrued by new target with respect to such foreign taxable year is allocated between old target and new target. * * *

(B) *Foreign income taxes imposed on partnerships and disregarded entities.* If a section 336(e) election is made for target and target holds an interest in a disregarded entity (as described in § 301.7701–2(c)(2)(i) of this chapter) or partnership, the rules of § 1.901–2(f)(4) and (5) apply to determine the person who is considered for Federal income tax purposes to pay foreign income tax imposed at the entity level on the income of the disregarded entity or partnership.

(iii) *Disallowance of foreign tax credits under section 901(m).* For rules that may apply to disallow foreign tax credits by reason of a section 336(e) election, see section 901(m) and §§ 1.901(m)–1 through 1.901(m)–8.

* * * * *

■ **Par. 8.** Section 1.336–5 is revised to read as follows:

§ 1.336–5 Applicability dates.

Except as otherwise provided in this section, the provisions of §§ 1.336–1 through 1.336–4 apply to any qualified stock disposition for which the disposition date is on or after May 15, 2013. The provisions of § 1.336–1(b)(5)(i)(A) relating to section 1022 apply on and after January 19, 2017. The provisions of § 1.336–2(g)(3)(ii) and (iii) apply to foreign income taxes paid or accrued in taxable years beginning on or after [date final regulations are filed with the **Federal Register**].

■ **Par. 9.** Section 1.338–9 is amended by revising paragraph (d) to read as follows:

§ 1.338–9 International aspects of section 338.

* * * * *

(d) *Allocation of foreign income taxes*—(1) *In general.* Except as provided in paragraph (d)(3) of this section, if a section 338 election is made for target (whether foreign or domestic), and target's taxable year under foreign law (if any) does not close at the end of the acquisition date, foreign income tax as defined in § 1.901–2(a)(1)) (other than a withholding tax as defined in section 901(k)(1)(B)) paid or accrued by new target with respect to such foreign taxable year is allocated between old target and new target. If there is more than one section 338 election with respect to target during target's foreign taxable year, foreign income tax paid or accrued with respect to that foreign taxable year is allocated among all old targets and new targets. The allocation is made based on the respective portions of the taxable income (as determined under foreign law) for the foreign taxable year that are attributable under the principles of § 1.1502–76(b) to the period of existence of each old target and new target during the foreign taxable year.

(2) *Foreign income taxes imposed on partnerships and disregarded entities.* If a section 338 election is made for target and target holds an interest in a disregarded entity (as described in § 301.7701–2(c)(2)(i) of this chapter) or partnership, the rules of § 1.901–2(f)(4) and (5) apply to determine the person who is considered for Federal income tax purposes to pay foreign income tax imposed at the entity level on the

income of the disregarded entity or partnership.

(3) *Disallowance of foreign tax credits under section 901(m).* For rules that may apply to disallow foreign tax credits by reason of a section 338 election, see section 901(m) and §§ 1.901(m)–1 through 1.901(m)–8.

(4) *Applicability date.* This paragraph (d) applies to foreign income taxes paid or accrued in taxable years beginning on or after [date final regulations are filed with the **Federal Register**].

* * * * *

§ 1.367(b)–2 [Amended]

■ **Par. 10.** Section 1.367(b)–2 is amended by removing the last sentence of paragraph (e)(4), *Example 1.*

§ 1.367(b)–3 [Amended]

■ **Par. 11.** Section 1.367(b)–3 is amended:

■ 1. In paragraph (b)(3)(ii):

■ i. By removing the last sentence of *Example 1.*(ii).

■ ii. By removing the last sentence of *Example 2.*(ii).

■ 2. By removing the last sentence of paragraph (c)(5), *Example 1.*(iii).

■ **Par. 12.** Section 1.367(b)–4 is amended:

■ 1. By revising paragraph (b)(2)(i)(B).

■ 2. By adding a sentence to the end of paragraph (h).

The revision and addition read as follows:

§ 1.367(b)–4 Acquisition of foreign corporate stock or assets by a foreign corporation in certain nonrecognition transactions.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) Immediately after the exchange, a domestic corporation directly or indirectly owns 10 percent or more of the voting power or value of the transferee foreign corporation; and

* * * * *

(h) * * * Paragraph (b)(2)(i)(B) of this section applies to exchanges completed in taxable years of exchanging shareholders ending on or after November 2, 2020, and to taxable years of exchanging shareholders ending before November 2, 2020 resulting from an entity classification election made under § 301.7701–3 of this chapter that was effective on or before November 2, 2020 but was filed on or after November 2, 2020.

■ **Par. 13.** Section 1.367(b)–7 is amended:

■ 1. By adding a sentence to the end of paragraph (b)(1).

■ 2. By revising paragraph (g).

■ 3. By adding paragraph (h).

The revisions and additions read as follows:

§ 1.367(b)–7 Carryover of earnings and profits and foreign income taxes in certain foreign-to-foreign nonrecognition transactions.

* * * * *

(b) * * *

(1) * * * See paragraph (g) of this section for rules applicable to taxable years of foreign corporations beginning on or after January 1, 2018, and taxable years of United States shareholders in which or with which such taxable years of foreign corporations end (''post-2017 taxable years'').

* * * * *

(g) *Post-2017 taxable years.* As a result of the repeal of section 902 effective for taxable years of foreign corporations beginning on or after January 1, 2018, all foreign target corporations, foreign acquiring corporations, and foreign surviving corporations are treated as nonpooling corporations in post-2017 taxable years. Any amounts remaining in post-1986 undistributed earnings and post-1986 foreign income taxes of any such corporation in any separate category as of the end of the foreign corporation's last taxable year beginning before January 1, 2018, are treated as earnings and taxes in a single pre-pooling annual layer in the foreign corporation's post-2017 taxable years for purposes of this section. Foreign income taxes that are related to non-previously taxed earnings of a foreign acquiring corporation and a foreign target corporation that were accumulated in taxable years before the current taxable year of the foreign corporation, or in a foreign target's taxable year that ends on the date of the section 381 transaction, are not treated as current year taxes (as defined in § 1.960–1(b)(4)) of a foreign surviving corporation in any post-2017 taxable year. In addition, foreign income taxes that are related to a hovering deficit are not treated as current year taxes of the foreign surviving corporation in any post-2017 taxable year, regardless of whether the hovering deficit is absorbed.

(h) *Applicability dates.* Except as otherwise provided in this paragraph (h), this section applies to foreign section 381 transactions that occur on or after November 6, 2006. Paragraph (g) of this section applies to taxable years of foreign corporations ending on or after November 2, 2020, and to taxable years of United States shareholders in which or with which such taxable years of foreign corporations end.

■ **Par. 14.** Section 1.367(b)–10 is amended:

■ 1. In paragraph (c)(1), by removing the language ''sections 902 or'' and adding in its place the language ''section''.

■ 2. By revising the heading and adding a sentence to the end of paragraph (e).

The revision and addition read as follows:

§ 1.367(b)–10 Acquisition of parent stock or securities for property in triangular reorganizations.

* * * * *

(e) *Applicability dates.* * * * Paragraph (c)(1) of this section applies to deemed distributions that occur in taxable years ending on or after November 2, 2020.

§ 1.461–1 [Amended]

■ **Par. 15.** Section 1.461–1 is amended by removing the language ''paragraph (b)'' and adding in its place the language ''paragraph (g)'' in the last sentence of paragraph (a)(4).

■ **Par. 16.** Section 1.861–3 is amended:

■ 1. By revising the section heading.

■ 2. By redesignating paragraph (d) as paragraph (e).

■ 3. By adding a new paragraph (d).

■ 4. In newly redesignated paragraph (e):

■ i. By revising the heading.

■ ii. By removing ''this paragraph'' and adding ''this paragraph (e),'' in its place.

■ iii. By adding a sentence to the end of the paragraph.

The revisions and additions read as follows:

§ 1.861–3 Dividends and income inclusions under sections 951, 951A, and 1293 and associated section 78 dividends.

* * * * *

(d) *Source of income inclusions under sections 951, 951A, and 1293 and associated section 78 dividends.* For purposes of sections 861 and 862 and §§ 1.861–1 and 1.862–1, and for purposes of applying this section, the amount included in gross income of a United States person under sections 951, 951A, and 1293 and the associated section 78 dividend for the taxable year with respect to a foreign corporation are treated as dividends received directly by the United States person from the foreign corporation that generated the inclusion. See section 904(h) and § 1.904–5(m) for rules concerning the resourcing of inclusions under sections 951, 951A, and 1293.

(e) *Applicability dates.* * * * Paragraph (d) of this section applies to taxable years ending on or after November 2, 2020.

■ **Par. 17.** Section 1.861–8, as amended in FR Doc. 2020–21819, published elsewhere in this issue of the **Federal**

Register, is further amended by revising paragraph (e)(4)(i) and adding paragraph (h)(4) to read as follows:

§ 1.861–8 Computation of taxable income from sources within the United States and from other sources and activities.

* * * * *

(e) * * *

(4) * * *

(i) *Expenses attributable to controlled services.* If a taxpayer performs a controlled services transaction (as defined in § 1.482–9(l)(1)), which includes any activity by one member of a group of controlled taxpayers (the renderer) that results in a benefit to a controlled taxpayer (the recipient), and the renderer charges the recipient for such services, section 482 and § 1.482–1 provide for an allocation where the charge is not consistent with an arm's length result. The deductions for expenses of the taxpayer attributable to the controlled services transaction are considered definitely related to the amounts so charged and are to be allocated to such amounts.

* * * * *

(h) * * *

(4) Paragraph (e)(4)(i) of this section applies to taxable years ending on or after November 2, 2020.

■ **Par. 18.** Section 1.861–9, as amended in FR Doc. 2020–21819, published elsewhere in this issue of the **Federal Register**, is further amended:

■ 1. By adding a sentence to the end of paragraph (g)(3).

■ 2. By redesignating paragraph (k) as paragraph (l).

■ 3. By adding a new paragraph (k).

■ 4. By revising newly redesignated paragraph (l).

The additions and revision read as follows:

§ 1.861–9 Allocation and apportionment of interest expense and rules for asset-based apportionment.

* * * * *

(g) * * *

(3) * * * For purposes of applying section 904 as the operative section, the statutory or residual grouping of income that assets generate, have generated, or may reasonably be expected to generate is determined after taking into account any reallocation of income required under § 1.904–4(f)(2)(vi).

* * * * *

(k) *Election to capitalize certain expenses in determining tax book value of assets*—(1) *In general.* Solely for purposes of apportioning interest expenses under the asset method described in paragraph (g) of this section, a taxpayer may elect to determine the tax book value of its assets by capitalizing and amortizing its research and experimental and advertising expenditures incurred in each taxable year under the rules described in paragraphs (k)(2) and (3) of this section. Any election made pursuant to this paragraph (k)(1) by a taxpayer must also be made by or on behalf of all members of an affiliated group of corporations as defined in §§ 1.861–11(d) and 1.861–11T(d) that includes the taxpayer. A taxpayer that makes an election under this paragraph (k)(1) for a taxable year must determine the tax book value of its assets for the taxable year as if it had capitalized its research and experimental and advertising expenditures under paragraphs (k)(2) and (3) of this section in every prior taxable year. Any election made pursuant to this paragraph (k)(1) applies to all subsequent taxable years of the taxpayer unless revoked by the taxpayer. Revocation of such an election requires the consent of the Commissioner.

(2) *Research and experimental expenditures*—(i) *In general.* A taxpayer making an election under paragraph (k)(1) of this section must capitalize its specified research or experimental expenditures paid or incurred during the taxable year (for purposes of apportioning interest expense under the asset method described in paragraph (g) of this section) under the rules in section 174, as contained in Pub. L. 115–97, title I, section 13206(a), except that the 15-year amortization period that applies to foreign research applies to all research whether conducted within or outside the United States.

(ii) *Character of asset.* The tax book value of the asset created as a result of capitalizing and amortizing specified research or experimental expenditures is apportioned to statutory and residual groupings by first assigning the asset to SIC code categories based on the SIC code categories of the specified research or experimental expenditures used to generate the asset, and then apportioning the tax book value of the asset in proportion to the taxpayer's sales in each statutory and residual grouping in the SIC code group for the taxable year in which the expenditures are or were incurred. The rules in § 1.861–17 (without regard to the exclusive apportionment rule in § 1.861–17(c)) apply for purposes of the preceding sentence.

(iii) *Effect of section 13206(a) of Public Law 115–97, title I.* Beginning with the first taxable year in which the rules in section 13206(a) of Public Law 115–97, title I, for capitalizing specified research or experimental expenditures for Federal income tax purposes become effective, the election in paragraph (k)(1) of this section will no longer apply to research and experimental expenditures incurred in that taxable year and subsequent taxable years, and the general rules for capitalizing and amortizing specified research or experimental expenditures under section 174 will apply instead in determining the tax book value of assets attributable to such expenditures for purposes of apportioning expenses under the asset method.

(3) *Advertising expenditures*—(i) *In general.* A taxpayer making an election under paragraph (k)(1) of this section must capitalize and amortize fifty percent of its specified advertising expenses in each taxable year for purposes of apportioning expenses under the asset method described in paragraph (g) of this section. The share of specified advertising expenses that are charged to the capital account is treated as being amortized ratably over the 10-year period beginning with the midpoint of the taxable year in which such expenses are paid or incurred. The tax book value of the asset created as a result of capitalizing specified advertising expenses is apportioned once, in the taxable year that the expenses are incurred, to the statutory and residual groupings based on the character of the gross income that would be generated by selling products to, or performing services for, the persons to whom the specified advertising expenses are directed, and ratably apportioning the tax book value of the asset based on a reasonable estimate of the number of such persons with respect to each such grouping in such taxable year. Therefore, for example, if 80 percent of specified advertising expenses incurred in Year 1 for promoting Product X relate to advertising viewed by persons within the United States and 20 percent relate to advertising viewed by persons outside the United States, and sales of Product X to persons within the United States would be U.S. source general category income and sales of Product X to persons outside the United States would be foreign source general category income, then for purposes of section 904 as the operative section, 80 percent of the asset is treated as a U.S. source general category asset and 20 percent of the asset is treated as a foreign source general category asset (regardless of the actual amount of sales or gross income generated from product sales in the taxable year). In subsequent years, the amortizable portion of the asset created from specified advertising expenses is treated as being amortized

ratably among the statutory and residual groupings to which the tax book value of the asset was assigned in the taxable year that it was created.

(ii) *Specified advertising expenses.* The term *specified advertising expenses* means any amount paid or incurred in a taxable year (but only to the extent otherwise deductible in such taxable year), for the development, production, or placement (including any form of transmission, broadcast, publication, display, or distribution) of any communication to the general public (or portions thereof) which is intended to promote the taxpayer (or any related person under § 1.861–8(c)(4)) or a trade or business of the taxpayer (or any related person), or any service, facility, or product provided pursuant to such trade or business.

(l) *Applicability dates.* (1) Except as provided in paragraphs (l)(2) and (3) of this section, this section applies to taxable years that both begin after December 31, 2017, and end on or after December 4, 2018.

(2) Paragraphs (b)(1)(i), (b)(8), and (e)(9) of this section apply to taxable years that end on or after December 16, 2019. For taxable years that both begin after December 31, 2017, and end on or after December 4, 2018, and also end before December 16, 2019, see § 1.861–9T(b)(1)(i) as contained in 26 CFR part 1 revised as of April 1, 2019.

(3) Paragraph (k) of this section applies to taxable years beginning on or after [date final regulations are filed with the **Federal Register**].

■ **Par. 19.** Section 1.861–10 is amended:

■ 1. By adding paragraph (a).

■ 2. By revising paragraphs (e)(8)(v) and (f).

■ 3. By adding paragraphs (g) and (h).

The additions and revisions read as follows:

§ 1.861–10 Special allocations of interest expense.

(a) *In general.* This section applies to all taxpayers and provides exceptions to the rules of § 1.861–9 that require the allocation and apportionment of interest expense on the basis of all assets of all members of the affiliated group. Section 1.861–10T(b) describes the direct allocation of interest expense to the income generated by certain assets that are subject to qualified nonrecourse indebtedness. Section 1.861–10T(c) describes the direct allocation of interest expense to income generated by certain assets that are acquired in an integrated financial transaction. Section 1.861–10T(d) provides special rules that apply to all transactions described in § 1.861–10T(b) and (c). Paragraph (e) of this section requires the direct allocation of third-party interest expense of an affiliated group to such group's investment in related controlled foreign corporations in cases involving excess related person indebtedness (as defined therein). See also § 1.861–9T(b)(5), which requires the direct allocation of amortizable bond premium. Paragraph (f) of this section provides a special rule for certain regulated utility companies. Paragraph (g) of this section requires the direct allocation of interest expense in the case of certain foreign banking branches. Paragraph (h) of this section sets forth applicability dates.

* * * * *

(e) * * *

(8) * * *

(v) *Classification of loans between controlled foreign corporations.* In determining the amount of related group indebtedness for any taxable year, loans outstanding from one controlled foreign corporation to a related controlled foreign corporation are not treated as related group indebtedness. For purposes of determining the foreign base period ratio under paragraph (e)(2)(iv) of this section for a taxable year that ends on or after November 2, 2020, the rules of this paragraph (e)(8)(v) apply to determine the related group debt-to-asset ratio in each taxable year included in the foreign base period, including in taxable years that end before November 2, 2020.

* * * * *

(f) *Indebtedness of certain regulated utilities.* If an automatically excepted regulated utility trade or business (as defined in § 1.163(j)–1(b)(15)(i)(A)) has qualified nonrecourse indebtedness within the meaning of the second sentence in § 1.163(j)–10(d)(2), interest expense from the indebtedness is directly allocated to the taxpayer's assets in the manner and to the extent provided in § 1.861–10T(b).

(g) *Direct allocation of interest expense incurred by foreign banking branches*—(1) *In general.* The foreign banking branch interest expense of a foreign banking branch is directly allocated to the foreign banking branch income of that foreign banking branch, to the extent of the foreign banking branch income. For rules that may apply to foreign banking branch interest expense in excess of amounts allocated under this paragraph (g), see § 1.861–9.

(2) *Adjustments to asset value.* For purposes of applying § 1.861–9 to apportion interest expense in excess of the interest expense directly allocated under paragraph (g)(1) of this section, the value of the assets of the foreign banking branch for the year (as determined under § 1.861–9T(g)(3)) is reduced (but not below zero) by an amount equal to the liabilities of that branch with respect to which the interest expense was directly allocated under paragraph (g)(1) of this section. For purposes of this paragraph (g), the amount of a liability with respect to a foreign currency hedge described in § 1.861–9T(b)(2) or derivative financial product described in § 1.861–9T(b)(6) is zero.

(3) *Definitions.* The following definitions apply for purposes of this paragraph (g).

(i) *Bank.* The term *bank* means a bank, as defined by section 2(c) of the Bank Holding Company Act of 1956 (12 U.S.C. 1841(c)) without regard to 12 U.S.C. 1841(c)(2)(C) and (G)), that is licensed or otherwise authorized to accept deposits, and accepts deposits in the ordinary course of business.

(ii) *Foreign banking branch.* The term *foreign banking branch* means a foreign branch as defined in § 1.904–4(f)(3), other than a disregarded entity (as defined in § 1.904–4(f)(3)), that is owned by a bank and gives rise to a taxable presence in a foreign country.

(iii) *Foreign banking branch income.* The term *foreign banking branch income* means gross income assigned to foreign branch category income (within the meaning of § 1.904–4(f)(1)) that is attributable to a foreign banking branch. Foreign banking branch income also includes gross income attributable to a foreign banking branch that would be assigned to the foreign branch category but is assigned to a separate category for foreign branch category income that is resourced under an income tax treaty. See § 1.904–4(k).

(iv) *Foreign banking branch interest expense.* The term *foreign banking branch interest expense* means the interest expense that is regarded for Federal income tax purposes and that is recorded on the separate books and records (as defined in § 1.989(a)–1(d)(1) and (2)) of a foreign banking branch.

(v) *Liability.* The term *liability* means a deposit or other debt obligation, transaction, or series of transactions resulting in expense or loss described in § 1.861–9T(b)(1)(i).

(h) *Applicability dates.* Except as provided in this paragraph (h), this section applies to taxable years ending on or after December 4, 2018. Paragraph (e)(8)(v) of this section applies to taxable years ending on or after November 2, 2020, and paragraphs (f) and (g) of this section apply to taxable years beginning on or after [date final regulations are filed with the **Federal Register**].

■ **Par. 20.** Section 1.861–14, as amended in FR Doc. 2020–21819, published elsewhere in this issue of the **Federal**

Register, is further amended by revising paragraphs (h) and (k) to read as follows:

§ 1.861–14 Special rules for allocating and apportioning certain expenses (other than interest expense) of an affiliated group of corporations.

* * * * *

(h) *Special rule for the allocation and apportionment of section 818(f)(1) items of a life insurance company*—(1) *In general.* Except as provided in paragraph (h)(2) of this section, life insurance company items specified in section 818(f)(1) (''section 818(f)(1) items'') are allocated and apportioned as if all members of the life subgroup were a single corporation (''life subgroup method''). See also § 1.861–8(e)(16) for rules on the allocation of reserve expenses with respect to dividends received by a life insurance company.

(2) *Alternative separate entity treatment.* A consolidated group may choose not to apply the life subgroup method and may instead allocate and apportion section 818(f)(1) items solely among items of the life insurance company that generated the section 818(f)(1) items (''separate entity method''). A consolidated group indicates its choice to apply the separate entity method by applying this paragraph (h)(2) for purposes of the allocation and apportionment of section 818(f)(1) items on its Federal income tax return filed for its first taxable year to which this section applies. A consolidated group's use of the separate entity method constitutes a binding choice to use the method chosen for that year for all members of the consolidated group and all taxable years of such members thereafter. The taxpayer's choice of a method may not be revoked without the prior consent of the Commissioner.

* * * * *

(k) *Applicability date.* Except as provided in this paragraph (k), this section applies to taxable years beginning after December 31, 2019. Paragraph (h) of this section applies to taxable years beginning on or after [date final regulations are filed with the **Federal Register**].

■ **Par. 21.** Section 1.861–20, as added in FR Doc. 2020–21819, published elsewhere in this issue of the **Federal Register**, is amended:

■ 1. In paragraph (b)(4), by removing the language ''301(c)(3)(A)'' and adding in its place the language ''301(c)(3)(A) or section 731(a)''.

■ 2. By revising paragraphs (b)(7), (19), and (23).

■ 3. By revising the first and second sentences in paragraph (c) introductory text.

■ 4. In paragraph (d)(2)(ii)(B), by adding the text '', and paragraph (d)(3)(ii)(B) of this section for rules regarding the assignment of foreign gross income arising from a distribution by a partnership'' at the end of the paragraph.

■ 5. By adding paragraph (d)(2)(ii)(D).

■ 6. In paragraph (d)(3)(i)(A), by removing the text ''or an inclusion of foreign law pass-through income'' and adding the language '', an inclusion of foreign law pass-through income, or gain from a disposition under both foreign and Federal income tax law'' in its place.

■ 7. By adding paragraphs (d)(3)(i)(D), (d)(3)(ii) and (v), (g)(10) through (13), and (h).

■ 8. By revising paragraph (i).

The additions and revisions read as follows:

§ 1.861–20 Allocation and apportionment of foreign income taxes.

* * * * *

(b) * * *

(7) *Foreign income tax.* The term *foreign income tax* has the meaning provided in § 1.901–2(a).

* * * * *

(19) *U.S. capital gain amount.* The term *U.S. capital gain amount* means gain recognized by a taxpayer on the sale, exchange, or other disposition of stock or an interest in a partnership or, in the case of a distribution with respect to stock or a partnership interest, the portion of the distribution to which section 301(c)(3)(A) or 731(a)(1), respectively, applies. A U.S. capital gain amount includes gain that is subject to section 751 and § 1.751–1, but does not include any portion of the gain recognized by a taxpayer that is included in gross income as a dividend under section 964(e) or 1248.

* * * * *

(23) *U.S. return of capital amount.* The term *U.S. return of capital amount* means, in the case of the sale, exchange, or other disposition of either stock or an interest in a partnership, the taxpayer's adjusted basis of the stock or partnership interest, or in the case of a distribution with respect to stock or a partnership interest, the portion of the distribution to which section 301(c)(2) or 733, respectively, applies.

* * * * *

(c) * * * A foreign income tax (other than certain in lieu of taxes described in paragraph (h) of this section) is allocated and apportioned to the statutory and residual groupings that include the items of foreign gross income included in the base on which the tax is imposed. Each such foreign income tax (that is, each separate levy) is allocated and apportioned separately under the rules in paragraphs (c) through (f) of this section. * * *

* * * * *

(d) * * *

(2) * * *

(ii) * * *

(D) *Foreign law transfers between taxable units.* An item of foreign gross income arising from an event that foreign law treats as a transfer of property, or as giving rise to an item of accrued income, gain, deduction, or loss with respect to a transaction, between taxable units (as defined in paragraph (d)(3)(v)(E) of this section) of the same taxpayer, but that is not treated as a disregarded payment (as defined in paragraph (d)(3)(v)(E) of this section) for Federal income tax purposes in the same U.S. taxable year in which the foreign income tax is paid or accrued, is characterized and assigned to the grouping to which a disregarded payment in the amount of the item of foreign gross income (or the gross receipts giving rise to the item of foreign gross income) would be assigned under the rules of paragraph (d)(3)(v) of this section if the event giving rise to the foreign gross income resulted in a disregarded payment in the U.S. taxable year in which the foreign income tax is paid or accrued. For example, an item of foreign gross income that a taxpayer recognizes by reason of a foreign law distribution (such as a stock dividend or a consent dividend) from a disregarded entity is assigned to the same statutory or residual groupings to which the foreign gross income would be assigned if a distribution of property in the amount of the taxable distribution under foreign law were made for Federal income tax purposes on the date on which the foreign law distribution occurred.

* * * * *

(3) * * *

(i) * * *

(D) *Foreign gross income items arising from a disposition of stock.* An item of foreign gross income that arises from a transaction that is treated as a sale, exchange, or other disposition of stock in a corporation for Federal income tax purposes is assigned first, to the extent of any U.S. dividend amount that results from the disposition, to the same statutory or residual grouping (or ratably to the groupings) to which the U.S. dividend amount is assigned under Federal income tax law. If the foreign gross income item exceeds the U.S.

dividend amount, the foreign gross income item is next assigned, to the extent of the U.S. capital gain amount, to the statutory or residual grouping (or ratably to the groupings) to which the U.S. capital gain amount is assigned under Federal income tax law. Any excess of the foreign gross income item over the sum of the U.S. dividend amount and the U.S. capital gain amount is assigned to the same statutory or residual grouping (or ratably to the groupings) to which earnings equal to such excess amount would be assigned if they were recognized for Federal income tax purposes in the U.S. taxable year in which the disposition occurred. These earnings are deemed to arise in the statutory and residual groupings in the same proportions as the proportions in which the tax book value of the stock is (or would be if the taxpayer were a United States person) assigned to the groupings under the asset method in § 1.861–9 in the U.S. taxable year in which the disposition occurs. See paragraph (g)(10) of this section (*Example 9*).

(ii) *Items of foreign gross income included by a taxpayer by reason of its ownership of an interest in a partnership*—(A) *Scope.* The rules of this paragraph (d)(3)(ii) apply to assign to a statutory or residual grouping certain items of foreign gross income that a taxpayer includes in foreign taxable income by reason of its ownership of an interest in a partnership. See paragraphs (d)(1) and (2) of this section for rules that apply in characterizing items of foreign gross income that are attributable to a partner's distributive share of income of a partnership. See paragraph (d)(3)(iii) of this section for rules that apply in characterizing items of foreign gross income that are attributable to an inclusion under a foreign law inclusion regime.

(B) *Foreign gross income items arising from a distribution with respect to an interest in a partnership.* If a partnership makes a distribution that is treated as a distribution of property for both foreign law and Federal income tax purposes, the foreign gross income arising from the distribution (including foreign gross income attributable to a distribution from a partnership that foreign law classifies as a dividend from a corporation) is, to the extent of the U.S. capital gain amount, assigned to the statutory and residual groupings to which the U.S. capital gain amount is assigned under Federal income tax law. If the foreign gross income arising from the distribution exceeds the U.S. capital gain amount, such excess amount is assigned to the statutory and residual groupings to which earnings equal to such excess amount would be assigned if they were recognized in the U.S. taxable year in which the distribution is made. These earnings are deemed to arise in the statutory and residual groupings in the same proportions as the proportions in which the tax book value of the partnership interest or the partner's pro rata share of the partnership assets, as applicable, is assigned (or would be assigned if the partner were a United States person) for purposes of apportioning the partner's interest expense under § 1.861–9(e) in the U.S. taxable year in which the distribution is made.

(C) *Foreign gross income items arising from the disposition of an interest in a partnership.* An item of foreign gross income arising from the sale, exchange, or other disposition of an interest in a partnership for Federal income tax purposes is assigned first, to the extent of the U.S. capital gain amount, to the statutory or residual grouping (or ratably to the groupings) to which the U.S. capital gain amount is assigned. Any excess of the foreign gross income item over the U.S. capital gain amount is assigned to the statutory and residual grouping (or ratably to the groupings) to which a distributive share of income of the partnership in the amount of such excess would be assigned if such income was recognized for Federal income tax purposes in the U.S. taxable year in which the disposition occurred. The items constituting this distributive share of income are deemed to arise in the statutory and residual groupings in the same proportions as the proportions in which the tax book value of the partnership interest, or the partner's pro rata share of the partnership assets, as applicable, is assigned (or would be assigned if the partner were a United States person) for purposes of apportioning the partner's interest expense under § 1.861–9(e) in the U.S. taxable year in which the disposition occurred.

* * * * *

(v) *Disregarded payments*—(A) *In general.* This paragraph (d)(3)(v) applies to assign to a statutory or residual grouping a foreign gross income item that a taxpayer includes by reason of the receipt of a disregarded payment. In the case of a taxpayer that is an individual or a domestic corporation, this paragraph (d)(3)(v) applies to a disregarded payment made between a taxable unit that is a foreign branch, a foreign branch owner, or a non-branch taxable unit, and another such taxable unit of the same taxpayer. In the case of a taxpayer that is a foreign corporation, this paragraph (d)(3)(v) applies to a disregarded payment made between taxable units that are tested units of the same taxpayer. For purposes of this paragraph (d)(3)(v), an individual or corporation is treated as the taxpayer with respect to its distributive share of foreign income taxes paid or accrued by a partnership, estate, trust or other pass-through entity. The rules of paragraph (d)(3)(v)(B) of this section apply to attribute U.S. gross income comprising the portion of a disregarded payment that is a reattribution payment to a taxable unit, and to associate the foreign gross income item arising from the receipt of the reattribution payment with the statutory and residual groupings to which that U.S. gross income is assigned. The rules of paragraph (d)(3)(v)(C) of this section apply to assign to statutory and residual groupings items of foreign gross income arising from the receipt of the portion of a disregarded payment that is a remittance or a contribution. The rules of paragraph (d)(3)(v)(D) of this section apply to assign to statutory and residual groupings items of foreign gross income arising from disregarded payments in connection with disregarded sales or exchanges of property. Paragraph (d)(3)(v)(E) of this section provides definitions that apply for purposes of this paragraph (d)(3)(v) and paragraph (g) of this section.

(B) *Reattribution payments*—(*1*) *In general.* This paragraph (d)(3)(v)(B) assigns to a statutory or residual grouping a foreign gross income item that a taxpayer includes by reason of the receipt by a taxable unit of the portion of a disregarded payment that is a reattribution payment. The foreign gross income item is assigned to the statutory or residual groupings to which one or more reattribution amounts that constitute the reattribution payment are assigned upon receipt by the taxable unit. If a reattribution payment comprises multiple reattribution amounts and the amount of the foreign gross income item that is attributable to the reattribution payment differs from the amount of the reattribution payment, foreign gross income is apportioned among the statutory and residual groupings in proportion to the reattribution amounts in each statutory and residual grouping. The statutory or residual grouping of a reattribution amount received by a taxable unit is the grouping that includes the U.S. gross income attributed to the taxable unit by reason of its receipt of the gross reattribution amount, regardless of whether, after taking into account disregarded payments made by the

taxable unit, the taxable unit has an attribution item as a result of its receipt of the reattribution amount. See paragraph (g)(13) of this section (*Example 12*).

(*2*) *Attribution of U.S. gross income to a taxable unit.* This paragraph (d)(3)(v)(B)(*2*) provides attribution rules to determine the reattribution amounts received by a taxable unit in the statutory and residual groupings in order to apply paragraph (d)(3)(v)(B)(*1*) of this section to assign foreign gross income items arising from a reattribution payment to the groupings. In the case of a taxpayer that is an individual or a domestic corporation, the attribution rules in § 1.904–4(f)(2) apply to determine the reattribution amounts received by a taxable unit in the separate categories (as defined in § 1.904–5(a)(4)(v)) in order to apply paragraph (d)(3)(v)(B)(*1*) of this section for purposes of § 1.904–6(b)(2)(i). In the case of a taxpayer that is a foreign corporation, the attribution rules in § 1.954–1(d)(1)(iii) apply to determine the reattribution amounts received by a taxable unit in the statutory and residual groupings in order to apply paragraph (d)(3)(v)(B)(*1*) of this section for purposes of §§ 1.951A–2(c)(3), 1.954–1(c)(1)(i) and (d)(1)(iv), and 1.960–1(d)(3)(ii). For purposes of other operative sections (as described in § 1.861–8(f)(1)), the principles of § 1.904–4(f)(2)(vi) or § 1.954–1(d)(1)(iii), as applicable, apply to determine the reattribution amounts received by a taxable unit in the statutory and residual groupings. The rules and principles of § 1.904–4(f)(2)(vi) or § 1.954–1(d)(1)(iii), as applicable, apply to determine the extent to which a disregarded payment made by the taxable unit is a reattribution payment and the reattribution amounts that constitute a reattribution payment, and to adjust the U.S. gross income initially attributed to each taxable unit to reflect the reattribution payments that the taxable unit makes and receives. The rules in this paragraph (d)(3)(v)(B)(*2*) limit the amount of a disregarded payment that is a reattribution payment to the U.S. gross income of the payor taxable unit that is recognized in the U.S. taxable year in which the disregarded payment is made.

(*3*) *Effect of reattribution payment on foreign gross income items of payor taxable unit.* The statutory or residual grouping to which an item of foreign gross income of a taxable unit is assigned is determined without regard to reattribution payments made by the taxable unit, and without regard to whether the taxable unit has one or more attribution items after taking into account such reattribution payments. No portion of the foreign gross income of the payor taxable unit is treated as foreign gross income of the payee taxable unit by reason of the reattribution payment, notwithstanding that U.S. gross income of the payor taxable unit that is used to assign foreign gross income of the payor taxable unit to statutory and residual groupings is reattributed to the payee taxable unit under paragraph (d)(3)(v)(B)(*1*) of this section by reason of the reattribution payment. See paragraph (e) of this section for rules reducing the amount of a foreign gross income item of a taxable unit by deductions allowed under foreign law, including deductions by reason of disregarded payments made by a taxable unit that are included in the foreign gross income of the payee taxable unit.

(C) *Remittances and contributions*—(*1*) *Remittances*—(*i*) *In general.* An item of foreign gross income that a taxpayer includes by reason of the receipt of a remittance by a taxable unit is assigned to the statutory or residual groupings of the recipient taxable unit that correspond to the groupings out of which the payor taxable unit made the remittance under the rules of this paragraph (d)(3)(v)(C)(*1*)(*i*). A remittance paid by a taxable unit is considered to be made ratably out of all of the accumulated after-tax income of the taxable unit. The accumulated after-tax income of the taxable unit that pays the remittance is deemed to have arisen in the statutory and residual groupings in the same proportions as the proportions in which the tax book value of the assets of the taxable unit are (or would be if the owner of the taxable unit were a United States person) assigned for purposes of apportioning interest expense under the asset method in § 1.861–9 in the taxable year in which the remittance is made. See paragraph (g)(11) and (12) of this section (*Example 10* and *11*). If the payor taxable unit is determined to have no assets under paragraph (d)(3)(v)(C)(*1*)(*ii*) of this section, then the foreign gross income that is included by reason of the receipt of the remittance is assigned to the residual grouping.

(*ii*) *Assets of a taxable unit.* The assets of a taxable unit are determined in accordance with § 1.987–6(b), except that for purposes of applying § 1.987–6(b)(2) under this paragraph (d)(3)(v)(C)(*1*)(*ii*), a taxable unit is deemed to be a section 987 QBU (within the meaning of § 1.987–1(b)(2)) and assets of the taxable unit include stock held by the taxable unit and the portion of the tax book value of a reattribution asset that is assigned to the taxable unit. The portion of the tax book value of a reattribution asset that is assigned to a taxable unit is an amount that bears the same ratio to the total tax book value of the reattribution asset as the sum of the attribution items of that taxable unit arising from gross income produced by the reattribution asset bears to the total gross income produced by the reattribution asset. The portion of a reattribution asset that is assigned to a taxable unit under this paragraph (d)(3)(v)(C)(*1*)(*ii*) is not treated as an asset of the taxable unit making the reattribution payment for purposes of applying paragraph (d)(3)(v)(C)(*1*)(*i*) of this section.

(*2*) *Contributions.* An item of foreign gross income that a taxpayer includes by reason of the receipt of a contribution by a taxable unit is assigned to the residual grouping. See, however, § 1.904–6(b)(2)(ii) (assigning certain items of foreign gross income to the foreign branch category for purposes of applying section 904 as the operative section).

(*3*) *Disregarded payment that comprises both a reattribution payment and a remittance or contribution.* If both a reattribution payment and either a remittance or a contribution result from a single disregarded payment, the foreign gross income is first attributed to the portion of the disregarded payment that is a reattribution payment to the extent of the amount of the reattribution payment, and any excess of the foreign gross income item over the amount of the reattribution payment is then to attributed to the portion of the disregarded payment that is a remittance or contribution.

(D) *Disregarded payments in connection with disregarded sales or exchanges of property.* An item of foreign gross income attributable to gain recognized under foreign law by reason of a disregarded payment received in exchange for property is characterized and assigned under the rules of paragraph (d)(2) of this section. If a taxpayer recognizes U.S. gross income as a result of a disposition of property that was previously received in exchange for a disregarded payment, any item of foreign gross income that the taxpayer recognizes as a result of that same disposition is assigned to a statutory or residual grouping under paragraph (d)(1) of this section, without regard to any reattribution of the U.S. gross income under § 1.904–4(f)(2)(vi)(A) (or the principles of § 1.904–4(f)(2)(vi)(A)) by reason of a disregarded payment described in § 1.904–4(f)(2)(vi)(B)(*2*) (or by reason of § 1.904–4(f)(2)(vi)(D)). See paragraph (d)(3)(v)(B)(*3*) of this section.

(E) *Definitions.* The following definitions apply for purposes of this paragraph (d)(3)(v) and paragraph (g) of this section.

(*1*) *Attribution item.* The term *attribution item* means the portion of an item of gross income, computed under Federal income tax law, that is attributed to a taxable unit after taking into account all reattribution payments made and received by the taxable unit.

(*2*) *Contribution.* The term *contribution* means:

(*i*) A transfer of property (within the meaning of section 317(a)) to a taxable unit that is disregarded for Federal income tax purposes and that would be treated as a contribution to capital described in section 118 or a transfer described in section 351 if the taxable unit were a corporation under Federal income tax law; or

(*ii*) The excess of a disregarded payment made by a taxable unit to another taxable unit that the first taxable unit owns over the portion of the disregarded payment that is a reattribution payment.

(*3*) *Disregarded entity.* The term *disregarded entity* means an entity described in § 301.7701–2(c)(2) of this chapter that is disregarded as an entity separate from its owner for Federal income tax purposes.

(*4*) *Disregarded payment.* The term *disregarded payment* means an amount of property (within the meaning of section 317(a)) that is transferred to or from a taxable unit, including a payment in exchange for property or in satisfaction of an account payable, or a remittance or contribution, in connection with a transaction that is disregarded for Federal income tax purposes and that is reflected on the separate set of books and records of the taxable unit. A disregarded payment also includes any other amount that is reflected on the separate set of books and records of a taxable unit in connection with a transaction that is disregarded for Federal income tax purposes and that would constitute an item of accrued income, gain, deduction, or loss of the taxable unit if the transaction to which the amount is attributable were regarded for Federal income tax purposes.

(*5*) *Reattribution amount.* The term *reattribution amount* means an amount of gross income, computed under Federal income tax law, that is initially assigned to a single statutory or residual grouping that includes gross income of a taxable unit but that is, by reason of a disregarded payment made by that taxable unit, attributed to another taxable unit under paragraph (d)(3)(v)(B)(*2*) of this section.

(*6*) *Reattribution asset.* The term *reattribution asset* means an asset that produces one or more items of gross income, computed under Federal income tax law, to which a disregarded payment is allocated under the rules of paragraph (d)(3)(v)(B)(*2*) of this section.

(*7*) *Reattribution payment.* The term *reattribution payment* means the portion of a disregarded payment equal to the sum of all reattribution amounts that are attributed to the recipient of the disregarded payment.

(*8*) *Remittance.* The term *remittance* means:

(*i*) A transfer of property (within the meaning of section 317(a)) by a taxable unit that would be treated as a distribution by a corporation to a shareholder with respect to its stock if the taxable unit were a corporation under Federal income tax law; or

(*ii*) The excess of a disregarded payment made by a taxable unit to a second taxable unit (including a second taxable unit that shares the same owner as the payor taxable unit) over the portion of the disregarded payment that is a reattribution payment, other than an amount that is treated as a contribution under paragraph (d)(3)(v)(E)(*2*)(*i*) of this section.

(*9*) *Taxable unit.* In the case of a taxpayer that is an individual or a domestic corporation, the term *taxable unit* means a foreign branch, a foreign branch owner, or a non-branch taxable unit, as defined in § 1.904–6(b)(2)(i)(B). In the case of a taxpayer that is a foreign corporation, the term *taxable unit* means a tested unit, as defined in § 1.954–1(d)(2).

* * * * *

(g) * * *

(10) *Example 9: Gain on disposition of stock*—(i) *Facts.* USP owns all of the outstanding stock of CFC, which conducts business in Country A. In Year 1, USP sells all of the stock of CFC to US2 for $1,000x. For Country A tax purposes, USP's basis in the stock of CFC is $200x. Accordingly, USP recognizes $800x of gain on which Country A imposes $80x of foreign income tax based on its rules for taxing capital gains of nonresidents. For Federal income tax purposes, USP's basis in the stock of CFC is $400x. Accordingly, USP recognizes $600x of gain on the sale of the stock of CFC, of which $150x is included in the gross income of USP as a dividend under section 1248(a) that, as provided in section 1248(j), is treated as a dividend eligible for the deduction under section 245A(a). Under paragraphs (b)(20) and (19) of this section, respectively, the sale of CFC stock by USP gives rise to a $150x U.S. dividend amount and a $450x U.S. capital gain amount. Under §§ 1.904–4(d) and 1.904–5(c)(4), the $150x U.S. dividend amount is general category section 245A subgroup income, and the $450x U.S. capital gain amount is passive category income to USP. For purposes of allocating and apportioning its interest expense under §§ 1.861–9(g)(2)(i)(B) and 1.861–13, USP's stock in CFC is characterized as general category stock in the section 245A subgroup.

(ii) *Analysis.* For purposes of allocating and apportioning the $80x of Country A foreign income tax, the $800x of Country A gross income from the sale of the stock of CFC is first assigned to separate categories. Under paragraph (d)(3)(i)(D) of this section, the $800x of Country A gross income is first assigned to the separate category to which the $150x U.S. dividend amount is assigned, to the extent thereof, and is next assigned to the separate category to which the $450x U.S. capital gain amount is assigned, to the extent thereof. Accordingly, $150x of Country A gross income is assigned to the general category in the section 245A subgroup, and $450x of Country A gross income is assigned to the passive category. Under paragraph (d)(3)(i)(D) of this section, the remaining $200x of Country A gross income is assigned to the statutory and residual groupings to which earnings of CFC in that amount would be assigned if they were recognized for Federal income tax purposes in the U.S. taxable year in which the disposition occurred. These earnings are all deemed to arise in the section 245A subgroup of the general category, based on USP's characterization of its stock in CFC. Thus, under paragraph (d)(3)(i)(D) of this section the $800x of foreign gross income, and therefore the foreign taxable income, is characterized as $350x ($150x + $200x) of income in the general category section 245A subgroup and $450x of income in the passive category. This is the result even though for Country A tax purposes all $800x of Country A gross income is characterized as gain from the sale of stock, which would be passive category income under section 904(d)(2)(B)(i), because the income is assigned to a separate category based on the characterization of the gain under Federal income tax law. Under paragraph (f) of this section, the $80x of Country A tax is ratably apportioned between the general category section 245A subgroup and the passive category based on the relative amounts of foreign taxable income in each grouping. Accordingly, $35x ($80x

× $350x / $800x) of the Country A tax is apportioned to the general category section 245A subgroup, and $45x ($80x × $450x / $800x) of the Country A tax is apportioned to the passive category. See also § 1.245A(d)–1 for rules that may disallow a foreign tax credit or deduction for the $35x of Country A tax apportioned to the general category section 245A subgroup.

(11) *Example 10: Disregarded transfer of built-in gain property*—(i) *Facts.* USP owns FDE, a disregarded entity that is treated for Federal income tax purposes as a foreign branch operating in Country A. FDE transfers Asset F, equipment used in FDE's trade or business in Country A, for no consideration to USP in a transaction that is a remittance described in paragraph (d)(3)(v)(E)(*8*)(*i*) of this section for Federal income tax purposes but is treated as a distribution of Asset F from a corporation to its shareholder, USP, for Country A tax purposes. At the time of the transfer, Asset F has a fair market value of $250x and an adjusted basis of $100x for both Federal and Country A income tax purposes. Country A imposes $30x of tax on FDE with respect to the $150x of built-in gain on a deemed sale of Asset F, which is recognized for Country A tax purposes by reason of the transfer to USP. If FDE had sold Asset F for $250x in a transaction that was regarded for Federal income tax purposes, FDE would also have recognized gain of $150x for Federal income tax purposes, and that gain would have been characterized as foreign branch category income as defined in § 1.904–4(f). Country A also imposes $25x of withholding tax, a separate levy, on USP by reason of the distribution of Asset F, valued at $250x, to USP.

(ii) *Analysis*—(A) *Net income tax on built-in gain.* For purposes of allocating and apportioning the $30x of Country A foreign income tax imposed on FDE by reason of the deemed sale of Asset F for Country A tax purposes, under paragraph (c)(1) of this section the $150x of Country A gross income from the deemed sale of Asset F is first assigned to a separate category. Because the transaction is disregarded for Federal income tax purposes, there is no corresponding U.S. item. However, FDE would have recognized gain of $150x, which would have been a corresponding U.S. item, if the deemed sale had been recognized for Federal income tax purposes. Therefore, under paragraph (d)(2)(i) of this section, the item of foreign gross income is characterized and assigned to the grouping to which such corresponding U.S. item would have been assigned if the deemed sale were recognized under Federal income tax law. Because the sale of Asset F in a regarded transaction would have resulted in foreign branch category income, the foreign gross income is characterized as foreign branch category income. Under paragraph (f) of this section, the $30x of Country A tax is also allocated to the foreign branch category, the statutory grouping to which the $150x of Country A gross income is assigned. No apportionment of the $30x is necessary because the class of gross income to which the foreign gross income is allocated consists entirely of a single statutory grouping, foreign branch category income.

(B) *Withholding tax on distribution.* For purposes of allocating and apportioning the $25x of Country A withholding tax imposed on USP by reason of the transfer of Asset F, under paragraph (c)(1) of this section the $250x of Country A gross income from the distribution of Asset F is first assigned to a separate category. The transfer of Asset F is a remittance from FDE to USP, and thus there is no corresponding U.S. item. Under paragraph (d)(3)(v)(C)(*1*)(*i*) of this section, the item of foreign gross income is assigned to the groupings to which the income out of which the payment is made is assigned; the payment is considered to be made ratably out of all of the accumulated after-tax income of FDE, as computed for Federal income tax purposes; and the accumulated after-tax income of FDE is deemed to have arisen in the statutory and residual groupings in the same proportions as those in which the tax book value of FDE's assets in the groupings, determined in accordance with paragraph (d)(3)(v)(C)(*1*)(*ii*) of this section, are assigned for purposes of apportioning USP's interest expense. Because all of FDE's assets produce foreign branch category income, under paragraph (d)(3)(v)(C)(*1*) of this section the foreign gross income is characterized as foreign branch category income. Under paragraph (f) of this section, the $25x of Country A withholding tax is also allocated entirely to the foreign branch category, the statutory grouping to which the $250x of Country A gross income is assigned. No apportionment of the $25x is necessary because the class of gross income to which the foreign gross income is allocated consists entirely of a single statutory grouping, foreign branch category income.

(12) *Example 11: Disregarded payment that is a remittance*—(i) *Facts.* USP owns all of the outstanding stock of CFC1. CFC1, a tested unit within the meaning of § 1.954–1(d)(2) (the ''CFC1 tested unit''), owns all of the interests in FDE, a disregarded entity that is organized in Country B. CFC1's interests in FDE are also a tested unit within the meaning of § 1.954–1(d)(2) (the ''FDE tested unit''). The sole assets of FDE (determined in accordance with paragraph (d)(3)(v)(C)(*1*)(*ii*) of this section) consist of all of the outstanding stock of CFC3, a controlled foreign corporation organized in Country B. In Year 1, CFC3 pays a $400x dividend to FDE that is excluded from CFC1's foreign personal holding company income (''FPHCI'') by reason of section 954(c)(6). FDE makes no payments to CFC1 and pays no Country B tax in Year 1. In Year 2, FDE makes a $400x payment to CFC1 that is a remittance (as defined in paragraph (d)(3)(v)(E) of this section). Under the laws of Country B, the remittance gives rise to a $400x dividend. Country B imposes a 5% ($20x) withholding tax (which is an eligible current year tax as defined in § 1.960–1(b)) on CFC1 on the dividend. In Year 2, CFC3 pays no dividends to FDE, and FDE earns no income. For Federal income tax purposes, the $400x payment from FDE to CFC1 is a disregarded payment and results in no income to CFC1. For purposes of this paragraph (g)(12) (*Example 11*), section 960(a) is the operative section and the income groups described in § 1.960–1(d)(2) are the statutory and residual groupings. See § 1.960–1(d)(3)(ii)(A) (applying § 1.960–1 to allocate and apportion current year taxes to income groups). For Federal income tax purposes, in Year 2 the stock of CFC3 owned by FDE has a tax book value of $1,000x, $750x of which is assigned under the asset method in § 1.861–9 (as applied by treating CFC1 as a United States person) to the general category tested income group described in § 1.960–1(d)(2)(ii)(C), and $250x of which is assigned to a passive category FPHCI group described in § 1.960–1(d)(2)(ii)(B)(*2*)(*i*).

(ii) *Analysis.* (A) The $20x Country B withholding tax on the remittance from FDE is imposed on a $400x item of foreign gross income that CFC1 includes in income by reason of its receipt of a disregarded payment. In order to allocate and apportion the $20x of Country B withholding tax under paragraph (c) of this section for purposes of § 1.960–1(d)(3)(ii)(A), paragraph (d)(3)(v) of this section applies to assign the $400x item of foreign gross dividend income to a statutory or residual grouping. Under paragraph (d)(3)(v)(C)(*1*) of this section, the $400x item of foreign gross income is assigned to the statutory or residual

groupings that include the U.S. gross income that is attributable to the CFC1 tested unit under the attribution rules in § 1.954–1(d)(1)(iii) and that correspond to the statutory and residual groupings out of which FDE made the remittance.

(B) Under paragraph (d)(3)(v)(C)(*1*)(*i*) of this section, FDE is considered to pay the remittance ratably out of all of its accumulated after-tax income, which is deemed to have arisen in the statutory and residual groupings in the same proportions as the proportions in which the tax book value of FDE's assets would be assigned (if CFC1 were a United States person) for purposes of apportioning interest expense under the asset method in Year 2, the taxable year in which FDE made the remittance. Accordingly, $300x ($400x × $750x / $1,000x) of the remittance is deemed to be made out of the general category tested income of the FDE tested unit, and $100x ($400x × $250x / $1,000x) of the remittance is deemed to be made out of the passive category FPHCI of the FDE tested unit.

(C) Under paragraph (d)(3)(v)(C)(*1*)(*i*) of this section, $300x of the $400x item of foreign gross income from the remittance, and therefore an equal amount of foreign taxable income, is assigned to the income group that includes general category tested income attributable to the CFC1 tested unit, and $100x of this foreign gross income item, and therefore an equal amount of foreign taxable income, is assigned to the income group that includes passive category FPHCI attributable to the CFC1 tested unit. Under paragraph (f) of this section, the $20x of Country B withholding tax is ratably apportioned between the income groups based on the relative amounts of foreign taxable income in each grouping. Accordingly, $15x ($20x × $300x / $400x) of the Country B withholding tax is apportioned to the income group that includes general category tested income attributable to the CFC1 tested unit, and $5x ($20x × $100x / $400x) of the Country B withholding tax is apportioned to the income group that includes passive category FPHCI attributable to the CFC1 tested unit. See § 1.960–2 for rules on determining the amount of such taxes that may be deemed paid under section 960(a) and (d).

(13) *Example 12: Disregarded payment that is a reattribution payment*—(i) *Facts.* (A) USP owns all of the outstanding stock of CFC1, a tested unit within the meaning of § 1.954–1(d)(2) (the ''CFC1 tested unit''). CFC1 owns all of the interests in FDE1, a disregarded entity organized in Country B. CFC1's interests in FDE1 are also a tested unit within the meaning of § 1.954–1(d)(2) (the ''FDE1 tested unit''). Country B imposes a 20 percent net income tax on its residents. CFC1 also owns all of the interests in FDE2, a disregarded entity organized in Country C. CFC1's interests in FDE2 are also a tested unit within the meaning of § 1.954–1(d)(2) (the ''FDE2 tested unit''). Country C imposes a 15 percent net income tax on its residents. Each of the taxes imposed by Countries B and C is a foreign income tax within the meaning of § 1.901–2(a) and a separate levy within the meaning of § 1.901–2(d). For purposes of this paragraph (g)(13) (*Example 12*), the operative section is the high-tax exception of § 1.954–1(d), and the statutory groupings are the general gross item groupings of each tested unit, as defined in § 1.954–1(d)(1)(ii)(A).

(B) FDE2 owns Asset A, which is intangible property that has a tax book value of $10,000x and is properly reflected on the separate set of books and records of FDE2. In Year 1, pursuant to a license agreement between FDE1 and FDE2 for the use of Asset A, FDE1 makes a disregarded royalty payment to FDE2 of $1,000x that would be a deductible royalty payment if regarded for Federal income tax purposes. Because it is disregarded for Federal income tax purposes, the $1,000x disregarded royalty payment by FDE1 to FDE2 results in no income to CFC1 for Federal income tax purposes. Also in Year 1, pursuant to a sub-license agreement between FDE1 and a third party for the use of Asset A, FDE1 earns $1,000x of royalty income for Federal income tax purposes (the ''U.S. gross royalty'') that is gross tested income (as defined in § 1.951A–2(c)(1)) and properly reflected on the separate set of books and records of FDE1.

(C) Under the laws of Country B, the transaction that gives rise to the $1,000x item of U.S. gross royalty income causes FDE1 to include a $1,200x item of gross royalty income in its Country B taxable income (the ''Country B gross royalty''). In addition, FDE1 deducts its $1,000x disregarded royalty payment to FDE2 for Country B tax purposes. For Country B tax purposes, FDE1 therefore has $200x ($1,200x − $1,000x) of taxable income on which Country B imposes $40x (20% × $200x) of net income tax.

(D) Under the laws of Country C, the $1,000x disregarded royalty payment from FDE1 to FDE2 causes FDE2 to include a $1,000x item of gross royalty income in its Country C taxable income (the ''Country C gross royalty''). FDE2 makes no deductible payments under the laws of Country C. For Country C tax purposes, FDE2 therefore has $1,000x of taxable income on which Country C imposes $150x (15% × $1,000x) of net income tax.

(ii) *Analysis*—(A) *Country B net income tax.* (*1*) The Country B net income tax is imposed on foreign taxable income of FDE1 that consists of a $1,200x item of Country B gross royalty income and a $1,000x item of royalty expense. For Federal income tax purposes, the FDE1 tested unit has a $1,000x item of U.S. gross royalty income that is initially attributable to it under paragraph (d)(3)(v)(B)(*2*) of this section and § 1.954–1(d)(1)(iii). The transaction that produced the $1,000x item of U.S. gross royalty income also produced the $1,200x item of Country B gross royalty income. Under paragraph (b)(2) of this section, the $1,000x item of U.S. gross royalty income is therefore the corresponding U.S. item for the $1,200x item of Country B gross royalty income of FDE1.

(*2*) The $1,000x disregarded royalty payment from FDE1 to FDE2 is allocated under paragraph (d)(3)(v)(B)(*2*) of this section and § 1.954–1(d)(1)(iii) to the $1,000x of U.S. gross income of the FDE1 tested unit to the extent of that gross income. As a result, the $1,000x disregarded royalty payment causes the $1,000x item of U.S. gross royalty income to be reattributed from the FDE1 tested unit to the FDE2 tested unit, and results in a $1,000x reattribution amount that is also a reattribution payment.

(*3*) The $1,200x Country B gross royalty item that is included in the Country B taxable income of FDE1 is assigned under paragraph (d)(1) of this section to the statutory or residual grouping to which the $1,000x corresponding U.S. item is initially assigned under § 1.954–1(d)(1)(iii), namely, the general gross item grouping of the FDE1 tested unit. This assignment is made without regard to the $1,000x reattribution payment from the FDE1 tested unit to the FDE2 tested unit or to the fact that the FDE1 tested unit has no attribution item arising from its $1,000x item of U.S. gross royalty income, which is all reattributed to the FDE2 tested unit; none of the FDE1 tested unit's $1,200x Country B gross royalty income is reattributed to the FDE2 tested unit for this purpose. See paragraph (d)(3)(v)(B)(*3*) of this section. Under paragraph (f) of this section, all of the $40x of Country B net income tax is allocated to the general gross item group of the FDE1 tested unit, the statutory grouping to which the $1,200x item of Country B gross royalty income of FDE1 is assigned. No apportionment of the $40x is necessary because the class of gross income to which the foreign gross

income is allocated consists entirely of a single statutory grouping.

(B) *Country C net income tax.* The Country C net income tax is imposed on foreign taxable income of FDE2 that consists of a $1,000x item of Country C gross royalty income. For Federal income tax purposes, under paragraph (d)(3)(v)(B)(*2*) of this section and § 1.954–1(d)(1)(iii), the FDE2 tested unit has a reattribution amount of $1,000x of U.S. gross royalty income by reason of its receipt of the $1,000x reattribution payment from FDE1. The $1,000x item of U.S. gross royalty income that is included in the taxable income of the FDE2 tested unit by reason of the $1,000x reattribution payment is assigned under paragraph (d)(3)(v)(B)(*1*) of this section to the statutory or residual grouping to which the $1,000x reattribution amount of U.S. gross royalty income that constitutes the reattribution payment is assigned upon receipt by the FDE2 tested unit under § 1.954–1(d)(1)(iii), namely, the general gross item group of the FDE2 tested unit. Under paragraph (d)(3)(v)(B)(*1*) of this section, the $1,000x item of Country C gross royalty income is assigned to the statutory grouping to which the $1,000x corresponding U.S. item is assigned. Accordingly, under paragraph (f) of this section, all of the $150x of Country C net income tax is allocated to the general gross item group of the FDE2 tested unit, the statutory grouping to which the $1,000x item of Country C gross royalty income of FDE2 is assigned. No apportionment of the $150x is necessary because the class of gross income to which the foreign gross income is allocated consists entirely of a single statutory grouping.

(h) *Allocation and apportionment of certain foreign in lieu of taxes described in section 903.* A tax that is a foreign income tax by reason of § 1.903–1(c)(1) is allocated and apportioned to statutory and residual groupings in the same proportions as the foreign taxable income that comprises the excluded income (as defined in § 1.903–1(c)(1)). See paragraph (f) of this section for rules on allocating and apportioning certain withholding taxes described in § 1.903–1(c)(2).

(i) *Applicability date.* Except as provided in this paragraph (i), this section applies to taxable years beginning after December 31, 2019. Paragraphs (b)(19) and (23) and (d)(3)(i), (ii), and (v) of this section apply to taxable years that begin after December 31, 2019, and end on or after November 2, 2020. Paragraph (h) of this section applies to taxable years beginning after [date final regulations are filed with the **Federal Register**].

■ **Par. 22.** Section 1.901–1 is amended:

■ 1. By revising the section heading and paragraphs (a) through (d).

■ 2. In paragraph (e), by removing the language ''a husband and wife'' and adding the language ''spouses'' in its place.

■ 3. By revising paragraphs (f) and (h)(1).

■ 4. By removing paragraph (h)(2).

■ 5. By redesignating paragraph (h)(3) as paragraph (h)(2).

■ 6. By revising the heading and second sentence in paragraph (j).

The revisions and additions read as follows:

§ 1.901–1 Allowance of credit for foreign income taxes.

(a) *In general.* Citizens of the United States, domestic corporations, certain aliens resident in the United States or Puerto Rico, and certain estates and trusts may choose to claim a credit, as provided in section 901, against the tax imposed by chapter 1 of the Internal Revenue Code (Code) for certain taxes paid or accrued to foreign countries and possessions of the United States, subject to the conditions prescribed in this section.

(1) *Citizen of the United States.* An individual who is a citizen of the United States, whether resident or nonresident, may claim a credit for—

(i) The amount of any foreign income taxes, as defined in § 1.901–2(a), paid or accrued (as the case may be, depending on the individual's method of accounting for such taxes) during the taxable year;

(ii) The individual's share of any such taxes of a partnership of which the individual is a member, or of an estate or trust of which the individual is a beneficiary; and

(iii) In the case of an individual who has made an election under section 962, the taxes deemed to have been paid under section 960 (see § 1.962–1(b)(2)).

(2) *Domestic corporation.* A domestic corporation may claim a credit for—

(i) The amount of any foreign income taxes, as defined in § 1.901–2(a), paid or accrued (as the case may be, depending on the corporation's method of accounting for such taxes) during the taxable year;

(ii) The corporation's share of any such taxes of a partnership of which the corporation is a member, or of an estate or trust of which the corporation is a beneficiary; and

(iii) The taxes deemed to have been paid under section 960.

(3) *Alien resident of the United States or Puerto Rico.* Except as provided in a Presidential proclamation described in section 901(c), an individual who is a resident alien of the United States (as defined in section 7701(b)), or an individual who is a bona fide resident of Puerto Rico (as defined in section 937(a)) during the entire taxable year, may claim a credit for—

(i) The amount of any foreign income taxes, as defined in § 1.901–2(a), paid or accrued (as the case may be, depending on the individual's method of accounting for such taxes) during the taxable year;

(ii) The individual's share of any such taxes of a partnership of which the individual is a member, or of an estate or trust of which the individual is a beneficiary; and

(iii) In the case of an individual who has made an election under section 962, the taxes deemed to have been paid under section 960 (see § 1.962–1(b)(2)).

(4) *Estates and trusts.* An estate or trust may claim a credit for:

(i) The amount of any foreign income taxes, as defined in § 1.901–2(a), paid or accrued (as the case may be, depending on the estate or trust's method of accounting for such taxes) during the taxable year to the extent not allocable to and taken into account by its beneficiaries under paragraph (a)(1)(ii), (a)(2)(ii), or (a)(3)(ii) of this section (see section 642(a)); and

(ii) In the case of an estate or trust that has made an election under section 962, the taxes deemed to have been paid under section 960 (see § 1.962–1(b)(2)).

(b) *Limitations.* Certain Code sections, including sections 245A(d) and (e)(3), 814, 901(e) through (m), 904, 906, 907, 908, 909, 911, 965(g), 999, and 6038, reduce, defer, or otherwise limit the credit against the tax imposed by chapter 1 of the Code for certain amounts of foreign income taxes.

(c) *Deduction denied if credit claimed*—(1) *In general.* Except as provided in paragraphs (c)(2) and (3) of this section, if a taxpayer chooses with respect to any taxable year to claim a foreign tax credit to any extent, such choice will be considered to apply to all of the foreign income taxes paid or accrued (as the case may be, depending on the taxpayer's method of accounting for such taxes) in such taxable year, and no portion of any such taxes is allowed as a deduction from gross income in any taxable year. See section 275(a)(4).

(2) *Exception for taxes not subject to section 275.* Foreign income taxes for which a credit is disallowed and to which section 275 does not apply may be allowed as a deduction under section 164(a)(3). See, for example, sections 901(f), 901(j)(3), 901(k)(7), 901(l)(4), 901(m)(6), and 908(b). For rules on the year in which a deduction for foreign income taxes is allowed under section

164(a)(3), see §§ 1.446–1(c)(1)(ii), 1.461–2(a)(2), and 1.461–4(g)(6)(iii)(B).

(3) *Exception for additional taxes paid by an accrual basis taxpayer that relate to a prior year for which the taxpayer deducted foreign income taxes.* In a taxable year in which a taxpayer chooses to claim a credit for foreign income taxes accrued in that year (including a cash method taxpayer who has made an election under section 905(a) to claim credits in the year the taxes accrue), additional foreign income taxes that are finally determined and paid as a result of a foreign tax redetermination in that taxable year may be claimed as a deduction in such taxable year, if the additional foreign income taxes relate to a prior taxable year in which the taxpayer chose to claim a deduction, rather than a credit, for foreign income taxes paid or accrued (as the case may be, depending on the taxpayer's overall method of accounting) in that prior year.

(4) *Example.* The following example illustrates the application of paragraph (c)(3) of this section.

(i) *Facts.* USC is a domestic corporation that is engaged in a trade or business in Country X through a branch. USC uses an accrual method of accounting and uses the calendar year as its taxable year for U.S. and Country X tax purposes. For taxable years 1 through 3, USC chooses to deduct foreign income taxes, including Country X income taxes, for Federal income tax purposes in the U.S. taxable year in which the taxes accrue. In years 4 through 6, USC chooses to claim a credit under section 901 for foreign income taxes that accrued in those years. In year 6, USC pays an additional $50x in tax to Country X with respect to year 1 as a result of a Country X tax audit.

(ii) *Analysis.* The additional $50x of Country X tax for year 1 that is paid by USC in year 6 cannot be claimed as a deduction on an amended return for year 1, because those taxes did not accrue until year 6. See section 461(f) (flush language); §§ 1.461–1(a)(2)(i) and 1.461–2(a)(2). In addition, because the additional $50x of Country X tax liability relates to and is considered to accrue in year 1 for foreign tax credit purposes, USC cannot claim a credit for the $50x on its Federal income tax return for year 6. See § 1.905–1(d)(1). However, pursuant to paragraph (c)(3) of this section, USC can claim a deduction for the additional $50x of year 1 Country X tax on its Federal income tax return for year 6, in addition to claiming a credit for foreign income taxes that accrued in year 6.

(d) *Period during which election can be made or changed*—(1) *In general.* The taxpayer may, for a particular taxable year, elect to claim the benefits of section 901 (or claim a deduction in lieu of electing a foreign tax credit) at any time before the expiration of the period within which a claim for credit or refund of Federal income tax for such taxable year that is attributable to such credit or deduction, as the case may be, may be made or, if longer, the period prescribed by section 6511(c) if the refund period for that taxable year is extended by an agreement to extend the assessment period under section 6501(c)(4). Thus, an election to claim a credit for foreign income taxes paid or accrued (as the case may be, depending on the taxpayer's method of accounting for such taxes) in a particular taxable year can be made within the period prescribed by section 6511(d)(3)(A) for claiming a credit or refund of Federal income tax for that taxable year that is attributable to a credit for the foreign income taxes paid or accrued in that particular taxable year or, if longer, the period prescribed by section 6511(c) with respect to that particular taxable year. A choice to claim a deduction under section 164(a)(3), rather than a credit, for foreign income taxes paid or accrued in a particular taxable year can be made within the period prescribed by section 6511(a) or 6511(c), as applicable, for claiming a credit or refund of Federal income tax for that particular taxable year.

(2) *Manner in which election is made or changed.* A taxpayer claims a deduction or elects to claim a credit for foreign income taxes paid or accrued in a particular taxable year by filing an original or amended return for that taxable year within the relevant period specified in paragraph (d)(1) of this section. A claim for credit shall be accompanied by Form 1116 in the case of an individual, estate or trust, and by Form 1118 in the case of a corporation (and an individual, estate or trust making an election under section 962). See §§ 1.905–3 and 1.905–4 for rules requiring the filing of amended returns for all affected years when a timely change in the taxpayer's election results in U.S. tax deficiencies.

* * * * *

(f) *Taxes against which credit not allowed.* The credit for foreign income taxes is allowed only against the tax imposed by chapter 1 of the Code, except that it is not allowed against tax that, under section 26(b)(2), is treated as a tax not imposed under such chapter.

* * * * *

(h) * * *

(1) Except as provided in paragraphs (c)(2) and (3) of this section, a taxpayer who deducts foreign income taxes paid or accrued (as the case may be, depending on the taxpayer's method of accounting for such taxes) for that taxable year (see sections 164 and 275); and

* * * * *

(j) *Applicability date.* * * * This section applies to foreign taxes paid or accrued in taxable years beginning on or after [date final regulations are filed with the **Federal Register**].

■ **Par. 23.** Section 1.901–2 is amended:

■ 1. By revising paragraphs (a) heading and (a)(1).

■ 2. By removing the undesignated paragraph following paragraph (a)(1).

■ 3. By revising paragraphs (a)(3), (b) heading, (b)(1), (b)(2) heading, and (b)(2)(i).

■ 4. By removing the undesignated paragraph following paragraph (b)(2)(i) and paragraph (b)(2)(ii).

■ 5. By redesignating paragraphs (b)(2)(iii) and (iv) as paragraphs (b)(2)(ii) and (iii), respectively.

■ 6. By revising paragraphs (b)(3), (b)(4) heading, and (b)(4)(i).

■ 7. By removing the undesignated paragraph following paragraph (b)(4)(i).

■ 8. By revising paragraph (b)(4)(iv).

■ 9. By adding paragraph (b)(5).

■ 10. By revising paragraphs (c) and (d)(1).

■ 11. By removing the last sentence of paragraph (d)(2).

■ 12. By revising paragraphs (e) heading, (e)(1), and (e)(2)(i).

■ 13. By redesignating paragraph (e)(2)(ii) as paragraph (e)(2)(iv).

■ 14. By adding a new paragraph (e)(2)(ii) and paragraph (e)(2)(iii).

■ 15. By removing the undesignated sentence after paragraph (e)(3)(iii)(C) and paragraph (e)(3)(v).

■ 16. By revising paragraphs (e)(4) and (e)(5)(i).

■ 17. By redesignating paragraph (e)(5)(ii) as paragraph (e)(5)(iii).

■ 18. By adding a new paragraph (e)(5)(ii) and paragraph (e)(6).

■ 19. In paragraph (f)(3)(ii)(A), by removing the language ''§ 1.909–2T(b)(2)(vi)'' and adding the language ''§ 1.909–2(b)(2)(vi)'' in its place.

■ 20. In paragraph (f)(3)(iii)(B)(*2*), by removing the language ''§ 1.909–2T(b)(3)(i)'' and adding the language ''§ 1.909–2(b)(3)(i)'' in its place.

■ 21. By revising paragraph (f)(4).

■ 22. By redesignating paragraphs (f)(5) and (6) as paragraphs (f)(6) and (7), respectively.

■ 23. By adding a new paragraph (f)(5).

■ 24. By revising newly redesignated paragraph (f)(6).

■ 25. In newly redesignated paragraph (f)(7) introductory text, by removing the

language ''paragraphs (f)(3) and (f)(4)'' and adding the language ''paragraphs (f)(3) through (6)'' in its place.

■ 26. In newly redesignated paragraph (f)(7), by removing *Example 3.*

■ 27. By revising paragraphs (g) and (h).

The revisions and additions read as follows:

§ 1.901–2 Income, war profits, or excess profits tax paid or accrued.

(a) *Definition of foreign income tax*—(1) *Overview and scope.* Paragraphs (a), (b), and (c) of this section define a foreign income tax for purposes of section 901. Paragraph (d) of this section contains rules describing what constitutes a separate levy. Paragraph (e) of this section provides rules for determining the amount of foreign income tax paid by a person. Paragraph (f) of this section contains rules for determining by whom foreign income tax is paid. Paragraph (g) of this section defines the terms used in this section. Paragraph (h) of this section provides the applicability date for this section.

(i) *In general.* Section 901 allows a credit for the amount of income, war profits, and excess profits taxes paid during the taxable year to any foreign country, and section 903 provides that for purposes of Part III of subchapter N of the Code and sections 164(a) and 275(a), such taxes include a tax paid in lieu of a tax on income, war profits or excess profits that is otherwise generally imposed by a foreign country (collectively, for purposes of this section, a ''foreign income tax''). Whether a foreign levy is a foreign income tax is determined independently for each separate levy. A foreign tax either is or is not a foreign income tax, in its entirety, for all persons subject to the foreign tax.

(ii) *Requirements.* A foreign levy is a foreign income tax only if—

(A) It is a foreign tax; and

(B) Either:

(*1*) The foreign tax is a net income tax, as defined in paragraph (a)(3) of this section; or

(*2*) The foreign tax is a tax in lieu of an income tax, as defined in § 1.903–1(b).

* * * * *

(3) *Net income tax.* A foreign tax is a net income tax only if the foreign tax meets the net gain and jurisdictional nexus requirements in paragraphs (b) and (c) of this section.

(b) *Net gain requirement*—(1) *In general.* A foreign tax satisfies the net gain requirement only if the tax satisfies the realization, gross receipts, and cost recovery requirements in paragraphs (b)(2), (3), and (4) of this section, respectively, or if the foreign tax is a surtax described in paragraph (b)(5) of this section. Paragraphs (b)(2) through (5) of this section are applied with respect to a foreign tax solely on the basis of the foreign tax law governing the calculation of the foreign taxable base, unless otherwise provided, and without any consideration of the rate of tax imposed on the foreign taxable base.

(2) *Realization requirement*—(i) *In general.* A foreign tax satisfies the realization requirement if it is imposed upon one or more of the events described in paragraphs (b)(2)(i)(A) through (C) of this section. If a foreign tax meets the realization requirements in paragraphs (b)(2)(i)(A) through (C) of this section except with respect to one or more specific and defined classes of nonrealization events (such as, for example, imputed rental income from a personal residence used by the owner), and as judged based on the application of the foreign tax to all taxpayers subject to the foreign tax, the incidence and amounts of gross receipts attributable to such nonrealization events is insignificant relative to the incidence and amounts of gross receipts attributable to events covered by the foreign tax that do meet the realization requirement, then the foreign tax is treated as meeting the realization requirement in paragraph (b)(2) of this section (despite the fact that the foreign tax is also imposed on the basis of some nonrealization events, and that some persons subject to the foreign tax may only be taxed on nonrealization events).

(A) *Realization events.* The foreign tax is imposed upon or after the occurrence of events (''realization events'') that result in the realization of income under the income tax provisions of the Internal Revenue Code.

(B) *Pre-realization recapture events.* The foreign tax is imposed upon the occurrence of an event before a realization event (a ''pre-realization event'') that results in the recapture (in whole or part) of a tax deduction, tax credit, or other tax allowance previously accorded to the taxpayer (for example, the recapture of an incentive tax credit if required investments are not completed within a specified period).

(C) *Pre-realization timing difference events.* The foreign tax is imposed upon the occurrence of a pre-realization event, other than one described in paragraph (b)(2)(i)(B) of this section, but only if the foreign country does not, upon the occurrence of a later event, impose tax under the same or a separate levy (a ''second tax'') on the same taxpayer (for purposes of this paragraph (b)(2)(i)(C), treating a disregarded entity as defined in § 301.7701–3(b)(2)(i)(C) of this chapter as a taxpayer separate from its owner), with respect to the income on which tax is imposed by reason of such pre-realization event (or, if it does impose a second tax, a credit or other comparable relief is available against the liability for such a second tax for tax paid on the occurrence of the pre-realization event) and—

(*1*) The imposition of the tax upon such pre-realization event is based on the difference in the fair market value of property at the beginning and end of a period;

(*2*) The pre-realization event is the physical transfer, processing, or export of readily marketable property (as defined in paragraph (b)(2)(ii) of this section) and the imposition of the tax upon the pre-realization event is based on the fair market value of such property; or

(*3*) The pre-realization event relates to a deemed distribution (for example, by a corporation to a shareholder) or inclusion (for example, under a controlled foreign corporation inclusion regime) of amounts (such as earnings and profits) that meet the realization requirement in paragraph (b)(2) of this section in the hands of the person that, under foreign tax law, is deemed to distribute such amounts.

* * * * *

(3) *Gross receipts requirement*—(i) *Rule.* A foreign tax satisfies the gross receipts requirement if it is imposed on the basis of actual gross receipts, on the basis of the amount of deemed gross receipts arising from pre-realization timing difference events described in paragraph (b)(2)(i)(C) of this section, or on the basis of gross receipts from an insignificant non-realization event that is described in the second sentence of paragraph (b)(2) of this section. A taxpayer's actual gross receipts are determined taking into account the gross receipts that are properly allocated to such taxpayer under a foreign tax meeting the jurisdictional nexus requirements of paragraph (c)(1)(i) or (c)(2) of this section.

(ii) *Examples.* The following examples illustrate the rules of paragraph (b)(3)(i) of this section.

(A) *Example 1: Cost-plus tax*—(*1*) *Facts.* Country X imposes a ''cost-plus tax'' on country X corporations that serve as regional headquarters for affiliated nonresident corporations, and this tax is a separate levy (within the meaning of paragraph (d) of this section). A headquarters company for purposes of this tax is a corporation that performs administrative, management or coordination functions solely for nonresident affiliated entities. Due to the difficulty of determining on a case-

by-case basis the arm's length gross receipts that headquarters companies would charge affiliates for such services, gross receipts of a headquarters company are deemed, for purposes of this tax, to equal 110 percent of the business expenses incurred by the headquarters company.

(*2*) *Analysis.* Because the cost-plus tax is based on costs and not on gross receipts, under paragraph (b)(3)(i) of this section the cost-plus tax does not satisfy the gross receipts requirement.

(B) *Example 2: Petroleum taxed on extraction*—(*1*) *Facts.* Country X imposes a tax that is a separate levy (within the meaning of paragraph (d) of this section) on income from the extraction of petroleum. Under the terms of that tax, gross receipts from extraction income are deemed to equal 105 percent of the fair market value of petroleum extracted.

(*2*) *Analysis.* Because it is imposed on deemed gross receipts that exceed the fair market value of the petroleum extracted, the tax on extraction income does not satisfy the gross receipts requirement of paragraph (b)(3)(i) of this section.

(4) *Cost recovery requirement*—(i) *In general*—(A) *Requirement.* A foreign tax satisfies the cost recovery requirement if the base of the tax is computed by reducing gross receipts (as described in paragraph (b)(3) of this section) to permit recovery of the significant costs and expenses (including significant capital expenditures) attributable, under reasonable principles, to such gross receipts. In addition, a foreign tax satisfies the cost recovery requirement if the foreign tax law permits recovery of an amount that by its terms may be greater, but can never be less, than the actual amounts of such significant costs and expenses (for example, under a provision identical to percentage depletion allowed under section 613). A foreign tax whose base is gross receipts or gross income for which no reduction is allowed under foreign tax law for costs and expenses does not satisfy the cost recovery requirement, even if in practice there are few costs and expenses attributable to all or particular types of gross receipts included in the foreign tax base. See paragraph (b)(4)(iv) of this section (*Example 3*).

(B) *Significant costs and expenses*—(*1*) *Timing of recovery.* A foreign tax law permits recovery of significant costs and expenses even if such costs and expenses are recovered earlier or later than they are recovered under the Internal Revenue Code, unless the time of recovery is so much later (for example, after the property becomes worthless or is disposed of) as effectively to constitute a denial of such recovery. The amount of costs and expenses that are considered to be recovered under the foreign tax law is neither discounted nor augmented by taking into account the time value of money attributable to any acceleration or deferral of a tax benefit resulting from the foreign law cost recovery method compared to when tax would be paid under the Internal Revenue Code. Therefore, the cost recovery requirement is satisfied where items deductible under the Internal Revenue Code are capitalized under the foreign tax law and recovered either immediately, on a recurring basis over time, or upon the occurrence of some future event, or where the recovery of items capitalized under the Internal Revenue Code occurs more or less rapidly than under the foreign tax law.

(*2*) *Amounts that must be recovered.* Whether a cost or expense is significant for purposes of this paragraph (b)(4)(i) is determined based on whether, for all taxpayers in the aggregate to which the foreign tax applies, the item of cost or expense constitutes a significant portion of the taxpayers' total costs and expenses. However, costs and expenses related to capital expenditures, interest, rents, royalties, services, or research and experimentation are always treated as significant costs or expenses for purposes of this paragraph (b)(4)(i). Foreign tax law is considered to permit recovery of significant costs and expenses even if recovery of all or a portion of certain costs or expenses is disallowed, if such disallowance is consistent with the types of disallowances required under the Internal Revenue Code. For example, foreign tax law is considered to permit recovery of significant costs and expenses if such law disallows interest deductions equal to a certain percentage of adjusted taxable income similar to the limitation under section 163(j), disallows interest and royalty deductions in connection with hybrid transactions similar to those described in section 267A, or disallows certain expenses based on public policy considerations similar to those disallowances contained in section 162. A foreign tax law that does not permit recovery of one or more significant costs or expenses does not meet the cost recovery requirement, even if it provides alternative allowances that in practice equal or exceed the amount of nonrecovered costs or expenses. However, in determining whether a foreign tax (the ''tested foreign tax'') meets the cost recovery requirement, it is immaterial whether the tested foreign tax allows a deduction for other taxes that would qualify as foreign income taxes (determined without regard to whether such other tax allows a deduction for the tested foreign tax). See paragraph (b)(4)(iv) of this section (*Example 5*).

(*3*) *Attribution of costs and expenses to gross receipts.* Principles used in the foreign tax law to attribute costs and expenses to gross receipts may be reasonable even if they differ from principles that apply under the Internal Revenue Code (for example, principles that apply under section 265, 465 or 861(b) of the Internal Revenue Code).

* * * * *

(iv) *Examples.* The following examples illustrate the rules of this paragraph (b)(4).

(A) *Example 1: Tax on gross interest income of certain residents; no deductions allowed*—(*1*) *Facts.* Country X imposes a net income tax on corporations resident in Country X; however, that income tax is not applicable to banks. Country X also imposes a tax (the ''bank tax'') of 1 percent on the gross amount of interest income derived by banks resident in Country X; no deductions are allowed. Banks resident in Country X incur substantial costs and expenses (for example, interest expense) attributable to their interest income.

(*2*) *Analysis.* Because the terms of the bank tax do not permit recovery of significant costs and expenses attributable to the gross receipts included in the tax base, under paragraph (b)(4)(i) of this section the bank tax does not satisfy the cost recovery requirement.

(B) *Example 2: Tax on gross interest income of nonresidents; no deductions allowed*—(*1*) *Facts.* Country X imposes a net income tax on nonresident persons engaged in a trade or business in Country X. Country X also imposes a tax (the ''bank tax'') of 1 percent on the gross amount of interest income earned by nonresident banks from loans to residents of Country X if such banks are not engaged in a trade or business in Country X or if such interest income is not considered attributable to a trade or business conducted in Country X. Under Country X tax law, no deductions are allowed in determining the base of the bank tax. Banks incur substantial costs and expenses (for example, interest expense) attributable to their interest income.

(*2*) *Analysis.* Because no deductions are allowed in determining the base of the bank tax, under paragraph (b)(4)(i) of this section the bank tax does not satisfy the cost recovery requirement.

(C) *Example 3: Payroll tax*—(*1*) *Facts.* A foreign country imposes payroll tax at the rate of 10 percent on the amount of gross wages realized by resident employees; no deductions are allowed in computing the base of the payroll tax.

(*2*) *Analysis.* Because the foreign tax law does not allow for the recovery of any costs and expenses attributable to gross receipts included in the taxable base, under paragraph (b)(4)(i) of this section the payroll tax does not satisfy the cost recovery requirement.

(D) *Example 4: Tax on gross wages reduced by allowable deductions*–(*1*) *Facts.* A foreign country imposes a tax at the rate of 40 percent on the realized gross receipts of its residents, including gross income from wages, reduced by deductions for significant costs and expenses attributable to the gross receipts included in the taxable base.

(*2*) *Analysis.* Because foreign tax law allows for the recovery of significant costs and expenses attributable to gross receipts included in the taxable base, under paragraph (b)(4)(i) of this section the tax satisfies the cost recovery requirement.

(E) *Example 5: No deduction for another net income tax*—(*1*) *Facts.* Each of Country X and Province Y (a political subdivision of Country X) imposes a tax on resident corporations, called the ''Country X income tax'' and the ''Province Y income tax,'' respectively. Each tax has an identical base, which is computed by reducing a corporation's realized gross receipts by deductions that, based on the laws of Country X and Province Y, generally permit recovery of the significant costs and expenses (including significant capital expenditures) that are attributable under reasonable principles to such gross receipts. However, the Country X income tax does not allow a deduction for the Province Y income tax for which a taxpayer is liable, nor does the Province Y income tax allow a deduction for the Country X income tax for which a taxpayer is liable.

(*2*) *Analysis.* Under paragraph (d)(1)(i) of this section, each of the Country X income tax and the Province Y income tax is a separate levy. Without regard to whether the Province Y income tax may allow a deduction for the Country X income tax, and without regard to whether the Country X income tax may allow a deduction for the Province Y income tax, both taxes would qualify as net income taxes under paragraph (a)(3) of this section. Therefore, under paragraph (b)(4)(i)(B)(*2*) of this section the fact that neither levy's base allows a deduction for the other levy is immaterial, and both levies satisfy the cost recovery requirement.

(5) *Surtax on net income tax.* A foreign tax satisfies the net gain requirement in this paragraph (b) if the base of the foreign tax is the amount of a net income tax. For example, if a tax (surtax) is computed as a percentage of a separate levy that is itself a net income tax, then such surtax is considered to satisfy the net gain requirement.

(c) *Jurisdictional nexus requirement.* A foreign tax meets the jurisdictional nexus requirement only if the tax satisfies the requirements of paragraph (c)(1) of this section (with respect to a separate levy imposed on nonresidents of the foreign country) or paragraph (c)(2) of this section (with respect to a separate levy imposed on residents of the foreign country).

(1) *Tax on nonresidents.* Each of the items of income of nonresidents of a foreign country that is subject to the foreign tax must satisfy the requirements of paragraph (c)(1)(i), (ii), or (iii) of this section.

(i) *Income attribution based on activities nexus.* The income that is taxable in the foreign country is limited to income that is attributable, under reasonable principles, to the nonresident's activities within the foreign country (including the nonresident's functions, assets, and risks located in the foreign country), without taking into account as a significant factor the location of customers, users, or any other similar destination-based criterion. For purposes of the preceding sentence, attribution of income under reasonable principles includes rules similar to those for determining effectively connected income under section 864(c).

(ii) *Nexus based on source of income.* The amount of income (other than income from sales or other dispositions of property) that is taxable in the foreign country on the basis of source (instead of on the basis of activities as described in paragraph (c)(1)(i) of this section) is based on income arising from sources within the foreign country that imposes the tax, but only if the sourcing rules of the foreign tax law are reasonably similar to the sourcing rules that apply for Federal income tax purposes. In particular, a foreign tax on income from services must be sourced based on where the services are performed, and not based on the location of the service recipient.

(iii) *Nexus based on situs of property.* The amount of income from sales or dispositions of property that is taxable in the foreign country on the basis of the situs of real or movable property (instead of on the basis of activities as described in paragraph (c)(1)(i) of this section) includes only gains that are attributable to the disposition of real property situated in the foreign country or movable property forming part of the business property of a taxable presence in the foreign country (including, for purposes of this paragraph (c)(1)(iii), interests in a company or other entity to the extent attributable to such real property or business property).

(2) *Tax on residents.* A foreign tax imposed on residents of the foreign country imposing the foreign tax may be imposed on the worldwide income of the resident, but must provide that any allocation to or from the resident of income, gain, deduction, or loss with respect to transactions between such resident and organizations, trades, or businesses owned or controlled directly or indirectly by the same interests (that is, any allocation made pursuant to the foreign country's transfer pricing rules) is determined under arm's length principles, without taking into account as a significant factor the location of customers, users, or any other similar destination-based criterion.

(3) *Example.* The following example illustrates the rules of this paragraph (c).

(i) *Facts.* Country X imposes a separate levy on nonresident companies that furnish specified types of electronically supplied services to users located in Country X (the ''ESS tax''). The base of the ESS tax is computed by taking the nonresident company's overall net income (determined under rules consistent with paragraph (b) of this section) related to supplying electronically supplied services, and deeming a portion of such net income to be attributable to a deemed permanent establishment of the nonresident company in Country X. The amount of the nonresident company's net income attributable to the deemed permanent establishment is determined on a formulary basis based on the percentage of the nonresident company's total users that are located in Country X.

(ii) *Analysis.* The taxable base of the ESS tax is not computed based on a nonresident company's activities located in Country X, but instead takes into account the location of the nonresident company's users. Therefore, the ESS tax does not meet the requirement in paragraph (c)(1)(i) of this section. The ESS tax also does not meet the requirement in paragraph (c)(1)(ii) of this section because it is not imposed on the basis of source, and it does not meet the requirement in paragraph (c)(1)(iii) of this section because it is not imposed on the sale or other disposition of property.

(iii) *Alternative facts.* Instead of imposing the ESS tax by deeming

nonresident companies to have a permanent establishment in Country X, Country X treats gross income from electronically supplied services provided to users located in Country X as sourced in Country X. The gross income sourced to Country X is reduced by costs that are reasonably attributed to such gross income, to arrive at the taxable base of the ESS tax. The amount of the nonresident's gross income that is sourced to Country X is determined by multiplying the nonresident's total gross income by the percentage of its total users that are located in Country X.

(iv) *Analysis.* Country X tax law's rule for sourcing electronically supplied services is not based on where the services are performed, but is based on the location of the service recipient. Therefore, the ESS tax, which is imposed on the basis of source, does not meet the requirement in paragraph (c)(1)(ii) of this section. The ESS tax also does not meet the requirement in paragraph (c)(1)(i) of this section because it is not imposed on the basis of a nonresident's activities located in Country X, and it does not meet the requirement in paragraph (c)(1)(iii) of this section because it is not imposed on the sale or other disposition of property.

(d) * * *

(1) *In general.* Each foreign levy must be analyzed separately to determine whether it is a net income tax within the meaning of paragraph (a)(3) of this section and whether it is a tax in lieu of an income tax within the meaning of § 1.903–1(b)(2). Whether a single levy or separate levies are imposed by a foreign country depends on U.S. principles and not on whether foreign tax law imposes the levy or levies pursuant to a single or separate statutes. A foreign levy is a separate levy described in this paragraph (d)(1) if it is described in paragraph (d)(1)(i), (ii), or (iii) of this section. In the case of levies that apply to dual capacity taxpayers, see also § 1.901–2A(a).

(i) *Taxing authority.* A levy imposed by one taxing authority (for example, the national government of a foreign country) is always separate from a levy imposed by another taxing authority (for example, a political subdivision of that foreign country), even if the base of the levy is the same.

(ii) *Different taxable base.* Where the base of a foreign levy is computed differently for different classes of persons subject to the levy, the levy is considered to impose separate levies with respect to each such class of persons. For example, foreign levies identical to the taxes imposed by sections 1, 11, 541, 871(a), 871(b), 881, 882, 3101 and 3111 of the Internal Revenue Code are each separate levies, because the levies are imposed on different classes of taxpayers, and the base of each of those levies contains different items than the base of each of the others. A taxable base of a separate levy may consist of a particular type of income (for example, wage income, investment income, or income from self-employment). The taxable base of a separate levy may also consist of an amount unrelated to income (for example, wage expense or assets). A separate levy may provide that items included in the base of the tax are computed separately merely for purposes of a preliminary computation and are then combined as a single taxable base. Income included in the taxable base of a separate levy may also be included in the taxable base of another levy (which may or may not also include other items of income); separate levies are considered to be imposed if the taxable bases are not combined as a single taxable base. For example, a foreign levy identical to the tax imposed by section 1 is a separate levy from a foreign levy identical to the tax imposed by section 1411, because tax is imposed under each levy on a separate taxable base that is not combined with the other as a single taxable base. Where foreign tax law imposes a levy that is the sum of two or more separately computed amounts of tax, and each such amount is computed by reference to a different base, separate levies are considered to be imposed. Levies are not separate merely because different rates apply to different classes of taxpayers that are subject to the same provisions in computing the base of the tax. For example, a foreign levy identical to the tax imposed on U.S. citizens and resident alien individuals by section 1 of the Internal Revenue Code is a single levy notwithstanding that the levy has graduated rates and applies different rate schedules to unmarried individuals, married individuals who file separate returns, and married individuals who file joint returns. In addition, in general, levies are not separate merely because some provisions determining the base of the levy apply, by their terms or in practice, to some, but not all, persons subject to the levy. For example, a foreign levy identical to the tax imposed by section 11 of the Internal Revenue Code is a single levy even though some provisions apply by their terms to some but not all corporations subject to the section 11 tax (for example, section 465 is by its terms applicable to corporations described in sections 465(a)(1)(B), but not to other corporations), and even though some provisions apply in practice to some but not all corporations subject to the section 11 tax (for example, section 611 does not, in practice, apply to any corporation that does not have a qualifying interest in the type of property described in section 611(a)).

(iii) *Tax imposed on nonresidents.* A foreign levy imposed on nonresidents is always treated as a separate levy from that imposed on residents, even if the base of the tax as applied to residents and nonresidents is the same, and even if the levies are treated as a single levy under foreign tax law. In addition, a withholding tax (as defined in section 901(k)(1)(B)) that is imposed on gross income of nonresidents is treated as a separate levy as to each separate class of income described in section 61 (for example, interest, dividends, rents, or royalties) subject to the withholding tax.

* * * * *

(e) *Amount of foreign income tax that is creditable*—(1) *In general.* Credit is allowed under section 901 for the amount of foreign income tax that is paid by the taxpayer. The amount of foreign income tax paid by the taxpayer is determined separately for each taxpayer.

(2) * * *

(i) *Refundable amounts.* An amount remitted to a foreign country is not an amount of foreign income tax paid to the extent that it is reasonably certain that the amount will be refunded, rebated, abated, or forgiven. It is reasonably certain that an amount will be refunded, rebated, abated, or forgiven to the extent the amount exceeds a reasonable approximation of final foreign income tax liability to the foreign country. See section 905(c) and § 1.905–3 for the required redeterminations if amounts claimed as a credit (on either the cash or accrual basis) exceed the amount of the final foreign income tax liability.

(ii) *Credits.* Except as provided in paragraph (e)(2)(iii) of this section, an amount of foreign income tax liability is not an amount of foreign income tax paid to the extent the foreign income tax is reduced, satisfied or otherwise offset by a tax credit, regardless of whether the amount of the tax credit is refundable in cash to the extent it exceeds the taxpayer's liability for foreign income tax.

(iii) *Overpayments of tax applied as a credit.* An amount of foreign income tax paid is not reduced (or treated as constructively refunded) solely by reason of the fact that the amount paid is allowed (or may be allowed) as a credit to reduce the amount of a

different separate levy owed by the taxpayer. See paragraphs (e)(2)(ii) and (e)(4) of this section. However, under paragraph (e)(2)(i) of this section (and taking into account any redetermination required under section 905(c) and § 1.905–3), an amount remitted with respect to a separate levy for a foreign taxable period that constitutes an overpayment of the taxpayer's final liability for that levy for that period, and that is refundable in cash at the taxpayer's option, is not an amount of tax paid. Therefore, if such an overpayment of one tax is applied as a credit against a different foreign income tax liability owed by the taxpayer for the same or a different taxable period, the credited amount may qualify as an amount of that different foreign income tax paid, if it does not exceed a reasonable approximation of the taxpayer's final foreign income tax liability for the taxable period to which the overpayment is applied.

* * * * *

(4) *Multiple levies*—(i) *In general.* If, under foreign law, a taxpayer's tentative liability for one levy (the ''reduced levy'') is or can be reduced by the amount of the taxpayer's liability for a different levy (the ''applied levy''), then the amount considered paid by the taxpayer to the foreign country pursuant to the applied levy is an amount equal to its entire liability for that applied levy (not limited to the amount applied to reduce the reduced levy), and the remainder of the total amount paid is considered paid pursuant to the reduced levy. See also paragraphs (e)(2)(ii) and (iii) of this section.

(ii) *Examples.* The following examples illustrate the rules of paragraphs (e)(2)(ii) and (iii) and (e)(4)(i) of this section.

(A) *Example 1: Tax reduced by credits*—(*1*) *Facts.* A's tentative liability for foreign income tax imposed by Country X is 100u (units of Country X currency). However, under Country X tax law, in determining A's final foreign income tax liability its tentative liability is reduced by a 15u credit for a separate Country X levy that does not qualify as a foreign income tax and that A accrued and paid on its gross services income, and is also reduced by a 5u credit for charitable contributions. Under Country X tax law, the amount of the charitable contributions credit is refundable in cash to the extent the credit exceeds the taxpayer's Country X income tax liability after applying the credit for the tax on gross services income. A timely remits the 80u due to Country X.

(*2*) *Analysis.* Under paragraphs (e)(2)(ii) and (e)(4) of this section, the amount of Country X income tax paid by A is 80u (100u tentative liability − 20u tax credits), and the amount of Country X tax on gross services income paid by A is 15u.

(B) *Example 2: Tax paid by credit for overpayment*—(*1*) *Facts.* The facts are the same as in paragraph (e)(4)(ii)(A)(*1*) of this section (the facts in *Example 1*), except that A's final Country X income tax liability of 80u is satisfied by applying a credit for an otherwise refundable 60u overpayment from the previous taxable year of A's liability for a separate levy imposed by Country X that is also a foreign income tax and remitting the balance due of 20u.

(*2*) *Analysis.* The result is the same as in paragraph (e)(4)(ii)(A)(*2*) of this section (the analysis in *Example 1).* Under paragraph (e)(2)(iii) of this section, the portion of A's Country X income tax liability that was satisfied by applying the 60u overpayment of A's different foreign income tax liability for the previous taxable year qualifies as an amount of Country X income tax paid, because that refundable overpayment exceeded (and so is not treated as a payment of) A's different foreign income tax liability for the previous taxable year.

(5) * * *

(i) *In general.* An amount remitted to a foreign country (a ''foreign payment'') is not a compulsory payment, and thus is not an amount of foreign income tax paid, to the extent that the foreign payment exceeds the amount of liability for foreign income tax under the foreign tax law (as defined in paragraph (g) of this section). A foreign payment does not exceed the amount of such liability if the foreign payment is determined by the taxpayer in a manner that is consistent with a reasonable interpretation and application of the substantive and procedural provisions of foreign tax law (including applicable tax treaties) in such a way as to reduce, over time, the taxpayer's reasonably expected liability under foreign law for foreign income tax, and if the taxpayer exhausts all effective and practical remedies, including invocation of competent authority procedures available under applicable tax treaties, to reduce, over time, the taxpayer's liability for foreign income tax (including liability pursuant to a foreign tax audit adjustment). See paragraph (e)(5)(ii) of this section for the effect of options and elections under foreign tax law. An interpretation or application of foreign law is not reasonable if there is actual notice or constructive notice (for example, a published court decision) to the taxpayer that the interpretation or application is likely to be erroneous. In interpreting foreign tax law, a taxpayer may generally rely on advice obtained in good faith from competent foreign tax advisors to whom the taxpayer has disclosed the relevant facts. Whether a taxpayer has satisfied its obligation to minimize the aggregate amount of its liability for foreign income taxes over time is determined without regard to the present value of a deferred tax liability or other time value of money considerations. In determining whether a taxpayer has exhausted all effective and practical remedies, a remedy is effective and practical only if the cost of pursuing it (including the risk of incurring an offsetting or additional tax liability) is reasonable in light of the amount at issue and the likelihood of success. An available remedy is considered effective and practical if an economically rational taxpayer would pursue it whether or not a compulsory payment of the amount at issue would be eligible for a U.S. foreign tax credit. A settlement by a taxpayer of two or more issues will be evaluated on an overall basis, not on an issue-by-issue basis, in determining whether an amount is a compulsory payment. A taxpayer is not required to alter its form of doing business, its business conduct, or the form of any business transaction in order to reduce its liability under foreign law for foreign income tax.

(ii) *Effect of foreign tax law elections*—(A) *In general.* Where foreign tax law includes options or elections whereby a taxpayer's foreign income tax liability may be shifted, in whole or part, to a different year or years, the taxpayer's use or failure to use such options or elections does not result in a foreign payment in excess of the taxpayer's liability for foreign income tax. Except as provided in paragraph (e)(5)(ii)(B) of this section, where foreign tax law provides for options or elections whereby a taxpayer's foreign income tax liability may be permanently decreased in the aggregate over time, the taxpayer's failure to use such options or elections results in a foreign payment in excess of the taxpayer's liability for foreign income tax.

(B) *Exception for certain options or elections*—(*1*) *Entity classification elections.* If foreign tax law provides an option or election to treat an entity as fiscally transparent or non-fiscally transparent, a taxpayer's decision to use or not use such option or election is not considered to increase the taxpayer's liability for foreign income tax over time for purposes of this paragraph (e)(5).

(*2*) *Foreign consolidation, group relief, or other loss sharing regime.* If foreign tax law provides an option or election for one foreign entity to join in the filing

of a consolidated return with another foreign entity, or to surrender its loss in order to offset the income of another foreign entity pursuant to a foreign group relief or other loss-sharing regime, a taxpayer's decision whether to file a consolidated return, whether to surrender a loss, or whether to use a surrendered loss, is not considered to increase the taxpayer's liability for foreign income tax over time for purposes of this paragraph (e)(5).

* * * * *

(6) *Soak-up taxes*—(i) *In general.* An amount remitted to a foreign country is not an amount of foreign income tax paid to the extent that liability for the foreign income tax is dependent (by its terms or otherwise) on the availability of a credit for the tax against income tax liability to another country. Liability for foreign income tax is dependent on the availability of a credit for the foreign income tax against income tax liability to another country only if and to the extent that the foreign income tax would not be imposed on the taxpayer but for the availability of such a credit.

(ii) [Reserved]

(f) * * *

(4) *Taxes imposed on partnerships and disregarded entities*—(i) *Partnerships.* If foreign law imposes tax at the entity level on the income of a partnership, the partnership is considered to be legally liable for such tax under foreign law and therefore is considered to pay the tax for Federal income tax purposes. The rules of this paragraph (f)(4)(i) apply regardless of which person is obligated to remit the tax, which person actually remits the tax, or which person the foreign country could proceed against to collect the tax in the event all or a portion of the tax is not paid. See §§ 1.702–1(a)(6) and 1.704–1(b)(4)(viii) for rules relating to the determination of a partner's distributive share of such tax.

(ii) *Disregarded entities.* If foreign law imposes tax at the entity level on the income of an entity described in § 301.7701–2(c)(2)(i) of this chapter (a *disregarded entity*), the person (as defined in section 7701(a)(1)) who is treated as owning the assets of the disregarded entity for Federal income tax purposes is considered to be legally liable for such tax under foreign law. Such person is considered to pay the tax for Federal income tax purposes. The rules of this paragraph (f)(4)(ii) apply regardless of which person is obligated to remit the tax, which person actually remits the tax, or which person the foreign country could proceed against to collect the tax in the event all or a portion of the tax is not paid.

(5) *Allocation of taxes in the case of certain ownership changes*—(i) *In general.* If a partnership, disregarded entity, or corporation undergoes one or more covered events during its foreign taxable year that do not result in a closing of the foreign taxable year, then a portion of the foreign income tax (other than a withholding tax described in section 901(k)(1)(B)) paid or accrued by a person under paragraphs (f)(1) through (4) of this section with respect to the continuing foreign taxable year in which such change or changes occur is allocated to and among all persons that were predecessor entities or prior owners during such foreign taxable year. The allocation is made based on the respective portions of the taxable income (as determined under foreign law) for the continuing foreign taxable year that are attributable under the principles of § 1.1502–76(b) to the period of existence or ownership of each predecessor entity or prior owner during the continuing foreign taxable year. Foreign income tax allocated to a person that is a predecessor entity is treated (other than for purposes of section 986) as paid or accrued by the person as of the close of the last day of its last U.S. taxable year. Foreign income tax allocated to a person that is a prior owner, for example a transferor of a disregarded entity, is treated (other than for purposes of section 986) as paid or accrued by the person as of the close of the last day of its U.S. taxable year in which the covered event occurred.

(ii) *Covered event.* For purposes of this paragraph (f)(5), a covered event is a partnership termination under section 708(b)(1), a transfer of a disregarded entity, or a change in the entity classification of a disregarded entity or a corporation.

(iii) *Predecessor entity and prior owner.* For purposes of this paragraph (f)(5), a predecessor entity is a partnership or a corporation that undergoes a covered event as described in paragraph (f)(5)(ii) of this section. A prior owner is a person that either transfers a disregarded entity or owns a disregarded entity immediately before a change in the entity classification of the disregarded entity as described in paragraph (f)(5)(ii) of this section.

(iv) *Partnership variances.* In the case of a change in any partner's interest in the partnership (a variance), except as otherwise provided in section 706(d)(2) (relating to certain cash basis items) or 706(d)(3) (relating to tiered partnerships), foreign tax paid or accrued by the partnership during its U.S. taxable year in which the variance occurs is allocated between the portion of the U.S. taxable year ending on, and the portion of the U.S. taxable year beginning on the day after, the day of the variance. The allocation is made under the principles of this paragraph (f)(5) as if the variance were a covered event.

(6) *Allocation of foreign taxes in connection with elections under section 336(e) or 338 or § 1.245A–5(e).* For rules relating to the allocation of foreign taxes in connection with elections made pursuant to section 336(e), see § 1.336–2(g)(3)(ii). For rules relating to the allocation of foreign taxes in connection with elections made pursuant to section 338, see § 1.338–9(d). For rules relating to the allocation of foreign taxes in connection with elections made pursuant to § 1.245A–5(e)(3)(i), see § 1.245A–5(e)(3)(i)(B).

* * * * *

(g) *Definitions.* For purposes of this section and §§ 1.901–2A and 1.903–1, the following definitions apply.

(1) *Foreign country and possession (territory) of the United States.* The term *foreign country* means any foreign state, any possession (territory) of the United States, and any political subdivision of any foreign state or of any possession (territory) of the United States. The term *possession* (or *territory*) *of the United States* includes American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.

(2) *Foreign levy.* The term *foreign levy* means a levy imposed by a foreign country.

(3) *Foreign tax.* The term *foreign tax* means a foreign levy that is a tax as defined in paragraph (a)(2) of this section.

(4) *Foreign tax law.* The term *foreign tax law* means the laws of the foreign country imposing a foreign tax, as modified by applicable tax treaties. The foreign tax law is construed on the basis of the foreign country's statutes, regulations, case law, and administrative rulings or other official pronouncements, as modified by applicable income tax treaties.

(5) *Paid, payment, and paid by.* The term *paid* means ''paid'' or ''accrued''; the term *payment* means ''payment'' or ''accrual''; and the term *paid by* means ''paid by'' or ''accrued by or on behalf of,'' depending on whether the taxpayer claims the foreign tax credit for taxes paid (that is, remitted) or taxes accrued (as determined under § 1.905–1(d)) during the taxable year.

(6) *Resident and nonresident.* The terms *resident* and *nonresident,* when used in the context of the foreign tax law of a foreign country, have the meaning provided in paragraphs (g)(6)(i) and (ii) of this section.

(i) *Resident.* An individual is a resident of a foreign country if the individual is liable to income tax in such country by reason of the individual's residence, domicile, citizenship, or similar criterion under such country's foreign tax law. An entity (including a corporation, partnership, trust, estate, or an entity that is disregarded as an entity separate from its owner for Federal income tax purposes) is a resident of a foreign country if the entity is liable to tax on its income (regardless of whether tax is actually imposed) under the laws of the foreign country by reason of the entity's place of incorporation or place of management in that country (or in a political subdivision or local authority thereof), or by reason of a criterion of similar nature, or if the entity is of a type that is specifically identified as a resident in an income tax treaty with the United States to which the foreign country is a party. If an individual or entity is a resident of more than one country, a single country of residence will be determined based upon applicable rules for resolving dual residency under the foreign tax law of the foreign country or countries; if no resolution is reached, the individual or entity is treated as a resident of each country.

(ii) *Nonresident.* A nonresident with respect to a foreign country is any individual or entity that is not a resident of such foreign country.

(h) *Applicability date.* This section applies to foreign taxes paid or accrued in taxable years beginning on or after [date final regulations are filed with the **Federal Register**].

* * * * *

■ **Par. 24.** Section 1.903–1 is revised to read as follows:

§ 1.903–1 Taxes in lieu of income taxes.

(a) *Overview.* Section 903 provides that the term ''income, war profits, and excess profits taxes'' includes a tax paid in lieu of a tax on income, war profits, or excess profits that is otherwise generally imposed by any foreign country. Paragraphs (b) and (c) of this section define a tax described in section 903. Paragraph (d) of this section provides examples illustrating the application of this section. Paragraph (e) of this section sets forth the applicability date of this section. For purposes of this section and §§ 1.901–2 and 1.901–2A, a tax described in section 903 is referred to as a ''tax in lieu of an income tax'' or an ''in lieu of tax''; and the definitions in § 1.901–2(g) apply for purposes of this section. Determinations of the amount of a tax in lieu of an income tax that is paid by a person and determinations of the person by whom such tax is paid are made under § 1.901–2(e) and (f), respectively. Section 1.901–2A contains additional rules applicable to dual capacity taxpayers (as defined in § 1.901–2(a)(2)(ii)(A)).

(b) *Definition of tax in lieu of an income tax*—(1) *In general.* Paragraphs (b)(2) and (c) of this section provide the requirements for a foreign levy to qualify as a tax in lieu of an income tax. The rules of this section are applied independently to each separate levy (within the meaning of §§ 1.901–2(d) and 1.901–2A(a)). A foreign tax either is or is not a tax in lieu of an income tax in its entirety for all persons subject to the tax. It is immaterial whether the base of the in lieu of tax bears any relation to realized net gain. The base of the foreign tax may, for example, be gross income, gross receipts or sales, or the number of units produced or exported. The foreign country's reason for imposing a foreign tax on a base other than net income (for example, because of administrative difficulty in determining the amount of income that would otherwise be subject to a net income tax) is immaterial, although paragraph (c)(1) of this section generally requires a showing that the foreign country made a deliberate and cognizant choice to impose the in lieu of tax instead of a net income tax (see paragraph (c)(1)(iii) of this section).

(2) *Requirements.* A foreign levy is a tax in lieu of an income tax only if—

(i) It is a foreign tax; and

(ii) It satisfies the substitution requirement of paragraph (c) of this section.

(c) *Substitution requirement*—(1) *In general.* A foreign tax (the ''tested foreign tax'') satisfies the substitution requirement if, based on the foreign tax law, the requirements in paragraphs (c)(1)(i) through (iv) of this section are satisfied with respect to the tested foreign tax, or the tested foreign tax is a covered withholding tax described in paragraph (c)(2) of this section.

(i) *Existence of generally-imposed net income tax.* A separate levy that is a net income tax (as described in § 1.901–2(a)(3)) is generally imposed by the same foreign country (the ''generally-imposed net income tax'') that imposes the tested foreign tax.

(ii) *Non-duplication.* Neither the generally-imposed net income tax nor any other separate levy that is a net income tax is also imposed, in addition to the tested foreign tax, by the same foreign country on any persons with respect to any portion of the income to which the amounts (such as sales or units of production) that form the base of the tested foreign tax relate (the ''excluded income''). Therefore, a tested foreign tax does not meet the requirement of this paragraph (c)(1)(ii) if a net income tax imposed by the same foreign country applies to the excluded income of any persons that are subject to the tested foreign tax, even if not all of the persons subject to the tested foreign tax are subject to the net income tax.

(iii) *Close connection to excluded income.* But for the existence of the tested foreign tax, the generally-imposed net income tax would otherwise have been imposed on the excluded income. The requirement in the preceding sentence is met only if the imposition of such tested foreign tax bears a close connection to the failure to impose the generally-imposed net income tax on the excluded income; the relationship cannot be merely incidental, tangential, or minor. A close connection exists if the generally-imposed net income tax would apply by its terms to the income, but for the fact that the excluded income is expressly excluded. Otherwise, a close connection must be established with proof that the foreign country made a cognizant and deliberate choice to impose the tested foreign tax instead of the generally-imposed net income tax. Such proof must be based on foreign tax law, or the legislative history of either the tested foreign tax or the generally-imposed net income tax that describes the provisions excluding taxpayers subject to the tested foreign tax from the generally-imposed net income tax. If one tested foreign tax meets the requirements in this paragraph (c)(1), and another tested foreign tax that applies to the same class of taxpayers and relates to the same excluded income as the first tested foreign tax is enacted later in time (and not contemporaneously with the first tested foreign tax), there is a rebuttable presumption that such second tested foreign tax does not meet the close connection requirement in this paragraph (c)(1)(iii). Not all income derived by persons subject to the tested foreign tax need be excluded income, as long as the tested foreign tax applies only to amounts that relate to the excluded income.

(iv) *Jurisdiction to tax excluded income.* If the generally-imposed net income tax were applied to the excluded income, the generally-imposed net income tax would either continue to qualify as a net income tax described in § 1.901–2(a)(3), or would constitute a separate levy from the generally-imposed net income tax that would itself be a net income tax described in § 1.901–2(a)(3).

(2) *Covered withholding tax.* A tested foreign tax is a covered withholding tax if, based on the foreign tax law, the requirements in paragraphs (c)(1)(i) and (c)(2)(i) through (iii) of this section are met with respect to the tested foreign tax. See also § 1.901–2(d)(1)(iii) for rules treating withholding taxes as separate levies with respect to each class of income subject to the tax.

(i) *Withholding tax on nonresidents.* The tested foreign tax is a withholding tax (as defined in section 901(k)(1)(B)) that is imposed on gross income of persons who are nonresidents of the foreign country imposing the tested foreign tax. It is immaterial whether the tested foreign tax is withheld by the payor or is imposed directly on the nonresident taxpayer.

(ii) *Non-duplication.* The tested foreign tax is not in addition to any net income tax that is imposed by the foreign country on any portion of the net income attributable to the gross income that is subject to the tested foreign tax. Therefore, a tested foreign tax does not meet the requirement of this paragraph (c)(2)(ii) if by its terms it applies to gross income of nonresidents that are also subject to a net income tax imposed by the same foreign country on the same income, even if not all nonresidents subject to the tested foreign tax are also subject to the net income tax.

(iii) *Source-based jurisdictional nexus.* The income subject to the tested foreign tax satisfies the source requirement described in § 1.901–2(c)(1)(ii).

(d) *Examples.* The following examples illustrate the rules of this section.

(1) *Example 1: Tax on gross income from services; non-duplication requirement*—(i) *Facts.* Country X imposes a tax at the rate of 3 percent on the gross receipts of companies, wherever resident, from furnishing specified types of electronically supplied services to customers located in Country X (the ''ESS tax''). No deductions are allowed in determining the taxable base of the ESS tax. In addition to the ESS tax, Country X imposes a net income tax within the meaning of § 1.901–2(a)(3) on resident companies (the ''net income tax'') and also imposes a net income tax within the meaning of § 1.901–2(a)(3) on the income of nonresident companies that is attributable, under reasonable principles, to the nonresident's activities within Country X (the ''permanent establishment tax''). Both the net income tax and the permanent establishment tax, which are each separate levies under § 1.901–2(d)(1)(iii), qualify as generally-imposed net income taxes. The ESS tax applies to both resident and nonresident companies regardless of whether the company is also subject to the net income tax or permanent establishment tax, respectively.

(ii) *Analysis.* Under § 1.901–2(d)(1)(iii), the ESS tax comprises two separate levies, one imposed on resident companies (the ''resident ESS tax''), and one imposed on nonresident companies (the ''nonresident ESS tax''). Under paragraph (c)(1)(ii) of this section, neither the resident ESS tax nor the nonresident ESS tax satisfies the substitution requirement, because by its terms the income subject to the ESS tax is also subject to a generally-imposed net income tax imposed by Country X. Similarly, under paragraph (c)(2)(ii) of this section, the nonresident ESS tax is not a covered withholding tax because it is imposed in addition to the permanent establishment tax. It is immaterial that some nonresident taxpayers that are subject to the nonresident ESS tax are not also subject to the permanent establishment tax on the gross receipts included in the base of the nonresident ESS tax. Therefore, neither the resident ESS tax nor the nonresident ESS tax is a tax in lieu of an income tax.

(2) *Example 2: Tax on gross income from services; jurisdictional nexus*—(i) *Facts.* The facts are the same as in paragraph (d)(1)(i) of this section (the facts in *Example 1*), except that under Country X tax law, the nonresident ESS tax is imposed only if the nonresident company does not have a permanent establishment in Country X under domestic law or an applicable income tax treaty. In addition, the text of and legislative history to the nonresident ESS tax demonstrate that Country X made a cognizant and deliberate choice to impose the nonresident ESS tax instead of the permanent establishment tax with respect to the gross receipts that are subject to the nonresident ESS tax.

(ii) *Analysis*—(A) *General application of substitution requirement.* The nonresident ESS tax meets the requirements in paragraphs (c)(1)(i) and (ii) of this section because Country X has a generally-imposed net income tax, the permanent establishment tax, and neither the permanent establishment tax nor any other separate levy is imposed by Country X on a nonresident's gross income that forms the base of the nonresident ESS tax (which is the excluded income) in addition to the nonresident ESS tax. The text of and legislative history to the nonresident ESS tax demonstrate that Country X made a cognizant and deliberate choice to exclude the excluded income from the base of the generally-imposed permanent establishment tax. Therefore, the nonresident ESS tax meets the requirement in paragraph (c)(1)(iii) of this section because but for the existence of the tested foreign tax, the generally-imposed permanent establishment tax would otherwise have been imposed on the excluded income. However, if Country X had modified the permanent establishment tax to also apply to the excluded income, the modified permanent establishment tax would not qualify as a net income tax described in § 1.901–2(a)(3), because it would fail the jurisdictional nexus requirement in § 1.901–2(c)(1). First, the modified tax would not satisfy § 1.901–2(c)(1)(i) because the modified tax would not apply to income attributable under reasonable principles to the nonresident's activities within the foreign country, since the modified tax is determined by taking into account the location of customers. Second, the modified tax would not satisfy § 1.901–2(c)(1)(ii) because the excluded income is from services performed outside of Country X. Third, the modified tax would not satisfy the property nexus in § 1.901–2(c)(1)(iii) because the excluded income is not from sales of property located in Country X. Because if the Country X generally-imposed net income tax applied to excluded income it would not qualify as a net income tax described in § 1.901–2(a)(3), the nonresident ESS tax does not meet the requirement in paragraph (c)(1)(iv) of this section. Therefore, the nonresident ESS tax does not satisfy the substitution requirement in paragraph (c)(1) of this section.

(B) *Covered withholding tax analysis.* The nonresident ESS tax meets the requirement in paragraph (c)(1)(i) of this section, because there exists a generally-imposed net income tax (the permanent establishment tax), and it also meets the requirements in paragraphs (c)(2)(i) and (ii) of this section, because it is a withholding tax on gross income of nonresidents that is not also subject to the permanent establishment tax. However, the nonresident ESS tax does not meet the requirement in paragraph (c)(2)(iii) of this section because the services income subject to the nonresident ESS tax is from electronically supplied services performed outside of Country X. See § 1.901–2(c)(1)(ii). Therefore, the nonresident ESS tax is not a covered withholding tax under paragraph (c)(2) of this section. Because the nonresident ESS tax does not meet the substitution requirement of paragraph (c) of this

section, it is not a tax in lieu of an income tax.

(e) *Applicability date.* This section applies to foreign taxes paid or accrued in taxable years beginning on or after [date final regulations are filed with the **Federal Register**].

§ 1.904–2 [Amended]

■ **Par. 25.** Section 1.904–2(j)(1)(iii)(D) is amended by removing the language ''§ 1.904(f)–12(j)(5)'' and adding the language ''§ 1.904(f)–12(j)(6)'' in its place.

■ **Par. 26.** Section 1.904–4, as amended in FR Doc. 2020–21819, published elsewhere in this issue of the **Federal Register**, is further amended:

■ 1. By revising paragraph (b)(2)(i)(A).

■ 2. By revising the third sentence of paragraph (c)(4).

■ 3. By revising paragraphs (e)(1)(ii) and (e)(2) and (3).

■ 4. In paragraph (f)(1)(i) introductory text, by removing the language ''paragraph (f)(1)(ii) of this section'' and adding in its place the language ''paragraph (f)(1)(ii), (iii), or (iv) of this section''.

■ 5. By adding paragraphs (f)(1)(iii) and (iv).

■ 6. By removing and reserving paragraphs (f)(2)(ii) and (iii).

■ 7. By revising paragraphs (f)(2)(vi)(A) and (f)(2)(vi)(B)(*1*)(*ii*).

■ 8. By adding paragraph (f)(2)(vi)(G).

■ 9. By revising paragraph (f)(3)(v).

■ 10. By redesignating paragraphs (f)(3)(viii) and (ix) as paragraphs (f)(3)(ix) and (xii), respectively.

■ 11. By adding a new paragraph (f)(3)(viii).

■ 12. In newly redesignated paragraph (f)(3)(ix), by removing the language ''paragraph (f)(3)(viii)'' and adding the language ''paragraph (f)(3)(ix)'' in its place.

■ 13. By redesignating paragraph (f)(3)(x) as paragraph (f)(3)(xiii).

■ 14. By adding a new paragraph (f)(3)(x) and paragraph (f)(3)(xi).

■ 15. In paragraphs (f)(4)(i)(B)(*1*) and (*2*), by removing the language ''paragraph (f)(3)(viii)'' and adding the language ''paragraph (f)(3)(ix)'' in its place.

■ 16. In paragraphs (f)(4)(iv)(B)(*1*) and (f)(4)(v)(B)(*2*), by removing the language ''paragraph (f)(3)(x)'' and adding the language ''paragraph (f)(3)(xiii)'' in its place.

■ 17. By adding paragraphs (f)(4)(xiii) through (xvi) and (q)(3).

The additions and revisions read as follows:

§ 1.904–4 Separate application of section 904 with respect to certain categories of income.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(A) Income received or accrued by any person that is of a kind that would be foreign personal holding company income (as defined in section 954(c), taking into account any exceptions or exclusions to section 954(c), including, for example, section 954(c)(3), (c)(6), (h), or (i)) if the taxpayer were a controlled foreign corporation, including any amount of gain on the sale or exchange of stock in excess of the amount treated as a dividend under section 1248;

* * * * *

(c) * * *

(4) * * * The grouping rules of paragraphs (c)(3)(i) through (iv) of this section also apply separately to income attributable to each tested unit described in § 1.954–1(d)(2)(i) of a controlled foreign corporation, and to each foreign QBU of a noncontrolled 10-percent owned foreign corporation or any other look-through entity defined in § 1.904–5(i), or of any United States person.

* * * * *

(e) * * *

(1) * * *

(ii) *Definition of financial services income.* The term *financial services income* means income derived by a financial services entity, as defined in paragraph (e)(3) of this section, that is:

(A) Income derived in the active conduct of a banking, insurance, financing, or similar business (active financing income) as defined in paragraph (e)(2) of this section; or

(B) Passive income as defined in section 904(d)(2)(B) and paragraph (b) of this section as determined before the application of the exception for high-taxed income but after the application of the exception for export financing interest, but not including payments from a related person that is not a financial services entity (determined after the application of the financial services group rule of paragraph (e)(3)(ii) of this section) that are attributable to passive category income under the look-through rules of § 1.904–5.

(2) *Active financing income*—(i) *Income included.* For purposes of paragraph (e)(1) and (3) of this section, income is active financing income only if it is income from—

(A) Regularly making personal, mortgage, industrial, or other loans to customers in the ordinary course of the corporation's trade or business;

(B) Factoring evidences of indebtedness for customers;

(C) Purchasing, selling, discounting, or negotiating for customers notes, drafts, checks, bills of exchange, acceptances, or other evidences of indebtedness;

(D) Issuing letters of credit and negotiating drafts drawn thereunder for customers;

(E) Performing trust services, including as a fiduciary, agent, or custodian, for customers, provided such trust activities are not performed in connection with services provided by a dealer in stock, securities or similar financial instruments;

(F) Arranging foreign exchange transactions for, or engaging in foreign exchange transactions with, customers;

(G) Arranging interest rate, currency or commodities futures, forwards, options or notional principal contracts for, or entering into such transactions with, customers;

(H) Underwriting issues of stock, debt instruments or other securities under best efforts or firm commitment agreements for customers;

(I) Engaging in finance leasing (that is, is any lease that is a direct financing lease or a leveraged lease for accounting purposes and is also a lease for tax purposes) for customers;

(J) Providing charge and credit card services for customers or factoring receivables obtained in the course of providing such services;

(K) Providing traveler's check and money order services for customers;

(L) Providing correspondent bank services for customers;

(M) Providing paying agency and collection agency services for customers;

(N) Maintaining restricted reserves (including money or securities) in a segregated account in order to satisfy a capital or reserve requirement imposed by a local banking or securities regulatory authority;

(O) Engaging in hedging activities directly related to another activity described in this paragraph (e)(2)(i);

(P) Repackaging mortgages and other financial assets into securities and servicing activities with respect to such assets (including the accrual of interest incidental to such activity);

(Q) Engaging in financing activities typically provided in the ordinary course by an investment bank, such as project financing provided in connection with construction projects, structured finance (including the extension of a loan and the sale of participations or interests in the loan to other financial institutions or investors), and leasing activities to the extent incidental to such financing activities;

(R) Providing financial or investment advisory services, investment management services, fiduciary

services, or custodial services to customers;

(S) Purchasing or selling stock, debt instruments, interest rate or currency futures or other securities or derivative financial products (including notional principal contracts) from or to customers and holding stock, debt instruments and other securities as inventory for sale to customers, unless the relevant securities or derivative financial products are not held in a dealer capacity;

(T) Effecting transactions in securities for customers as a securities broker;

(U) Investing funds in circumstances in which the taxpayer holds itself out as providing a financial service by the acceptance or the investment of such funds, including income from investing deposits of money and income earned investing funds received for the purchase of traveler's checks or face amount certificates;

(V) Investments by an insurance company of its unearned premiums or reserves ordinary and necessary to the proper conduct of the insurance business (as defined in paragraph (e)(2)(ii) of this section);

(W) Activities generating income of a kind that would be insurance income as defined in section 953(a)(1) (including related person insurance income as defined in section 953(c)(2) and without regard to the exception in section 953(a)(2) for income that is exempt insurance income under section 953(e)), but with respect to investment income includible in section 953(a)(1) insurance income, only to the extent ordinary and necessary to the proper conduct of the insurance business (as defined in paragraph (e)(2)(ii) of this section); or

(X) Providing services as an insurance underwriter, insurance brokerage or agency services, or loss adjuster and surveyor services.

(ii) *Ordinary and necessary investment income of an insurance company.* For purposes of paragraphs (e)(2)(i)(V) and (W) of this section, income from investments by an insurance company is not ordinary and necessary to the proper conduct of the insurance business to the extent that the investment income component of paragraphs (e)(2)(i)(V) and (W) of this section exceeds the insurance company's investment income limitation. Any item of investment income falling under both paragraphs (e)(2)(i)(V) and (W) of this section is only counted once.

(A) *Insurance company investment income limitation.* An insurance company's investment income limitation for a taxable year is equal to the company's passive category income (as defined in section 904(d)(2)(B) and paragraph (b) of this section, but including income excluded from foreign personal holding company income under section 954(i)) multiplied by the proportion that the company's investment asset limitation (as determined under paragraph (e)(2)(ii)(B) of this section) bears to the value of the company's passive category assets (as determined under § 1.861–9(g)(2)) for such taxable year. For purposes of this paragraph (e)(2)(ii), the term *passive category asset* means an asset that is characterized as a passive category asset, under the rules of §§ 1.861–9 through 1.861–13.

(B) *Insurance company investment asset limitation.* For purposes of paragraph (e)(2)(ii)(A) of this section, the investment asset limitation equals the applicable percentage of the company's total insurance liabilities. The applicable percentage is—

(*1*) 200 percent of total insurance liabilities, for a domestic corporation taxable under part I of subchapter L of the Code or a foreign corporation that would be taxable under part I of subchapter L if it were a domestic corporation.

(*2*) 400 percent of total insurance liabilities, for a domestic corporation taxable under part II of subchapter L or a foreign corporation that would be taxable under part II of subchapter L if it were a domestic corporation.

(C) *Total insurance liabilities.* For purposes of paragraph (e)(2)(ii)(B) of this section—

(*1*) *Corporations taxable under part I of subchapter L.* In the case of a corporation taxable under part I of subchapter L (including a foreign corporation that is a section 953(d) company), the term total insurance liabilities means the sum of the total reserves (as defined in section 816(c)) plus (to the extent not included in total reserves) the items referred to in paragraphs (3), (4), (5), and (6) of section 807(c).

(*2*) *Corporations taxable under part II of subchapter L.* In the case of a corporation taxable under part II of subchapter L (including a foreign corporation that is a section 953(d) company), the term *total insurance liabilities* means the sum of unearned premiums (determined under § 1.832–4(a)(8)) and unpaid losses.

(*3*) *Controlled foreign insurance corporations.* In the case of a controlled foreign corporation that would be taxable under subchapter L if it were a domestic corporation, the term *total insurance liabilities* means the reserve determined in accordance with section 953(b)(3).

(D) *Example.* The following example illustrates the application of this paragraph (e)(2)(ii).

(*1*) *Facts.* X is a domestic nonlife insurance company taxable under part II of subchapter L. X has passive category assets valued under § 1.861–9(g)(2) at $1,000x, total insurance liabilities of $200x, and passive category income of $100x.

(*2*) *Analysis—Investment income limitation.* Pursuant to paragraph (e)(2)(ii)(B) of this section, the applicable percentage for nonlife insurance companies is 400 percent, and X has an investment asset limitation of $800x, which is equal to its total insurance liabilities of $200x multiplied by 400 percent. The proportion of its investment asset limitation ($800x) to its passive category assets ($1,000x) is 80 percent. Pursuant to paragraph (e)(2)(ii)(A) of this section, X has an investment income limitation equal to its passive category income ($100x) multiplied by 80 percent, or $80x. Under paragraph (e)(2)(ii) of this section, no more than $80x of X's $100x of income from investments qualifies as ordinary and necessary to the proper conduct of X's insurance business.

(3) *Financial services entities*—(i) *Definition of financial services entity*—(A) *In general.* The term *financial services entity* means an individual or corporation that is predominantly engaged in the active conduct of a banking, insurance, financing, or similar business (active financing business) for any taxable year. Except as provided in paragraph (e)(3)(ii) of this section, a determination of whether an individual or corporation is a financial services entity is done on an individual or entity-by-entity basis. An individual or corporation is predominantly engaged in the active financing business for any year if for that year more than 70 percent of its gross income is derived directly from active financing income under paragraph (e)(2) of this section with customers, or counterparties, that are not related to such individual or corporation under section 267(b) or 707 (except in the case of paragraph (e)(2)(i)(W) of this section which permits related party insurance).

(B) *Certain gross income included and excluded.* For purposes of applying the rules in paragraph (e)(3)(i)(A) of this section (including by reason of paragraph (e)(3)(ii) of this section), gross income includes interest on State and local bonds described in section 103(a), but does not include income from a distribution of previously taxed earnings and profits described in section 959(a) or (b). In addition, total gross income (for purposes of the

denominator of the 70-percent test) includes income received from related persons.

(C) *Treatment of partnerships and other pass-through entities.* For purposes of applying the rules in paragraph (e)(3)(i)(A) of this section (including by reason of paragraph (e)(3)(ii) of this section) with respect to an individual or corporation that is a direct or indirect partner in a partnership, the partner's distributive share of partnership income is characterized as if each partnership item of gross income were realized directly by the partner. For example, in applying section 954(h)(2)(B) under paragraph (e)(3)(i)(A) of this section, a customer with respect to a partnership is treated as a related person with respect to an individual or corporation that is a partner in the partnership if the customer is related to the individual or corporation under section 954(d)(3). The principles of this paragraph (e)(3)(i)(C) apply for an individual or corporation's share of income from any other pass-through entities.

(ii) *Financial services group.* A corporation that is a member of a financial services group is deemed to be a financial services entity regardless of whether it is a financial services entity under paragraph (e)(3)(i) of this section. For purposes of this paragraph (e)(3)(ii), a financial services group means an affiliated group as defined in section 1504(a) (but determined without regard to paragraphs (2) or (3) of section 1504(b)) if more than 70 percent of the affiliated group's gross income is active financing income under paragraph (e)(2) of this section. For purposes of determining whether an affiliated group is a financial services group under the previous sentence, only the income of group members that are domestic corporations, or foreign corporations that are controlled foreign corporations in which U.S. members of the affiliated group own, directly or indirectly, at least 80 percent of the total voting power and value of the stock, is included. In addition, indirect ownership is determined under section 318, and the income of the group does not include any income from transactions with other members of the group. Passive income will not be considered to be active financing income merely because that income is earned by a member of the group that is a financial services entity without regard to the rule of this paragraph (e)(3)(ii).

* * * * *

(f) * * *

(1) * * *

(iii) *Income arising from U.S. activities excluded from foreign branch category income.* Gross income that is attributable to a foreign branch and that arises from activities carried out in the United States by any foreign branch, including income that is reflected on a foreign branch's separate books and records, is not assigned to the foreign branch category. Instead, such income is assigned to the general category or a specified separate category under the rules of this section. However, under paragraph (f)(2)(vi) of this section, gross income (including U.S. source gross income) attributable to activities carried on outside the United States by the foreign branch may be assigned to the foreign branch category by reason of a disregarded payment to a foreign branch from a foreign branch owner or another foreign branch that is allocable to income recorded on the books and records of the payor foreign branch or foreign branch owner.

(iv) *Income arising from stock excluded from foreign branch category income*—(A) *In general.* Except as provided in paragraph (f)(1)(iv)(B) of this section, gross income that is attributable to a foreign branch and that comprises items of income arising from stock of a corporation (whether foreign or domestic), including gain from the disposition of such stock or any inclusion under section 951(a), 951A(a), 1248, or 1293(a), is not assigned to the foreign branch category. Instead, such income is assigned to the general category or a specified separate category under the rules of this section.

(B) *Exception for dealer property.* Paragraph (f)(1)(iv)(A) of this section does not apply to gain recognized from dispositions of stock in a corporation, if the stock would be dealer property (as defined in § 1.954–2(a)(4)(v)) if the foreign branch were a controlled foreign corporation.

* * * * *

(2) * * *

(vi) * * *

(A) *In general.* If a foreign branch makes a disregarded payment to its foreign branch owner or a second foreign branch, and the disregarded payment is allocable to gross income that would be attributable to the foreign branch under the rules in paragraphs (f)(2)(i) through (v) of this section, the gross income attributable to the foreign branch is adjusted downward (but not below zero) to reflect the allocable amount of the disregarded payment, and the gross income attributable to the foreign branch owner or the second foreign branch is adjusted upward by the same amount as the downward adjustment, translated (if necessary) from the foreign branch's functional currency to U.S. dollars (or the second foreign branch's functional currency, as applicable) at the spot rate (as defined in § 1.988–1(d)) on the date of the disregarded payment. For rules addressing multiple disregarded payments in a taxable year, see paragraph (f)(2)(vi)(F) of this section. Similarly, if a foreign branch owner makes a disregarded payment to its foreign branch and the disregarded payment is allocable to gross income attributable to the foreign branch owner, the gross income attributable to the foreign branch owner is adjusted downward (but not below zero) to reflect the allocable amount of the disregarded payment, and the gross income attributable to the foreign branch is adjusted upward by the same amount as the downward adjustment, translated (if necessary) from U.S. dollars to the foreign branch's functional currency at the spot rate on the date of the disregarded payment. An adjustment to the attribution of gross income under this paragraph (f)(2)(vi) does not change the total amount, character, or source of the United States person's gross income; does not change the amount of a United States person's income in any separate category other than the foreign branch and general categories (or a specified separate category associated with the foreign branch and general categories); and has no bearing on the analysis of whether an item of gross income is eligible to be resourced under an income tax treaty.

(B) * * *

(*1*) * * *

(*ii*) Disregarded payments from a foreign branch to its foreign branch owner or to another foreign branch are allocable to gross income attributable to the payor foreign branch to the extent a deduction for that payment or any disregarded cost recovery deduction relating to that payment, if regarded, would be allocated and apportioned to gross income attributable to the payor foreign branch under the principles of §§ 1.861–8 through 1.861–14T and 1.861–17 (without regard to exclusive apportionment) by treating foreign source gross income and U.S. source gross income in each separate category (determined before the application of this paragraph (f)(2)(vi) to the disregarded payment at issue) each as a statutory grouping.

* * * * *

(G) *Effect of disregarded payments made and received by non-branch taxable units*—(*1*) *In general.* For purposes of determining the amount,

source, and character of gross income attributable to a foreign branch and its foreign branch owner under paragraph (f)(2) of this section, the rules of paragraph (f)(2) of this section apply to a non-branch taxable unit as though the non-branch taxable unit were a foreign branch or a foreign branch owner, as appropriate, to attribute gross income to the non-branch taxable unit and to further attribute, under this paragraph (f)(2)(vi)(G), the income of a non-branch taxable unit to one or more foreign branches or to a foreign branch owner. See paragraph (f)(4)(xvi) of this section (*Example 16*).

(*2*) *Foreign branch group income.* The income of a foreign branch group is attributed to the foreign branch that owns the group. The income of a foreign branch group is the aggregate of the U.S. gross income that is attributed, under the rules of this paragraph (f)(2), to each member of the foreign branch group, determined after taking into account all disregarded payments made and received by each member.

(*3*) *Foreign branch owner group income.* The income of a foreign branch owner group is attributed to the foreign branch owner that owns the group. The income of a foreign branch owner group income is the aggregate of the U.S. gross income that is attributed, under the rules of this paragraph (f)(2), to each member of the foreign branch owner group, determined after taking into account all disregarded payments made and received by each member.

(3) * * *

(v) *Disregarded payment.* A disregarded payment includes an amount of property (within the meaning of section 317(a)) that is transferred to or from a non-branch taxable unit, foreign branch, or foreign branch owner, including a payment in exchange for property or in satisfaction of an account payable, or a remittance or contribution, in connection with a transaction that is disregarded for Federal income tax purposes and that is reflected on the separate set of books and records of a non-branch taxable unit (other than an individual or domestic corporation) or a foreign branch. A disregarded payment also includes any other amount that is reflected on the separate set of books and records of a non-branch taxable unit (other than an individual or a domestic corporation) or a foreign branch in connection with a transaction that is disregarded for Federal income tax purposes and that would constitute an item of accrued income, gain, deduction, or loss of the non-branch taxable unit (other than an individual or a domestic corporation) or the foreign branch if the transaction to which the amount is attributable were regarded for Federal income tax purposes.

* * * * *

(viii) *Foreign branch group.* The term *foreign branch group* means a foreign branch and one or more non-branch taxable units (other than an individual or a domestic corporation), to the extent that the foreign branch owns the non-branch taxable unit directly or indirectly through one or more other non-branch taxable units.

* * * * *

(x) *Foreign branch owner group.* The term *foreign branch owner group* means a foreign branch owner and one or more non-branch taxable units (other than an individual or a domestic corporation), to the extent that the foreign branch owner owns the non-branch taxable unit directly or indirectly through one or more other non-branch taxable units.

(xi) *Non-branch taxable unit.* The term *non-branch taxable unit* has the meaning provided in § 1.904–6(b)(2)(i)(B).

* * * * *

(4) * * *

(xiii) *Example 13: Disregarded payment from domestic corporation to foreign branch*—(A) *Facts.* P, a domestic corporation, owns FDE, a disregarded entity that is a foreign branch. FDE's functional currency is the U.S. dollar. In Year 1, P accrues and records on its books and records for Federal income tax purposes $400x of gross income from the license of intellectual property to unrelated parties that is not passive category income, all of which is U.S. source income. P also accrues $600x of foreign source passive category interest income. P compensates FDE for services that FDE performs in a foreign country with an arm's length payment of $350x, which FDE records on its books and records; the transaction is disregarded for Federal income tax purposes. Absent the application of paragraph (f)(2)(vi) of this section, the $400x of gross income earned by P from the license would be general category income that would not be attributable to FDE. If the payment were regarded for Federal income tax purposes, the deduction for the payment of $350x from P to FDE would be allocated and apportioned entirely to P's $400x of general category gross licensing income under the principles of §§ 1.861–8 and 1.861–8T (treating U.S. source general category gross income and foreign source passive category gross income each as a statutory grouping). There are no other expenses incurred by P or FDE.

(B) *Analysis.* The disregarded payment from P, a United States person, to FDE, its foreign branch, is not recorded on FDE's separate books and records (as adjusted to conform to Federal income tax principles) under paragraph (f)(2)(i) of this section because it is disregarded for Federal income tax purposes. The disregarded payment is allocable to gross income attributable to P because a deduction for the payment, if it were regarded, would be allocated and apportioned to the $400x of P's U.S. source licensing income. Accordingly, under paragraphs (f)(2)(vi)(A) and (f)(2)(vi)(B)(*3*) of this section, the amount of gross income attributable to the FDE foreign branch (and the gross income attributable to P) is adjusted in Year 1 to take the disregarded payment into account. Accordingly, $350x of P's $400x U.S. source general category gross income from the license is attributable to the FDE foreign branch for purposes of this section. Therefore, $350x of the U.S. source gross income that P earned with respect to its license in Year 1 constitutes U.S. source gross income that is assigned to the foreign branch category and $50x remains U.S. source general category income. P's $600x of foreign source passive category interest income is unchanged.

(xiv) *Example 14: Regarded payment from non-consolidated domestic corporation to a foreign branch*—(A) *Facts.* The facts are the same as in paragraph (f)(4)(xiii)(A) of this section (the facts of *Example 13*), except P wholly owns USS, and USS (rather than P) owns FDE. P and USS do not file a consolidated return. USS has no gross income other than the $350x foreign source services income it receives from P, through FDE, for Federal income tax purposes.

(B) *Analysis.* P has $400x of U.S. source general category gross income from the license and $600x of foreign source passive category interest income. The $350x services payment from P, a United States person, to FDE, a foreign branch of USS, is not a disregarded payment because the transaction is regarded for Federal income tax purposes. Under §§ 1.861–8 and 1.861–8T, P's $350x deduction for the services payment is allocated and apportioned to its U.S. source general category gross income. The payment of $350x from P to USS is services income attributable to FDE, and foreign branch category income of USS under paragraph (f)(2)(i) of this section. Accordingly, USS has $350x of foreign source foreign branch category gross income. P has $600x of foreign source passive category income and $400x of U.S. source general category gross income and a $350x deduction for the services payment,

resulting in $50x of U.S. source general category taxable income to P.

(xv) *Example 15: Regarded payment from a member of a consolidated group to a foreign branch of another member of the group*—(A) *Facts.* The facts are the same as in paragraph (f)(4)(xiv)(A) of this section (the facts of *Example 14*), except that P and USS are members of an affiliated group that files a consolidated return pursuant to section 1502 (P group).

(B) *Analysis*—(*1*) *Definitions under § 1.1502–13.* Under § 1.1502–13(b)(1), the $350x services payment from P, a United States person, to FDE, a foreign branch of USS, is an intercompany transaction between P and USS; USS is the selling member, P is the buying member, P has a corresponding deduction of $350x for the services payment, and USS has $350x of intercompany income. The payment is not a disregarded payment because the transaction is regarded for Federal income tax purposes.

(*2*) *Timing and attributes under § 1.1502–13*—(*i*) *Separate entity versus single entity analysis.* Under a separate entity analysis, the result is the same as in paragraph (f)(4)(xiv)(B) of this section (the analysis in *Example 14*), whereby P has $600x of foreign source passive category income and $50x of U.S. source general category income, and USS has $350x of foreign source foreign branch category income. In contrast, under a single entity analysis, the result is the same as in paragraph (f)(4)(xiii)(B) of this section (the analysis in *Example 13*), whereby P has $600x of foreign source passive category income, $50x of U.S. source general category income, and $350x of U.S. source foreign branch category income.

(*ii*) *Application of the matching rule.* Under the matching rule in § 1.1502–13(c), the timing, character, source, and other attributes of USS's $350x intercompany income and P's corresponding $350x deduction are redetermined to produce the effect of transactions between divisions of a single corporation, as if the services payment had been made to a foreign branch of that corporation. Accordingly, all of USS's foreign source income of $350x is redetermined to be U.S. source, rather than foreign source, income. Therefore, for purposes of § 1.1502–4(c)(1), the P group has $600x of foreign passive category income, $50x of U.S. source general category income, and $350x of U.S. source foreign branch category income.

(xvi) *Example 16: Disregarded payment made from non-branch taxable unit*—(A) *Facts.* The facts are the same as in paragraph (f)(4)(xiii)(A) of this section (the facts of *Example 13*), except that P also wholly owns FDE1, a disregarded entity that is a non-branch taxable unit. In addition, FDE1 (rather than P) is the entity that properly accrues and records on its books and records the $400x of U.S. source general category income from the license of intellectual property and the $600x of foreign source passive category interest income, and FDE1 (rather than P) is the entity that makes the $350x payment, which is disregarded for Federal income tax purposes, to FDE in compensation for services.

(B) *Analysis.* Under paragraph (f)(2)(vi)(G) of this section, the rules of paragraph (f)(2) of this section apply to attribute gross income to FDE1, a non-branch taxable unit, as though FDE1 were a foreign branch. Under these rules, the $400x of licensing income and the $600 of interest income are initially attributable to FDE1. This income is adjusted in Year 1 to take into account the $350x disregarded payment, which is allocable to the $400x of licensing income of FDE1. Accordingly, $50x of the $400x of U.S. source general category licensing income is attributable to FDE1 and $350x of this income is attributable to the FDE foreign branch. In order to determine the income that is attributable to P, the foreign branch owner, and FDE, the foreign branch, the income that is attributed to FDE1, after taking into account all of the disregarded payments that it makes and receives, must be further attributed to one or more foreign branches or a foreign branch owner under paragraph (f)(2)(vi)(G) of this section. Under paragraph (f)(2)(vi)(G) of this section, the income of FDE1 is attributed to the foreign branch group or foreign branch owner group of which it is a member. Because FDE1 is wholly owned by P, FDE is a member solely of the foreign branch owner group that is owned by P. See definition of ''foreign branch owner group'' in § 1.904–4(f)(3). All of the income that is attributed to FDE1 under paragraph (f)(2) of this section, namely, the $50x of U.S. source general category licensing income and the $600x of foreign source passive category interest income, is further attributed to P. See § 1.904–4(f)(2)(vi)(G)(*3*). Therefore, the result is the same as in paragraph (f)(4)(xiii)(B) of this section (the analysis in *Example 13*).

* * * * *

(q) * * *

(3) Paragraphs (e)(1)(ii) and (e)(2) and (3) of this section apply to taxable years beginning on or after [date final regulations are filed with the **Federal Register**]. Paragraph (f) of this section applies to taxable years that begin after December 31, 2019, and end on or after November 2, 2020.

■ **Par. 27.** Section 1.904–5 is amended by revising paragraphs (b)(2) and (o) as follows:

§ 1.904–5 Look-through rules as applied to controlled foreign corporations and other entities.

* * * * *

(b) * * *

(2) *Priority and ordering of look-through rules.* To the extent the look-through rules assign income to a separate category, the income is assigned to that separate category rather than the separate category to which the income would have been assigned under § 1.904–4 (not taking into account § 1.904–4(l)). See paragraph (k) of this section for ordering rules for applying the look-through rules.

* * * * *

(o) *Applicability dates.* Except as provided in this paragraph (o), this section is applicable for taxable years that both begin after December 31, 2017, and end on or after December 4, 2018. Paragraph (b)(2) of this section applies to taxable years beginning on or after [date final regulations are filed with the **Federal Register**].

■ **Par. 28.** Section 1.904–6, as amended in FR Doc. 2020–21819, published elsewhere in this issue of the **Federal Register**, is further amended by adding paragraph (b)(2) and revising paragraph (g) to read as follows:

§ 1.904–6 Allocation and apportionment of foreign income taxes.

* * * * *

(b) * * *

(2) *Disregarded payments*—(i) *In general*—(A) *Assignment of foreign gross income.* Except as provided in paragraph (b)(2)(ii) of this section, if a taxpayer that is an individual or a domestic corporation includes an item of foreign gross income by reason of the receipt of a disregarded payment by a foreign branch or foreign branch owner (as those terms are defined in § 1.904–4(f)(3)), or a non-branch taxable unit, the foreign gross income item is assigned to a separate category under § 1.861–20(d)(3)(v).

(B) *Definition of non-branch taxable unit.* The term *non-branch taxable unit* means a person or interest that is described in paragraph (b)(2)(i)(B)(*1*) or (*2*) of this section, respectively.

(*1*) *Persons.* A non-branch taxable unit described in this paragraph (b)(2)(i)(B)(*1*) means a person that is not otherwise a foreign branch owner and that is a U.S. individual, a domestic corporation, or a foreign or domestic

partnership (or other pass-through entity, as defined in § 1.904–5(a)(4)) an interest in which is owned, directly or indirectly through one or more other partnerships (or other pass-through entities), by a U.S. individual or a domestic corporation.

(*2*) *Interests.* A non-branch taxable unit described in this paragraph (b)(2)(i)(B)(*2*) means an interest of a foreign branch owner or an interest of a person described in paragraph (b)(2)(i)(B)(*1*) of this section that is not otherwise a foreign branch, and that is either a disregarded entity or a branch, as defined in § 1.267A–5(a)(2), including a branch described in § 1.954–1(d)(2)(i)(C) (modified by substituting the term ''person'' for ''controlled foreign corporation'').

(ii) *Foreign branch group contributions*—(A) *In general.* If a taxpayer includes an item of foreign gross income by reason of a foreign branch group contribution, the foreign gross income is assigned to the foreign branch category, or, in the case of a foreign branch owner that is a partnership, to the partnership's general category income that is attributable to the foreign branch. See, however, §§ 1.861–20(d)(3)(v)(C)(*2*) and 1.960–1(d)(3)(ii)(A) and (e) for rules providing that foreign income tax on a disregarded payment that is a contribution from a controlled foreign corporation to a taxable unit is assigned to the residual grouping and cannot be deemed paid under section 960.

(B) *Foreign branch group contribution.* A foreign branch group contribution is a contribution (as defined in § 1.861–20(d)(3)(v)(E)) made by a member of a foreign branch owner group to a member of a foreign branch group that the payor owns, made by a member of a foreign branch group to another member of that group that the payor owns, or made by a member of a foreign branch group to a member of a different foreign branch group that the payor owns. For purposes of this paragraph (b)(2)(ii)(B), the terms *foreign branch group* and *foreign branch owner group* have the meanings provided in § 1.904–4(f)(3).

* * * * *

(g) *Applicability date.* Except as otherwise provided in this paragraph (g), this section applies to taxable years that begin after December 31, 2019. Paragraph (b)(2) of this section applies to taxable years that begin after December 31, 2019, and end on or after November 2, 2020.

■ **Par. 29.** Section 1.904(f)–12 is amended by:

■ 1. Removing paragraph (j)(6).

■ 2. Redesignating paragraph (j)(5) as paragraph (j)(6).

■ 3. Adding a new paragraph (j)(5) and paragraph (j)(7).

The additions read as follows:

§ 1.904(f)–12 Transition rules.

* * * * *

(j) * * *

(5) *Treatment of net operating losses incurred in post-2017 taxable years that are carried back to pre-2018 taxable years*—(i) *In general.* Except as provided in paragraph (j)(5)(ii) of this section, a net operating loss (NOL) incurred in a taxable year beginning after December 31, 2017 (a ''post-2017 taxable year''), which is carried back, pursuant to section 172, to a taxable year beginning before January 1, 2018 (a ''pre-2018 carryback year''), will be carried back under the rules of § 1.904(g)–3(b). For purposes of applying the rules of § 1.904(g)–3(b), income in a pre-2018 separate category in the taxable year to which the net operating loss is carried back is treated as if it included only income that would be assigned to the post-2017 general category. Therefore, any separate limitation loss created by reason of a passive category component of an NOL from a post-2017 taxable year that is carried back to offset general category income in a pre-2018 carryback year will be recaptured in post-2017 taxable years as general category income, and not as a combination of general, foreign branch, and section 951A category income.

(ii) *Foreign source losses in the post-2017 separate categories for foreign branch category income and section 951A category income.* Net operating losses attributable to a foreign source loss in the post-2017 separate categories for foreign branch category income and section 951A category income are treated as first offsetting general category income in a pre-2018 carryback year to the extent available to be offset by the net operating loss carryback. If the sum of foreign source losses in the taxpayer's separate categories for foreign branch category income and section 951A category income in the year the net operating loss is incurred exceeds the amount of general category income that is available to be offset in the carryback year, then the amount of foreign source loss in each of the foreign branch and section 951A categories that is treated as offsetting general category income under this paragraph (j)(5)(ii), is determined on a proportionate basis. General category income in the pre-2018 carryback year is first offset by foreign source loss in the taxpayer's post-2017 separate category for general category income in the year the net operating loss is incurred before any foreign source loss in that year in the separate categories for foreign branch category income and section 951A category income is carried back to reduce general category income. To the extent a foreign source loss in a post-2017 separate category for foreign branch category income or section 951A category income offsets general category income in a pre-2018 taxable year under the rules of this paragraph (j)(5)(ii), no separate limitation loss account is created.

* * * * *

(7) *Applicability date.* Except as otherwise provided in this paragraph (j)(7), this paragraph (j) applies to taxable years ending on or after December 31, 2017. Paragraph (j)(5) of this section applies to carrybacks of net operating losses incurred in taxable years beginning on or after January 1, 2018.

■ **Par. 30.** Section 1.905–1 is amended by:

■ 1. Revising the section heading and paragraph (a).

■ 2. Redesignating paragraph (b) as paragraph (g).

■ 3. Adding a new paragraph (b) and paragraphs (c), (d), (e), and (f).

■ 4. Revising the heading of newly redesignated paragraph (g).

■ 5. Adding paragraph (h).

The revisions and additions read as follows:

§ 1.905–1 When credit for foreign income taxes may be taken.

(a) *Scope.* This section provides rules regarding when the credit for foreign income taxes (as defined in § 1.901–2(a)) may be taken, based on a taxpayer's method of accounting for such taxes. Paragraph (b) of this section provides the general rule. Paragraph (c) of this section sets forth rules for determining the taxable year in which taxpayers using the cash receipts and disbursement method of accounting for income (''cash method'') may claim a foreign tax credit. Paragraph (d) of this section sets forth rules for determining the taxable year in which taxpayers using the accrual method of accounting for income (''accrual method'') may claim a foreign tax credit. Paragraph (e) of this section provides rules for taxpayers using the cash method to claim foreign tax credits on the accrual basis pursuant to the election provided under section 905(a). Paragraph (f) of this section provides rules for when foreign income tax expenditures of a pass-through entity can be taken as a credit by the entity's partners, shareholders, or owners. Paragraph (g) of this section provides rules for when a foreign tax credit can be taken with

respect to blocked income. Paragraph (h) provides the applicability dates for this section.

(b) *General rule.* The credit for taxes provided in subpart A, part III, subchapter N, chapter 1 of the Code (the ''foreign tax credit'') may be taken either on the return for the year in which the taxes accrued or on the return for the year in which the taxes were paid, depending on whether the taxpayer uses the accrual or the cash receipts and disbursements method of accounting for purposes of computing taxable income and filing returns. However, regardless of the year in which the credit is claimed under the taxpayer's method of accounting for foreign income taxes, the foreign tax credit is allowed only to the extent the foreign income taxes are ultimately both owed and actually remitted to the foreign country (in the case of a taxpayer claiming the foreign tax credit on the accrual basis, within the time prescribed by section 905(c)(2)). See section 905(b) and §§ 1.901–1(a) and 1.901–2(e). Because the taxpayer's liability for foreign income tax may accrue (that is, become fixed and determinable) in a different taxable year than that in which the tax is paid (that is, remitted), the taxpayer's entitlement to the credit may be perfected, or become subject to adjustment, by reason of events that occur in a taxable year after the taxable year in which the credit is allowed. See section 905(c) and § 1.905–3(a) for rules relating to changes to the taxpayer's foreign income tax liability that require a redetermination of the allowable foreign tax credit and the taxpayer's U.S. tax liability.

(c) *Rules for cash method taxpayers*—(1) *Credit allowed in year paid.* Except as provided in paragraph (e) of this section, a taxpayer who uses the cash method may claim a foreign tax credit only in the taxable year in which the foreign income taxes are paid. Generally, foreign income taxes are considered paid in the taxable year in which the taxes are remitted to the foreign country. However, foreign withholding taxes described in section 901(k)(1)(B), as well as foreign net income taxes described in § 1.901–2(a)(3)(i) that are withheld from the taxpayer's gross income by the payor, are treated as paid in the year in which they are withheld. Foreign income taxes that have been withheld or remitted but which are not considered an amount of tax paid for purposes of section 901 under the rules of § 1.901–2(e) (for example, because the amount withheld or remitted was not a compulsory payment), however, are not eligible for a foreign tax credit. See §§ 1.901–2(e) and 1.905–3(b)(1)(ii)(B) (*Example 2*).

(2) *Adjustments to taxes claimed as a credit in the year paid.* A refund of foreign income taxes for which a foreign tax credit has been claimed on the cash basis, or a subsequent determination that the amount paid exceeds the taxpayer's liability for foreign income tax, requires a redetermination of foreign income taxes paid and the taxpayer's U.S. tax liability pursuant to section 905(c) and § 1.905–3. See § 1.905–3(a) and (b)(1)(ii)(G) (*Example 7*). Additional foreign income taxes paid that relate back to a prior year in which foreign income taxes were claimed as a credit on the cash basis, including by reason of the settlement of a dispute with the foreign tax authority, may only be claimed as a credit in the year the additional taxes are paid. The payment of such additional taxes does not result in a redetermination pursuant to section 905(c) or § 1.905–3 of the foreign income taxes paid in any prior year, although a redetermination of U.S. tax liability may be required due, for example, to a carryback of unused foreign tax under section 904(c) and § 1.904–2.

(d) *Rules for accrual method taxpayers*—(1) *Credit allowed in year accrued*—(i) *In general.* A taxpayer who uses the accrual method may claim a foreign tax credit only in the taxable year in which the foreign income taxes are considered to accrue for foreign tax credit purposes under the rules of this paragraph (d). Foreign income taxes accrue in the taxable year in which all the events have occurred that establish the fact of the liability and the amount of the liability can be determined with reasonable accuracy. See §§ 1.446–1(c)(1)(ii)(A) and 1.461–4(g)(6)(iii)(B). For purposes of the preceding sentence, a foreign income tax that is contingent on a future distribution of earnings does not meet the all events test until the earnings are distributed. A foreign income tax liability determined on the basis of a foreign taxable year becomes fixed and determinable at the close of the taxpayer's foreign taxable year. Therefore, foreign income taxes that are computed based on items of income, deduction, and loss that arise in a foreign taxable year accrue in the United States taxable year with or within which the taxpayer's foreign taxable year ends. Foreign withholding taxes that are paid with respect to a foreign taxable year and that represent advance payments of a foreign net income tax liability determined on the basis of that foreign taxable year accrue at the close of the foreign taxable year. Foreign withholding taxes imposed on a payment giving rise to an item of foreign gross income accrue on the date the payment from which the tax is withheld is made (or treated as made under foreign tax law).

(ii) *Relation-back rule for adjustments to taxes claimed as a credit in year accrued.* Additional tax paid as a result of a change in the foreign tax liability, including additional taxes paid when a contest with a foreign tax authority is resolved, relate back and are considered to accrue at the end of the foreign taxable year with respect to which the taxes were imposed (the ''relation-back year''). Additional withholding tax paid as a result of a change in the amount of an item of foreign gross income (such as pursuant to a foreign transfer pricing adjustment), also relate back and are considered to accrue in the year in which the payment from which the additional tax is withheld is made (or considered to have been made under foreign tax law). Foreign income taxes that are not paid within 24 months after the close of the taxable year in which they were accrued are treated as refunded pursuant to § 1.905–3(a); when subsequently paid, the foreign income taxes are allowed as a credit in the relation-back year. See § 1.905–3(b)(1)(ii)(E) (*Example 5*). For special rules that apply to determine when foreign income tax is considered to accrue in the case of certain ownership and entity classification changes, see §§ 1.336–2(g)(3)(ii), 1.338–9(d), 1.901–2(f)(5), and 1.1502–76.

(2) *Special rule for 52–53 week U.S. taxable years.* If a taxpayer has elected pursuant to section 441(f) to use a U.S. taxable year consisting of 52–53 weeks, and such U.S. taxable year closes within six calendar days of the end of the taxpayer's foreign taxable year, the determination of when foreign income taxes accrue under paragraph (d)(1) of this section is made by deeming the taxpayer's U.S. taxable year to end on the last day of its foreign taxable year.

(3) *Accrual of contested foreign tax liability.* A contested foreign income tax liability is finally determined and accrues for purposes of paragraph (d)(1) of this section when the contest is resolved. However, pursuant to section 905(c)(2), no credit is allowed for any accrued tax that is not paid within 24 months of the close of the relation-back year until the tax is actually remitted and considered paid. Thus, except as provided in paragraph (d)(4) of this section, a foreign tax credit for a contested foreign income tax liability cannot be claimed until such time as both the contest is resolved and the tax is actually paid, even if the contested liability (or portion thereof) has

previously been remitted to the foreign country. Once the contest is resolved and the foreign income tax liability is finally determined and paid, the tax liability accrues, and is considered actually to accrue in the relation-back year for purposes of the foreign tax credit. See paragraph (d)(1) of this section; see also section 6511(d)(3) and § 301.6511(d)–3 of this chapter for a special 10-year period of limitations for claiming a credit or refund of U.S. tax that is attributable to foreign income taxes for which a credit is allowed under section 901, which runs from the unextended due date of the return for the taxable year in which the foreign income taxes are paid (within the meaning of paragraph (c) of this section, for taxpayers claiming credits on the cash basis) or accrued (within the meaning of this paragraph (d)), for taxpayers claiming credits on the accrual basis).

(4) *Election to claim a provisional credit for contested taxes remitted before accrual*—(i) *Conditions of election.* A taxpayer may, under the conditions provided in this paragraph (d)(4), elect to claim a foreign tax credit (but not a deduction) for a contested foreign income tax liability (or a portion thereof) in the relation-back year when the contested amount (or a portion thereof) is remitted to the foreign country, notwithstanding that the liability is not finally determined and so has not accrued. To make the election, a taxpayer must file an amended return for the taxable year to which the contested tax relates, together with a Form 1116 (Foreign Tax Credit (Individual, Estate, or Trust)) or Form 1118 (Foreign Tax Credit—Corporations), and the agreement described in paragraph (d)(4)(ii) of this section. In addition, the taxpayer must, for each subsequent taxable year up to and including the taxable year in which the contest is resolved, file the annual certification described in paragraph (d)(4)(iii) of this section. Any portion of a contested foreign income tax liability for which a provisional credit is claimed under this paragraph (d)(4) that is subsequently refunded by the foreign country results in a foreign tax redetermination under § 1.905–3(a).

(ii) *Contents of provisional foreign tax credit agreement.* The provisional foreign tax credit agreement must contain the following:

(A) A statement that the document is an election and an agreement under the provisions of paragraph (d)(4) of this section;

(B) A description of contested foreign income tax liability, including the name of the foreign tax or taxes being contested, the name of the country imposing the tax, the amount of the contested tax, and the U.S. taxable year(s) and the income to which the contested foreign income tax liability relates;

(C) The amount of the contested foreign income tax liability in paragraph (d)(4)(ii)(B) of this section that has been remitted to the foreign country and the date of the remittance(s);

(D) An agreement by the taxpayer, for a period of three years from the later of the filing or the due date (with extensions) of the return for the taxable year in which the taxpayer notifies the Internal Revenue Service of the resolution of the contest, not to assert the statute of limitations on assessment as a defense to the assessment of additional taxes or interest related to the contested foreign income tax liability described in paragraph (d)(4)(ii)(B) of this section that may arise from a determination that the taxpayer failed to exhaust all effective and practical remedies to minimize its foreign income tax liability, so that the amount of the contested foreign income tax is not a compulsory payment and is not considered paid within the meaning of § 1.901–2(e)(5);

(E) A statement that the taxpayer agrees to comply with all the conditions and requirements of paragraph (d)(4) of this section, including to provide notice to the Internal Revenue Service upon the resolution of the contest, and to treat the failure to comply with such requirement as a refund of the contested foreign income tax liability that requires a redetermination of the taxpayer's U.S. tax liability pursuant to § 1.905–3(b); and

(F) Any additional information as may be prescribed by the Commissioner of Internal Revenue in Internal Revenue Service forms or instructions.

(iii) *Annual certification.* For each taxable year following the year in which an election pursuant to paragraph (d)(4) of this section is made up to and including the taxable year in which the contest is resolved, the taxpayer must include with its timely-filed return a certification containing the information described in paragraphs (d)(4)(iii)(A) through (C) of this section in the form or manner prescribed by the Commissioner of Internal Revenue in Internal Revenue Service forms or instructions.

(A) A description of the contested foreign income tax liability, including the name of the foreign tax or taxes, the country imposing the tax, the amount of the contested tax, and a description of the status of the contest.

(B) With the return for the taxable year in which the contest is resolved, notification that the contest has been resolved. Such notification must include the date of final resolution and the amount of the finally determined foreign income tax liability.

(C) Any additional information, which may include a copy of the final judgment, order, settlement, or other documentation of the contest resolution, as may be prescribed by the Commissioner of Internal Revenue in Internal Revenue Service forms or instructions.

(iv) *Signatory.* The provisional foreign tax credit agreement and the annual certification must be signed under penalties of perjury by a person authorized to sign the return of the taxpayer.

(v) *Failure to comply.* A taxpayer that fails to comply with the requirements for filing a provisional foreign tax credit agreement under paragraphs (d)(4)(i) and (ii) of this section will not be allowed a provisional credit for the contested foreign income tax liability. A taxpayer that fails to comply with the annual certification requirement of paragraph (d)(4)(iii) of this section will be treated as receiving a refund of the amount of the contested foreign income tax liability on the date the annual certification is required to be filed under paragraph (d)(4)(iii) of this section, resulting in a redetermination of the taxpayer's U.S. tax liability pursuant to § 1.905–3(b).

(5) *Correction of improper accruals*—(i) *In general.* The accrual of a foreign income tax expense generally involves the determination of the proper timing for recognizing the expense for Federal income tax purposes. Thus, foreign income tax expense is a material item within the meaning of section 446. See § 1.446–1(e)(2)(ii). As a material item, a change in the timing of accruing a foreign income tax expense is generally a change in method of accounting. See section 446(e). A change from an improper method of accruing foreign income taxes to the proper method of accrual described in this paragraph (d) is treated as a change in a method of accounting, regardless of whether the taxpayer (or a partner or beneficiary taking into account a distributive share of foreign income taxes paid by a partnership or other pass-through entity) chooses to claim a deduction or a credit for such taxes in any taxable year. For purposes of this paragraph (d)(5), an improper method of accruing foreign income taxes includes a method under which foreign income tax is accrued in a taxable year other than the taxable year in which the requirements

of the all events test in §§ 1.446–1(c)(1)(ii)(A) and 1.461–4(g)(6)(iii)(B) are met, or which fails to apply the relation-back rule in paragraph (d)(1) of this section that applies for purposes of the foreign tax credit, but does not include corrections to estimated accruals or errors in computing the amount of foreign income tax that is allowed as a deduction or credit in any taxable year. Taxpayers must file a Form 3115, Application for Change in Accounting Method, in accordance with Revenue Procedure 2015–13 (or any successor administrative procedure prescribed by the Commissioner) to obtain the Commissioner's permission to change from an improper method of accruing foreign income taxes to the proper method described in this paragraph (d). In order to prevent a duplication or omission of a benefit for foreign income taxes that accrue in any taxable year (whether through the double allowance or double disallowance of either a deduction or a credit, the allowance of both a deduction and a credit, or the disallowance of either a deduction or a credit, for the same amount of foreign income tax), the rules in paragraphs (d)(5)(ii) through (iv) of this section, describing a modified cut-off approach, apply if the Commissioner grants permission for the taxpayer to change to the proper method of accrual. Under the modified cut-off approach, a section 481(a) adjustment is neither required nor permitted with respect to the amounts of foreign income tax that were improperly accrued (or improperly not accrued) under the taxpayer's improper method in taxable years before the taxable year of change.

(ii) *Adjustments required to implement a change in method of accounting for accruing foreign income taxes.* A change from an improper method of accruing foreign income taxes to the proper method described in this paragraph (d) is made under the modified cut-off approach described in this paragraph (d)(5)(ii). Under the modified cut-off approach, the amount of foreign income tax in a statutory or residual grouping (such as a separate category as defined in § 1.904–5(a)(4)) that properly accrues in the taxable year of change (accounted for in the currency in which the foreign tax liability is denominated) is adjusted downward (but not below zero) by the amount of foreign income tax in the same grouping that the taxpayer improperly accrued in a prior taxable year and for which the taxpayer claimed a credit or a deduction in such prior taxable year, but only if the improperly-accrued amount of foreign income tax did not properly accrue in a taxable year before the taxable year of change. Conversely, under the modified cut-off approach, the amount of foreign income tax in any statutory or residual grouping that properly accrues in the taxable year of change (accounted for in the currency in which the foreign tax liability is denominated) is adjusted upward by the amount of foreign income tax in the same grouping that properly accrued in a taxable year before the taxable year of change but which, under the taxpayer's improper method of accounting, the taxpayer failed to accrue and claim as either a credit or a deduction in any taxable year before the taxable year of change. For purposes of the foreign tax credit, the adjusted amounts of accrued foreign income taxes, including any upward adjustment, are translated into U.S. dollars under § 1.986(a)–1 as if those amounts properly accrued in the taxable year of change. To the extent that the downward adjustment in any grouping required under this modified cut-off approach exceeds the amount of foreign income tax properly accruing in that grouping in the year of change, such excess will carry forward to each subsequent taxable year and reduce properly-accrued amounts of foreign income tax in the same grouping to the extent of those properly-accrued amounts, until all improperly-accrued amounts included in the downward adjustment are accounted for. See § 1.861–20 for rules that apply to assign foreign income taxes to statutory and residual groupings.

(iii) *Application of section 905(c)*—(A) *Two-year rule.* Except as otherwise provided in this paragraph (d)(5)(iii), if the taxpayer claimed a credit for improperly-accrued amounts in a taxable year before the taxable year of change, no adjustment is required under section 905(c)(2) and § 1.905–3(a) solely by reason of the improper accrual. For purposes of applying section 905(c)(2) and § 1.905–3(a) to improperly-accrued amounts of foreign income tax that were claimed as a credit in any taxable year before the taxable year of change, the 24-month period runs from the close of the U.S. taxable year(s) in which those amounts were accrued under the taxpayer's improper method and claimed as a credit. To the extent any improperly-accrued amounts remain unpaid as of the date 24 months after the close of the taxable year in which the amounts were improperly accrued and claimed as a credit, an adjustment is required under section 905(c)(2) and § 1.905–3(a) as if the improperly-accrued amounts were refunded as of the date 24 months after the close of such taxable year. See § 1.986(a)–1(c) (a refund or other downward adjustment to foreign income taxes paid or accrued on more than one date reduces the foreign income taxes paid or accrued on a last-in, first-out basis, starting with the amounts most recently paid or accrued).

(B) *Application of payments.* Amounts of foreign income tax that a taxpayer accrued and claimed as a credit or a deduction in a taxable year before the taxable year of change under the taxpayer's improper method, but that had properly accrued either in the taxable year the credit or deduction was claimed or in a different taxable year before the taxable year of change, are not included in the downward adjustment required by paragraph (d)(5)(ii) of this section. Remittances to the foreign country of such amounts (accounted for in the currency in which the foreign tax liability is denominated) are treated first as payments of the amounts of tax that had properly accrued in the taxable year claimed as a credit or deduction to the extent thereof, and then as payments of the amounts of tax that were improperly accrued in a different taxable year, on a last-in, first-out basis, starting with the most recent improperly-accrued amounts. Remittances to the foreign country of amounts of foreign income tax that properly accrue in or after the taxable year of change (accounted for in the foreign currency in which the foreign tax liability is denominated) but that are offset by the amounts included in the downward adjustment required by paragraph (d)(5)(ii) of this section are treated as payments of the amounts of tax that were improperly accrued before the taxable year of change and included in the downward adjustment on a last-in, first-out basis, starting with the most recent improperly-accrued amounts. Additional amounts of foreign income tax that first accrue in or after the taxable year of change but that relate to a taxable year before the taxable year of change are taken into account in the earlier of the taxable year of change or the taxable year or years in which they would have been considered to accrue based upon the taxpayer's improper method. Additional amounts of foreign income tax that first accrue in or after the taxable year of change and that relate to the taxable year of change or a taxable year after the year of change are taken into account in the proper relation-back year, but may then be subject to the downward adjustment required by paragraph (d)(5)(ii) of this section.

(iv) *Foreign income tax expense improperly accrued by a foreign corporation, partnership, or other pass-*

through entity. Foreign income tax expense of a foreign corporation reduces both the corporation's taxable income and its earnings and profits, and may give rise to an amount of foreign taxes deemed paid under section 960 that may be claimed as a credit by a United States shareholder that is a domestic corporation or that is a person that makes an election under section 962. If the Commissioner grants permission for a foreign corporation to change its method of accounting for foreign income tax expense, the duplication or omission of those expenses (accounted for in the functional currency of the foreign corporation) and the associated foreign income taxes (translated into dollars in accordance with § 1.986(a)–1) are accounted for by applying the rules in paragraph (d)(5)(ii) of this section as if the foreign corporation were itself eligible to, and did, claim a credit under section 901 for such amounts. In the case of a partnership or other pass-through entity that is granted permission to change its method of accounting for accruing foreign income taxes to a proper method as described in this paragraph (d), such partnership or other pass-through entity must provide its partners or other owners with the information needed for the partners or other owners to properly account for the improperly-accrued or unaccrued amounts under the rules in paragraph (d)(5)(ii) of this section as if their proportionate shares of foreign income tax expense were directly paid or accrued by them.

(6) *Examples.* The following examples illustrate the application of paragraph (d) of this section. Unless otherwise stated, for purposes of these examples it is presumed that the local currency in each of Country X and Country Y and the functional currency of any foreign branch is the Euro (€), and at all relevant times the exchange rate is $1:€1.

(i) *Example 1: Accrual of foreign income tax*—(A) *Facts.* A, a U.S. citizen, resides and works in Country X. A uses the calendar year as the U.S. taxable year, and has made an election under paragraph (e) of this section to claim foreign tax credits on an accrual basis. Country X has a tax year that begins on April 1 and ends on March 31. A's wages are subject to net income tax, at graduated rates, under Country X tax law and are subject to withholding on a monthly basis by A's employer in Country X. In the period between April 1, Year 1, and March 31, Year 2, A earns $50,000x in Country X wages, from which A's employer withholds $10,000x in tax. On December 1, Year 1, A receives a dividend distribution from a Country Y corporation, from which the corporation withheld $500x of tax. Country Y imposes withholding tax on dividends paid to nonresidents solely based on the gross amount of the dividend payment; A is not required to file a tax return in Country Y.

(B) *Analysis.* Under paragraph (d)(1) of this section, A's liability for Country X net income tax accrues on March 31, Year 2, the last day of the Country X taxable year. The Country X net income tax withheld by A's employer from A's wages is a reasonable approximation of, and represents an advance payment of, A's final net income tax liability for the year, which becomes fixed and determinable only at the close of the Country X taxable year. Thus, A cannot claim a credit for any portion of the Country X net income tax on A's Federal income tax return for Year 1, and may claim a credit for the entire Country X net income tax that accrues on March 31, Year 2, on A's Federal income tax return for Year 2. A may claim a credit for the Country Y withholding tax on A's Federal income tax return for Year 1, because the withholding tax accrued on December 1, Year 1.

(ii) *Example 2: 52–53 week taxable year*—(A) *Facts.* U.S.C., an accrual method taxpayer, is a domestic corporation that operates in branch form in Country X. U.S.C. uses the calendar year for Country X tax purposes. For Federal income tax purposes, U.S.C. elects pursuant to § 1.441–2(a) to use a 52–53 week taxable year that ends on the last Friday of December. In Year 1, U.S.C.'s U.S. taxable year ends on Friday, December 25; in Year 2, U.S.C.'s U.S. taxable year ends Friday, December 31. For its foreign taxable year ending December 31, Year 1, U.S.C. earns $10,000x of foreign source income through its Country X branch and incurs Country X foreign income tax of $500x; for Year 2, U.S.C. earns $12,000x and incurs Country X foreign income tax of $600x.

(B) *Analysis.* Under paragraph (d)(1) of this section, the $500x of Country X foreign income tax becomes fixed and determinable at the close of U.S.C.'s foreign taxable year, on December 31, Year 1, which is after the close of its U.S. taxable year (December 25, Year 1). The $600x of Country X foreign income tax becomes fixed and determinable on December 31, Year 2. Thus, both the Year 1 and Year 2 Country X foreign income taxes accrue in U.S.C.'s U.S. taxable year ending December 31, Year 2. However, pursuant to paragraph (d)(2) of this section, for purposes of determining the amount of foreign income taxes accrued in each taxable year for foreign tax credit purposes, U.S.C.'s U.S. taxable year is deemed to end on December 31, the end of U.S.C.'s Country X taxable year. U.S.C. may therefore claim a foreign tax credit for $500x of Country X foreign income tax on its Federal income tax return for Year 1 and a credit for $600x of Country X foreign income tax on its Federal income tax return for Year 2.

(iii) *Example 3: Contested tax*—(A) *Facts.* U.S.C. is a domestic corporation that operates in branch form in Country X. U.S.C. uses an accrual method of accounting and uses the calendar year as its U.S. and Country X taxable year. In Year 1, when the average exchange rate described in § 1.986(a)–1(a)(1) is $1:€1, U.S.C. earns €20,000x = $20,000x through its Country X branch for U.S. and Country X tax purposes and accrues Country X foreign income taxes of €500x = $500x, which U.S.C. claims as a credit on its Federal income tax return for Year 1. In Year 3, when the average exchange rate is $1:€1.2, Country X asserts that U.S.C. owes additional foreign income taxes of €100x with respect to U.S.C.'s Year 1 income. U.S.C. contests the liability but remits €40x to Country X with respect to the contested liability in Year 3. U.S.C. does not make an election under paragraph (d)(4) of this section to claim a provisional credit with respect to the €40x. In Year 6, after exhausting all effective and practical remedies, it is finally determined that U.S.C. is liable for €50x of additional Country X foreign income taxes with respect to its Year 1 income. U.S.C. pays an additional €10x to Country X on September 15, Year 6, when the spot rate described in § 1.986(a)–1(a)(2)(i) is $1:€2.

(B) *Analysis.* Pursuant to paragraph (d)(3) of this section, the additional liability asserted by Country X with respect to U.S.C.'s Year 1 income does not accrue until the contest is resolved in Year 6. U.S.C.'s remittance of €40x of contested tax in Year 3 is not a payment of accrued tax, and so is not a foreign tax redetermination. Both the €40x of Country X taxes paid in Year 3 and the €10x of Country X taxes paid in Year 6 accrue in Year 6, when the contest is resolved. Once accrued and paid, the €50x relates back for foreign tax credit purposes to Year 1, and can be claimed as a credit by U.S.C. on a timely-filed amended return for Year 1. Under § 1.986(a)–1(a), for foreign tax credit purposes the €40x paid in Year 3 is translated into dollars at the average exchange rate for Year 1 (€40x × $1 / €1 = $40x), and the €10x paid in Year 6 is translated into dollars at the spot rate on the date paid (€10x × $1 / €2 = $5x). Accordingly, after the €50x of Country

X income tax is paid in Year 6 U.S.C. may claim an additional foreign tax credit of $45x for Year 1.

(iv) *Example 4: Provisional credit for contested tax*—(A) *Facts.* The facts are the same as in paragraph (d)(6)(iii)(A) of this section (the facts of *Example 3*), except that U.S.C. pays the entire contested tax liability of €100x to Country X in Year 3 and elects under paragraph (d)(4) of this section to claim a provisional foreign tax credit on an amended return for Year 1. In Year 6, upon resolution of the contest, U.S.C. receives a refund of €50x from Country X.

(B) *Analysis.* In Year 3, U.S.C. may claim a provisional foreign tax credit for $100x (€100x translated at the average exchange rate for Year 1) of contested foreign tax paid to Country X by filing an amended return for Year 1, with Form 1118 attached, and a provisional foreign tax credit agreement described in paragraph (d)(4)(ii) of this section. In each year for Years 4 through 6, U.S.C. must attach the certification described in paragraph (d)(4)(iii) of this section to its timely-filed Federal income tax return. In Year 6, as a result of the €50x refund, U.S.C. must redetermine its U.S. tax liability for Year 1 and for any other affected year pursuant to § 1.905–3, reducing the Year 1 foreign tax credit by $50x (from $600x to $550x), and comply with the notification requirements in § 1.905–4. See § 1.986(a)–1(c) (refunds of foreign income tax translated into U.S. dollars at the rate used to claim the credit).

(v) *Example 5: Improperly accelerated accrual*—(A) *Facts*—(*1*) *Foreign income tax accrued and paid.* U.S.C. is a domestic corporation that operates a foreign branch in Country X. All of U.S.C.'s gross and taxable income is foreign source foreign branch category income, and all of its foreign income taxes are properly allocated and apportioned under § 1.861–20 to the foreign branch category. U.S.C. uses the accrual method of accounting and uses the calendar year as its U.S. taxable year. For Country X tax purposes, U.S.C. uses a fiscal year that ends on March 31. U.S.C. accrued €200x = $200x of Country X net income tax (as defined in § 1.901–2(a)(3)) for its foreign taxable year ending March 31, Year 2. It timely filed its Country X tax return and paid the €200x on January 15, Year 3. U.S.C. accrued and paid with its timely filed Country X tax returns €280x and €240x of Country X net income tax for its foreign taxable years ending on March 31 of Year 3 and Year 4, respectively, on January 15 of Year 4 and Year 5, respectively.

(*2*) *Improper accrual.* On its Federal income tax return for Year 1, U.S.C. improperly pro-rated and accelerated the accrual of Country X net income tax and claimed a credit for $150x, equal to three-fourths of the Country X net income tax of $200x that relates to U.S.C.'s foreign taxable year ending March 31, Year 2. Continuing with this improper method of accruing foreign income taxes, U.S.C. claimed a foreign tax credit of $260x on its U.S. tax return for Year 2, comprising $50x (one-fourth of the $200x of net income tax relating to its foreign taxable year ending March 31, Year 2) plus $210x (three-fourths of the $280x of net income tax relating to its foreign taxable year ending March 31, Year 3). Similarly, U.S.C. improperly accrued and claimed a foreign tax credit on its U.S. tax return for Year 3 for $250x of Country X net income tax, comprising $70x (one-fourth of the $280x that properly accrued in Year 3) plus $180x (three-fourths of the $240x that properly accrued in Year 4). In Year 4, U.S.C. realizes its mistake and, as provided in paragraph (d)(5)(i) of this section, files Form 3115 with the IRS to seek permission to change from an improper method to a proper method of accruing foreign income taxes.

TABLE 1 TO PARAGRAPH (d)(6)(v)(A)(*2*)

Country X taxable year ending in U.S. calendar taxable year	Net income tax properly accrued ($1 = €1))	Net income tax accrued under improper method ($1 = €1))
3/31/Y1 ends in Year 1	0	¾ (200x) = 150x.
3/31/Y2 ends in Year 2	200x	¼ (200x) + ¾ (280x) = 260x.
3/31/Y3 ends in Year 3	280x	¼ (280x) + ¾ (240x) = 250x.
3/31/Y4 ends in Year 4	240x	[year of change].

(B) *Analysis*—(*1*) *Downward adjustment.* Under paragraph (d)(5)(ii) of this section, in Year 4, the year of change, U.S.C. must reduce (but not below zero) the amount (in Euros) of Country X net income tax in the foreign branch category that properly accrues in Year 4, €240x, by the amount of foreign income tax that was accrued and claimed as either a deduction or a credit in a year before the year of change, and that had not properly accrued in either the year in which the tax was accrued under U.S.C.'s improper method or in any other taxable year before the taxable year of change. For all taxable years before the taxable year of change, under its improper method U.S.C. had accrued and claimed as a credit a total of €660x = $660x of foreign income tax, of which only €480x = $480x had properly accrued. Therefore, the downward adjustment required by paragraph (d)(5)(ii) of this section is €180x (€660x − €480x = €180x). In Year 4, U.S.C.'s foreign tax credit in the foreign branch category is reduced by $180x (€180x downward adjustment translated into dollars at $1:€1, the average exchange rate for Year 4), from $240x to $60x.

(*2*) *Application of section 905(c)*—(*i*) *Year 1.* Under paragraph (d)(5)(iii) of this section, the €200x U.S.C. paid on January 15, Year 3, that relates to its Country X taxable year ending on March 31, Year 2, is first treated as a payment of the €50x of that Country X net income tax liability that properly accrued and was claimed as a credit by U.S.C. in Year 2, and next as a payment of the €150x of that Country X net income tax liability that U.S.C. improperly accrued and claimed as a credit in Year 1. Because all €150x of the Country X net income tax that was improperly accrued and claimed as a credit in Year 1 was paid within 24 months of December 31, Year 1, no foreign tax redetermination occurs, and no redetermination of U.S. tax liability is required, for Year 1.

(*ii*) *Year 2.* Under paragraph (d)(5)(iii) of this section, the €280x U.S.C. paid on January 15, Year 4, that relates to its Country X taxable year ending on March 31, Year 3, is first treated as a payment of the €70x = $70x of that Country X net income tax liability that properly accrued and was claimed as a credit by U.S.C. in Year 3, and next as a payment of the €210x = $210x of that Country X net income tax liability that U.S.C. improperly accrued and claimed as a credit in Year 2. Together with the €50x = $50x of U.S.C.'s Country X net income

tax liability that properly accrued and was claimed as a credit in Year 2, all €260x of the Country X net income tax that was accrued and claimed as a credit in Year 2 under U.S.C.'s improper method was paid within 24 months of December 31, Year 2. Accordingly, no foreign tax redetermination occurs, and no redetermination of U.S. tax liability is required, for Year 2.

(*iii*) *Year 3.* Under paragraph (d)(5)(iii) of this section, the €240x U.S.C. paid on January 15, Year 5, that relates to its Country X taxable year ending on March 31, Year 4, is first treated as a payment of the €60x = $60x of that Country X net income tax liability that properly accrued and was claimed as a credit by U.S.C. in Year 4, and next as a payment of the €180x = $180x of that Country X net income tax liability that U.S.C. improperly accrued and claimed as a credit in Year 3. Together with the €70x = $70x of U.S.C.'s Country X net income tax liability that properly accrued and was claimed as a credit by U.S.C. in Year 3, all €250x of the Country X net income tax that was accrued and claimed as a credit in Year 3 under U.S.C.'s improper method was paid within 24 months of December 31, Year 3. Accordingly, no foreign tax redetermination occurs, and no redetermination of U.S. tax liability is required, for Year 3.

(*iv*) *Year 4.* Under paragraph (d)(5)(iii) of this section, €60x = $60x of U.S.C.'s January 15, Year 5 payment of €240x with respect to its Country X net income tax liability for Year 4 is treated as a payment of €60x = $60x of Country X net income tax that, after application of the downward adjustment required by paragraph (d)(5)(ii) of this section, was accrued and claimed as a credit in Year 4, the year of change.

(vi) *Example 6: Failure to pay improperly-accrued tax within 24 months*—(A) *Facts.* The facts the same as in paragraph (d)(6)(v) of this section (the facts in *Example 5*), except that U.S.C. does not pay its €240x tax liability for its Country X taxable year ending on March 31, Year 4, until January 15 of Year 6, when the spot rate described in § 1.986(a)–1(a)(2)(i) is $1:€1.5.

(B) *Analysis.* The results are the same as in paragraphs (d)(6)(v)(B)(*2*)(*i*) and (*ii*) of this section (the analysis in *Example 5* for Year 1 and Year 2). With respect to Year 3, because the €180x = $180x of Year 4 foreign income tax that was improperly accrued and credited in Year 3 was not paid within 24 months of the end of Year 3, under section 905(c)(2) and § 1.905–3(a) that €180x = $180x is treated as refunded on December 31, Year 5, requiring a redetermination of U.S.C.'s Federal income tax liability for Year 3 (to reverse out the credit claimed). When in Year 6 U.S.C. pays the €240x of Country X income tax liability for Year 4, however, under paragraph (d)(5)(iii) of this section that payment is first treated as a payment of the €60x = $60x that was properly accrued and claimed as a credit in Year 4, and then as a payment of the €180x that was improperly accrued and claimed as a credit in Year 3 and that was treated as refunded in Year 5. Under section 905(c)(2)(B) and § 1.905–3(a), that Year 6 payment of accrued but unpaid tax is a second foreign tax redetermination for Year 3 that also requires a redetermination of U.S.C.'s U.S. tax liability. Under § 1.986(a)–1(a)(2), the €180x of redetermined tax for Year 3 is translated into dollars at the spot rate on January 15, Year 6, when the tax is paid (€180x × $1 / €1.5 = $120x). Under § 1.905–4(b)(1)(iv), U.S.C. may file one amended return accounting for both foreign tax redeterminations (which occur in two consecutive taxable years) with respect to Year 3, which taken together result in a reduction in U.S.C.'s foreign tax credit for Year 3 from $250x to $190x ($250x originally accrued − $180x unpaid after 24 months + $120x paid in Year 6).

(vii) *Example 7: Additional payment of improperly-accrued tax*—(A) *Facts.* The facts are the same as in paragraph (d)(6)(v)(A) of this section (the facts in *Example 5*), except that in Year 6, Country X assessed additional net income tax of €100x with respect to U.S.C.'s Country X taxable year ending March 31, Year 3, and after exhausting all effective and practical remedies to reduce its liability for Country X income tax, U.S.C. pays the additional assessed tax on September 15, Year 7, when the spot rate described in § 1.986(a)–1(a)(2)(i) is $1:€0.5.

(B) *Analysis.* Under paragraph (d)(3) of this section, the additional €100x of Country X income tax U.S.C. paid in Year 7 with respect to its foreign taxable year that ended March 31, Year 3, relates back and is considered to accrue in Year 3. However, under its improper method of accounting U.S.C. had accrued and claimed foreign tax credits for Country X net income tax that related to Year 3 on its Federal income tax returns for both Year 2 and Year 3. Accordingly, under paragraph (d)(5)(iii)(B) of this section U.S.C. must redetermine its U.S. tax liability for both Year 2 and Year 3 (and any other affected years) to account for the additional €100x of Country X net income tax liability, using the improper method it used to accrue foreign income taxes before the year of change. Therefore, €75x = $150x of the €100x of additional tax is treated as if it accrued in Year 2, and €25x = $50x of the additional tax is treated as if it accrued in Year 3. Under § 1.905–4(b)(1)(iii), U.S.C. may claim a refund for any resulting overpayment of U.S. tax for Year 2 or Year 3 or any other affected year by filing an amended return within the period provided in section 6511.

(viii) *Example 8: Tax improperly accrued before year of change exceeds tax properly accrued in year of change*—(A) *Facts.* U.S.C. owns all of the stock in CFC, a controlled foreign corporation organized in Country X. Country X imposes net income tax on Country X corporations at a rate of 10% only in the year its earnings are distributed to its shareholders, rather than in the year the income is earned. Both U.S.C. and CFC use the calendar year as their taxable year for both Federal and Country X income tax purposes and CFC uses the Euro as its functional currency. In each of Years 1–3, CFC earns €1,000x for both Federal and Country X income tax purposes of general category foreign base company sales income (before reduction for foreign income taxes). CFC improperly accrues €100x of Country X net income tax with respect to €1,000x of income at the end of each of Years 1 and 2, even though no distribution is made in those years. In Year 1, for which the average exchange rate is $1:€1, U.S.C. computes and includes in income with respect to CFC $900x of subpart F income, claims a deemed paid foreign tax credit of $100x under section 960(a), and has a section 78 dividend of $100x. In Year 2, for which the average exchange rate is $1:€0.5, U.S.C. computes and includes in income with respect to CFC $1,800x of subpart F income, claims a deemed paid foreign tax credit of $200x under section 960(a), and has a section 78 dividend of $200x. In Year 2, CFC makes a distribution to U.S.C. of €400x of earnings and pays €40x of net income tax to Country X. In Year 3, for which the average exchange rate is $1:€1, CFC makes another distribution to U.S.C. of €500x of earnings and pays €50x in net income tax to Country X. In Year 3, U.S.C. realizes its mistake and seeks permission from the IRS for CFC to change to a proper method of accruing foreign income taxes. In Year 4, for which the average exchange rate is $1:€2, CFC makes a distribution of €700x of earnings and pays €70x of net income tax to Country X.

TABLE 2 TO PARAGRAPH (d)(6)(viii)(A)

Taxable year ending	Foreign income tax properly accrued	Foreign income tax accrued under improper method
12/31/Y1 ($1:€1)	0	€100x = $100x.
12/31/Y2 ($1:€0.5)	€40x = $80x	€100x = $200x.
12/31/Y3 ($1:€1)	€50x = $50x	[year of change].
12/31/Y4 ($1:€2)	€70x = $35x.	

(B) *Analysis*—(*1*) *Downward adjustment.* Under paragraph (d)(5)(iv) of this section, CFC applies the rules of paragraph (d)(5) of this section as if it claimed a foreign tax credit under section 901 for Country X taxes. Under paragraph (d)(5)(ii) of this section, in Year 3, the year of change, CFC must reduce (but not below zero) the amount (in Euros) of Country X net income tax allocated and apportioned to its general category foreign base company sales income group that properly accrues in Year 3, €50x, by the amount of foreign income tax (in Euros) that was improperly accrued in that statutory grouping in a year before the year of change, and that had not properly accrued in either the year accrued or in another taxable year before the year of change. For all taxable years before the year of change, under its improper method CFC had accrued a total of €200x of foreign income tax with respect to its general category foreign base company sales income group, of which only €40x had properly accrued. Therefore, the downward adjustment required by paragraph (d)(5)(ii) of this section is €160x (€200x − €40x = €160x). In Year 3, CFC's €50x of eligible foreign income taxes in the general category foreign base company sales income group is reduced by €50x to zero. The €110x balance of the downward adjustment carries forward to Year 4, and reduces CFC's €70x of eligible foreign income taxes in the general category foreign base company sales income group by €70x to zero. The remaining €40x balance of the downward adjustment carries forward to later years and will reduce CFC's eligible foreign income taxes in the general category foreign base company sales income group until all improperly-accrued amounts are accounted for.

(*2*) *Application of section 905(c)*—(*i*) *Year 2.* Under paragraph (d)(5)(iii) of this section, CFC's payment in Year 2 of the €40x of Country X net income tax that properly accrued in Year 2, before the year of change, is treated as a payment of €40x of foreign income tax that CFC properly accrued in Year 2. The €60x of foreign income tax that CFC improperly accrued in Year 2 that remains unpaid at the end of Year 2 is not adjusted in Year 2. Under paragraph (d)(5)(iii) of this section, CFC's payment in Year 3 of €50x of Country X net income tax that properly accrued but was offset by the downward adjustment in Year 3 is treated as a payment of €50x of the €60x of Country X net income tax most recently improperly accrued in Year 2. In addition, CFC's payment in Year 4 of €70x of Country X net income tax that properly accrued but was offset by the downward adjustment in Year 4 is treated first as a payment of the remaining €10x of Country X net income tax that was improperly accrued in Year 2. Because all €100x of foreign income tax accrued in Year 2 under CFC's improper method of accounting is treated as paid within 24 months of December 31, Year 2, no foreign tax redetermination occurs, and no redetermination of CFC's foreign base company sales income, earnings and profits, and eligible foreign income taxes, or of U.S.C.'s $1,800x subpart F inclusion, $200x deemed paid credit, and $200x section 78 dividend or its U.S. tax liability is required, for Year 2.

(*ii*) *Year 1.* Because all €100x of the tax CFC improperly accrued in Year 1 remained unpaid as of December 31, Year 3, the date 24 months after the end of Year 1, under section 905(c)(2) and § 1.905–3(a) that €100x is treated as refunded on December 31, Year 3. Under § 1.905–3(b)(2)(ii), U.S.C. must redetermine its Federal income tax liability for Year 1 to account for the foreign tax redetermination, increasing CFC's foreign base company sales income and earnings and profits by €100x, and decreasing its eligible foreign income taxes by $100x. However, under paragraph (d)(5)(iii)(B) of this section €60x = $30x of CFC's payment in Year 4 of €70x of Country X net income tax that properly accrued but was offset by the downward adjustment in Year 4 is treated as a payment of €60x of the €100x of Country X net income tax that was improperly accrued in Year 1 and treated as refunded in Year 3. Under § 1.905–4(b)(1)(iv), U.S.C. may account for the two foreign tax redeterminations that occurred in Years 3 and 4 on a single amended Federal income tax return for Year 1. CFC's foreign base company sales income (taking into account the reduction for foreign income taxes) and earnings and profits for Year 1 are recomputed as €1,000x − €100x + €100x − €60x = €940x, and its eligible foreign income taxes are recomputed as $100x − $100x + $30x = $30x. U.S.C.'s subpart F inclusion with respect to CFC for Year 1 (translated at the average exchange rate for Year 1 of $1:€1) is increased from $900x to $940x (€940x × $1/€1), and the amount of foreign taxes deemed paid under section 960(a) and the amount of the section 78 dividend are reduced from $100x to $30x.

(*iii*) *Summary.* As of the end of Year 4, CFC and U.S.C. have been allowed a $30x foreign tax credit for Year 1, and a $200x foreign tax credit for Year 2. If in a later taxable year CFC distributes additional earnings to U.S.C. and accrues €40x of additional Country X net income tax that is offset by the balance of the €40x downward adjustment, CFC's payment of that €40x Country X net income tax liability will be treated as a payment of the remaining €40x of Country X net income tax that was improperly accrued in Year 1 and treated as refunded as of the end of Year 3.

(ix) *Example 9: Improperly deferred accrual*—(A) *Facts*—(*1*) *Foreign income tax accrued and paid.* U.S.C. is a domestic corporation that operates a foreign branch in Country X. All of U.S.C.'s gross and taxable income is foreign source foreign branch category income, and all of its foreign income taxes are properly allocated and apportioned under § 1.861–20 to the foreign branch category. U.S.C. uses the accrual method of accounting and uses the calendar year as its taxable year for both Federal and Country X income tax purposes. U.S.C. accrued €160x of Country X net income tax (as defined in § 1.901–2(a)(3)) with respect to Year 1. U.S.C. filed its Country X tax return and paid the €160x on June 30, Year 2. U.S.C. accrued €180x, €240x, and €150x of Country X tax for Years 2, 3, and 4, respectively, and paid with its timely filed Country X tax returns these tax liabilities on June 30 of Years 3, 4, and 5, respectively. The average exchange rate described in § 1.986(a)–1(a)(1) is

$1:€0.5 in Year 1, $1:€1 in Year 2, $1:€1.25 in Year 3, and $1:€1.5 in Year 4.

(*2*) *Improper accrual.* On its Federal income tax return for Year 1, U.S.C. claimed no foreign tax credit. On its Federal income tax return for Year 2, U.S.C. improperly accrued and claimed a credit for $160x (€160x of Country X tax for Year 1 that it paid in Year 2, translated into dollars at the average exchange rate for Year 2). Continuing with this improper method of accounting, U.S.C. improperly accrued and claimed a credit in Year 3 for $144x (€180x of Country X tax for Year 2 that it paid in Year 3, translated into dollars at the average exchange rate for Year 3). In Year 4, U.S.C. realizes its mistake and seeks permission from the IRS to change to a proper method of accruing foreign income taxes.

TABLE 3 TO PARAGRAPH (d)(6)(ix)(A)(*2*)

Taxable year ending	Foreign income tax properly accrued	Foreign income tax accrued under improper method
12/31/Y1 ($1:€0.5)	€160x = $320x	0.
12/31/Y2 ($1:€1)	€180x = $180x	€160x = $160x.
12/31/Y3 ($1:€1.25)	€240x = $192x	€180x = $144x.
12/31/Y4 ($1:€1.5)	€150x = $100x	[year of change].

(B) *Analysis*—(*1*) *Upward adjustment.* Under paragraph (d)(5)(ii) of this section, in Year 4, the year of change, U.S.C. increases the amount of Country X net income tax allocated and apportioned to its foreign branch category that properly accrues in Year 4, €150x, by the amount of foreign income tax in that same grouping that properly accrued in a taxable year before the taxable year of change, but which, under its improper method of accounting, U.S.C. failed to accrue and claim as either a credit or deduction before the taxable year of change. For all taxable years before the taxable year of change, under a proper method, U.S.C. would have accrued a total of €580x of foreign income tax, of which it accrued and claimed a credit for only €340x under its improper method. Thus, in Year 4, U.S.C. increases its €150x of properly accrued foreign income taxes in the foreign branch category by €240x (€580x − €340x), and may claim a credit in that year for the total, €390x, or $260x (translated into dollars at the average exchange rate for Year 4, as if the total amount properly accrued in Year 4).

(*2*) *Application of section 905(c).* Under paragraph (d)(5)(iii) of this section, U.S.C.'s payment of the €160x of Year 1 tax that U.S.C. accrued and claimed as a credit in Year 2 under its improper method of accounting is first treated as a payment of the amount of that (Year 1) tax liability that properly accrued in Year 2. Since none of the €160x properly accrued in Year 2, the €160x is treated as a payment of that (Year 1) tax liability that U.S.C. improperly accrued and claimed as a credit in Year 2, €160x. Because all €160x of the Country X net income tax that was improperly accrued and claimed as a credit in Year 2 was paid within 24 months of the end of Year 2, no foreign tax redetermination occurs, and no redetermination of U.S.C.'s $160x foreign tax credit and U.S. tax liability is required, for Year 2. Similarly, because all €180x of the Year 2 Country X net income tax that was improperly accrued and claimed as a credit in Year 3 was paid within 24 months of the end of Year 3, no foreign tax redetermination occurs, and no redetermination of U.S.C.'s $144x foreign tax credit and U.S. tax liability is required, for Year 3.

(e) *Election by cash method taxpayer to take credit on the accrual basis*—(1) *In general.* A taxpayer who uses the cash method of accounting for income may elect to take the foreign tax credit in the taxable year in which the taxes accrue in accordance with the rules in paragraph (d) of this section. Except as provided in paragraph (e)(2) of this section, an election pursuant to this paragraph (e)(1) must be made on a timely-filed original return, by checking the appropriate box on Form 1116 (Foreign Tax Credit (Individual, Estate, or Trust)) or Form 1118 (Foreign Tax Credit—Corporations) indicating the cash method taxpayer's choice to claim the foreign tax credit in the year the foreign income taxes accrue. Once made, the election is irrevocable and must be followed for purposes of claiming a foreign tax credit for all subsequent years. See section 905(a).

(2) *Exception for cash method taxpayers claiming a foreign tax credit for the first time.* If the year with respect to which an election pursuant to paragraph (e)(1) of this section to claim the foreign tax credit on an accrual basis is made (the ''election year'') is the first year for which a taxpayer has ever claimed a foreign tax credit, the election to claim the foreign tax credit on an accrual basis can also be made on an amended return filed within the period permitted under § 1.901–1(d)(1). The election is binding in the election year and all subsequent taxable years in which the taxpayer claims a foreign tax credit.

(3) *Treatment of taxes that accrued in a prior year.* In the election year and subsequent taxable years, a cash method taxpayer that claimed foreign tax credits on the cash basis in a prior taxable year may claim a foreign tax credit not only for foreign income taxes that accrue in the election year, but also for foreign income taxes that accrued (or are considered to accrue) in a taxable year preceding the election year but that are paid in the election year or subsequent taxable year, as applicable. Under paragraph (c) of this section, foreign income taxes paid with respect to a taxable year that precedes the election year may be claimed as a credit only in the year the taxes are paid and do not require a redetermination under section 905(c) or § 1.905–3 of U.S. tax liability in any prior year.

(4) *Examples.* The following examples illustrate the application of paragraph (e) of this section.

(i) *Example 1*—(A) *Facts.* A, a U.S. citizen who is a resident of Country X, is a cash method taxpayer who uses the calendar year as the taxable year for both U.S. and Country X tax purposes. In Year 1 through Year 5, A claims foreign tax credits for Country X foreign income taxes on the cash method, in the year the taxes are paid. For Year 6, A makes a timely election to claim foreign tax credits on the accrual basis. In Year 6, A accrues $100x of Country X foreign income taxes with respect to Year 6. Also in Year 6, A pays $80x in foreign income taxes that had accrued in Year 5.

(B) *Analysis.* Pursuant to paragraph (e)(3) of this section, A can claim a foreign tax credit in Year 6 for the $100x of Country X taxes that accrued in Year 6 and for the $80x of Country X taxes

that accrued in Year 5 but that are paid in Year 6.

(ii) *Example 2*—(A) *Facts.* The facts are the same as in paragraph (e)(4)(i)(A) of this section (the facts of *Example 1*), except that in Year 7, A is assessed an additional $10x of foreign income tax by Country X with respect to A's income in Year 3. After exhausting all effective and practical remedies, A pays the additional $10x to Country X in Year 8.

(B) *Analysis.* Pursuant to paragraph (e)(3) of this section, A can claim a foreign tax credit in Year 8 for the additional $10x of foreign income tax paid to Country X in Year 8 with respect to Year 3.

(f) *Rules for creditable foreign tax expenditures of partners, shareholders, or beneficiaries of a pass-through entity*—(1) *Effect of pass-through entity's method of accounting on when foreign tax credit or deduction can be claimed.* Each partner that elects to claim the foreign tax credit for a particular taxable year may treat its distributive share of the creditable foreign tax expenditures (as defined in § 1.704–1(b)(4)(viii)(*b*)) of the partnership that are paid or accrued by the partnership, under the partnership's method of accounting, during the partnership's taxable year ending with or within the partner's taxable year, as foreign income taxes paid or accrued (as the case may be, according to the partner's method of accounting for such taxes) by the partner in that particular taxable year. See §§ 1.702–1(a)(6) and 1.703–1(b)(2). Under §§ 1.905–3(a) and 1.905–4(b)(2), additional creditable foreign tax expenditures of the partnership that result from a change in the partnership's foreign tax liability for a prior taxable year, including additional taxes paid when a contest with a foreign tax authority is resolved, must be identified by the partnership as a prior year creditable foreign tax expenditure in the information reported to its partners for its taxable year in which the additional tax is actually paid. Subject to the rules in paragraphs (c) and (e) of this section, a partner using the cash method of accounting for foreign income taxes may claim a credit (or a deduction) for its distributive share of such additional taxes in the partner's taxable year with or within which the partnership's taxable year ends. Subject to the rules in paragraph (d) of this section, a partner using the accrual method of accounting for foreign income taxes may claim a credit for the partner's distributive share of such additional taxes in the relation-back year, or may claim a deduction in its taxable year with or within which the partnership's taxable year ends. The principles of this paragraph (f)(1) apply to determine the year in which a shareholder of a S corporation, or the grantor or beneficiary of an estate or trust, may claim a foreign tax credit (or a deduction) for its proportionate share of foreign income taxes paid or accrued by the S corporation, estate or trust. See sections 642(a), 671, 901(b)(5), and 1373(a) and §§ 1.1363–1(c)(2)(iii) and 1.1366–1(a)(2)(iv). See §§ 1.905–3 and 1.905–4 for notifications and adjustments of U.S. tax liability that are required if creditable foreign tax expenditures of a partnership or S corporation, or foreign income taxes paid or accrued by a trust or estate, are refunded or otherwise reduced.

(2) *Provisional credit for contested taxes.* Under paragraph (d)(3) of this section, a contested foreign tax liability does not accrue until the contest is resolved and the amount of the liability has been finally determined. In addition, under section 905(c)(2), a foreign income tax that is not paid within 24 months of the close of the taxable year to which the tax relates may not be claimed as a credit until the tax is actually paid. Thus, a partnership or other pass-through entity cannot take the contested tax into account as a creditable foreign tax expenditure until both the contest is resolved and the tax is actually paid. However, to the extent that a partnership or other pass-through entity remits a contested foreign tax liability to a foreign country, a partner or other owner of such pass-through entity that claims foreign tax credits on the accrual basis, may, by complying with the rules in paragraph (d)(4) of this section, elect to claim a provisional credit for its distributive share of such contested tax liability in the relation-back year.

(3) *Example.* The following example illustrates the application of paragraph (f) of this section.

(i) *Facts.* ABC is a U.S. partnership that is engaged in a trade or business in Country X. ABC has two U.S. partners, A and B. For Federal income tax purposes, ABC and partner A both use the accrual method of accounting and utilize a taxable year ending on September 30. ABC uses a taxable year ending on September 30 for Country X tax purposes. B is a calendar year taxpayer that uses the cash method of accounting. For its taxable year ending September 30, Year 1, ABC accrues $500x in foreign income tax to Country X; each partner's distributive share of the foreign income tax is $250x. In its taxable year ending September 30, Year 5, ABC settles a contest with Country X with respect to its Year 1 tax liability and, as a result of such settlement, accrues an additional $100x in foreign income tax for Year 1. ABC remits the additional tax to Country X in January of Year 6. A and B both elect to claim foreign tax credits for their respective taxable Years 1 through 6.

(ii) *Analysis.* For its taxable year ending September 30, Year 1, A can claim a credit for its $250x distributive share of foreign income taxes paid by ABC with respect to ABC's taxable year ending September 30, Year 1. Pursuant to paragraph (f)(1) of this section, B can claim its distributive share of $250x of foreign income tax for its taxable year ending December 31, Year 1, even if ABC does not remit the Year 1 taxes to Country X until Year 2. Although the additional $100x of Country X foreign income tax owed by ABC with respect to Year 1 accrued in its taxable year ending September 30, Year 5, upon conclusion of the contest, because ABC uses the accrual method of accounting, it does not take the additional tax into account until the tax is actually paid, in its taxable year ending September 30, Year 6. See section 905(c)(2)(B) and paragraph (f)(1) of this section. Pursuant to § 1.905–4(b)(2), ABC is required to notify the IRS and its partners of the foreign tax redetermination. A's distributive share of the additional tax relates back, is considered to accrue, and may be claimed as a credit for Year 1; however, A cannot claim a credit for the additional tax until Year 6, when ABC remits the tax to Country X. See § 1.905–3(a). B's distributive share of the additional tax does not relate back to Year 1 and is creditable in B's taxable year ending December 31, Year 6.

(g) *Blocked income.* * * *

(h) *Applicability dates.* This section applies to foreign income taxes paid or accrued in taxable years beginning on or after [date final regulations are filed in the **Federal Register**]. In addition, the election described in paragraph (d)(4) of this section may be made with respect to amounts of contested tax that are remitted in taxable years beginning on or after [date final regulations are filed in the **Federal Register**] and that relate to a taxable year beginning before [date final regulations are filed in the **Federal Register**].

■ **Par. 31.** Section 1.905–3, as amended in FR Doc. 2020–21819, published elsewhere in this issue of the **Federal Register**, is further amended:

■ 1. In paragraph (a), by revising the first two sentences.

■ 2. By adding paragraph (b)(4).

■ 3. By revising paragraph (d).

The revisions and addition read as follows:

§ 1.905–3 Adjustments to U.S. tax liability and to current earnings and profits as a result of a foreign tax redetermination.

(a) * * * For purposes of this section and § 1.905–4, the term *foreign tax redetermination* means a change in the liability for foreign income taxes (as defined in § 1.901–2(a)) or certain other changes described in this paragraph (a) that may affect a taxpayer's U.S. tax liability, including by reason of a change in the amount of its foreign tax credit, a change to claim a foreign tax credit for foreign income taxes that it previously deducted, a change to claim a deduction for foreign income taxes that it previously credited, a change in the amount of its distributions or inclusions under sections 951, 951A, or 1293, a change in the application of the high-tax exception described in § 1.954–1(d), or a change in the amount of tax determined under sections 1291(c)(2) and 1291(g)(1)(C)(ii). In the case of a taxpayer that claims the credit in the year the taxes are paid, a foreign tax redetermination occurs if any portion of the tax paid is subsequently refunded, or if the taxpayer's liability is subsequently determined to be less than the amount paid and claimed as a credit. * * *

(b) * * *

(4) *Change in election to claim a foreign tax credit.* A redetermination of U.S. tax liability is required to account for the effect of a timely change by the taxpayer to claim a foreign tax credit or a deduction for foreign income taxes paid or accrued in any taxable year as permitted under § 1.901–1(d).

* * * * *

(d) *Applicability dates.* Except as provided in this paragraph (d), this section applies to foreign tax redeterminations occurring in taxable years ending on or after December 16, 2019, and to foreign tax redeterminations of foreign corporations occurring in taxable years that end with or within a taxable year of a United States shareholder ending on or after December 16, 2019 and that relate to taxable years of foreign corporations beginning after December 31, 2017. The first two sentences of paragraph (a) of this section, and paragraph (b)(4) of this section, apply to foreign tax redeterminations occurring in taxable years beginning on or after [date final regulations are filed with the **Federal Register**].

§ 1.954–1 [Amended]

■ **Par. 32.** Section 1.954–1, as proposed to be amended in 85 FR 44650 (July 23, 2020), is further amended by removing the second sentence in paragraph (d)(1)(iv)(A).

■ **Par. 33.** Section 1.960–1, as amended in FR Doc. 2020–21819, published elsewhere in this issue of the **Federal Register**, is further amended:

■ 1. By revising paragraph (b)(4).

■ 2. By redesignating paragraphs (b)(5) through (37) as paragraphs (b)(6) through (38), respectively.

■ 3. By adding a new paragraph (b)(5).

■ 4. By revising newly redesignated paragraph (b)(6) and paragraph (c)(1)(ii).

■ 5. By redesignating paragraphs (c)(1)(iii) through (vi) as paragraphs (c)(1)(iv) through (vii).

■ 6. By adding a new paragraph (c)(1)(iii).

■ 7. In newly redesignated paragraph (c)(1)(iv), by removing the language ''Third, current year taxes'' in the first sentence adding the language ''Fourth, eligible current year taxes'' in its place.

■ 8. In newly redesignated paragraph (c)(1)(v), by removing the language ''Fourth,'' from the first sentence and adding the language ''Fifth,'' in its place.

■ 9. In newly redesignated paragraph (c)(1)(vi), by removing the language ''Fifth,'' from the first sentence and adding the language ''Sixth,'' in its place.

■ 10. In newly redesignated paragraph (c)(1)(vii), by removing the language ''Sixth,'' from the first sentence and adding the language ''Seventh,'' in its place.

■ 11. In paragraph (d)(1), by removing the language ''the U.S. dollar amount of current year taxes'' from the first sentence and adding the language ''the U.S. dollar amount of eligible current year taxes'' in its place.

■ 12. In paragraph (d)(3)(i) introductory text, by removing the language ''current year taxes'' from the second sentence and adding the language ''eligible current year taxes'' in its place.

■ 13. In paragraph (d)(3)(ii)(A), by revising the last sentence.

■ 14. In paragraph (d)(3)(ii)(B), by removing the language ''a current year tax'' from the first sentence and adding the language ''an eligible current year tax'' in its place.

■ 15. In paragraph (f)(1)(ii), by removing the language ''tax'' from the fifth sentence and adding the language ''eligible current year tax'' in its place.

■ 16. In paragraph (f)(2)(ii)(B)(*1*), by removing the language ''current year taxes'' from the last sentence and adding the language ''eligible current year taxes'' in its place.

■ 17. In paragraph (f)(2)(ii)(B)(*2*), by removing the language ''current year taxes'' from the fifth sentence and adding the language ''eligible current year taxes'' in its place.

The additions and revisions read as follows:

§ 1.960–1 Overview, definitions, and computational rules for determining foreign income taxes deemed paid under section 960(a), (b), and (d).

* * * * *

(b) * * *

(4) *Current year tax.* The term *current year tax* means a foreign income tax that is paid or accrued by a controlled foreign corporation in a current taxable year (taking into account any adjustments resulting from a foreign tax redetermination (as defined in § 1.905–3(a)). See § 1.905–1 for rules on when foreign income taxes are considered paid or accrued for foreign tax credit purposes; see also § 1.367(b)–7(g) for rules relating to foreign income taxes associated with foreign section 381 transactions and hovering deficits.

(5) *Eligible current year tax.* The term *eligible current year tax* means a current year tax, except that an eligible current year tax does not include a current year tax paid or accrued by a controlled foreign corporation for which a credit is disallowed or suspended at the level of the controlled foreign corporation. See, for example, sections 245A(e)(3), 901(k)(1), (l), and (m), 909, and 6038(c)(1)(B). Eligible current year tax, however, includes a current year tax that may be deemed paid but for which a credit is reduced or disallowed at the level of the United States shareholder. See, for example, sections 901(e), 901(j), 901(k)(2), 908, 965(g), and 6038(c)(1)(A).

(6) *Foreign income tax.* The term *foreign income tax* has the meaning provided in § 1.901–2(a).

* * * * *

(c) * * *

(1) * * *

(ii) Second, deductions (other than for current year taxes) of the controlled foreign corporation for the current taxable year are allocated and apportioned to reduce gross income in the section 904 categories and the income groups within a section 904 category. See paragraph (d)(3)(i) of this section. Deductions for current year taxes (other than eligible current year taxes) of the controlled foreign corporation for the current taxable year are allocated and apportioned to reduce gross income in the section 904 categories and the income groups within a section 904 category. Additionally, the functional currency amounts of eligible current year taxes are allocated and apportioned to reduce gross income in the section 904 categories and the income groups within a section 904 category, and to reduce earnings and profits in the PTEP groups that were increased as provided in paragraph (c)(1)(i) of this section. No deductions other than eligible current year taxes

may be allocated and apportioned to PTEP groups. See paragraph (d)(3)(ii) of this section.

(iii) Third, for purposes of computing foreign taxes deemed paid, eligible current year taxes that were allocated and apportioned to income groups and PTEP groups in the section 904 categories are translated into U.S. dollars in accordance with section 986(a).

* * * * *

(d) * * *

(3) * * *

(ii) * * *

(A) * * * For purposes of determining foreign income taxes deemed paid under the rules in §§ 1.960–2 and 1.960–3, the U.S. dollar amount of eligible current year taxes is assigned to the section 904 categories, income groups, and PTEP groups (to the extent provided in paragraph (d)(3)(ii)(B) of this section) to which the eligible current year taxes are allocated and apportioned.

* * * * *

■ **Par. 34.** Section 1.960–2, as amended in FR Doc. 2020–21819, published elsewhere in this issue of the **Federal Register**, is further amended:

■ 1. In paragraph (b)(2), by removing the language ''current year taxes'' and adding the language ''eligible current year taxes'' in its place.

■ 2. In paragraph (b)(3)(i), by removing the language ''current year taxes'' each place it appears and adding the language ''eligible current year taxes'' in its place.

■ 3. In paragraph (b)(5)(i), by revising the seventh sentence.

■ 4. In paragraph (b)(5)(ii)(A), by revising the first and second sentences.

■ 5. In paragraph (b)(5)(ii)(B), by revising the first and second sentences.

■ 6. In paragraph (c)(4), by removing the language ''current year taxes'' and adding the language ''eligible current year taxes'' in its place.

■ 7. In paragraph (c)(5), by removing the language ''current year taxes'' each place it appears and adding the language ''eligible current year taxes'' in its place.

■ 8. In paragraph (c)(7)(i)(A), by revising the fifth sentence.

■ 9. In paragraph (c)(7)(i)(B), by revising the first and second sentences.

■ 10. In paragraph (c)(7)(ii)(A)(*1*), by revising the ninth and eleventh sentences.

■ 11. In paragraph (c)(7)(ii)(B)(*1*)(*i*), by revising the first and second sentences.

■ 12. In paragraph (c)(7)(ii)(B)(*1*)(*ii*), by removing the language ''foreign income taxes'' in the first sentence and adding the language ''eligible current year taxes'' in its place.

The additions and revisions read as follows:

§ 1.960–2 Foreign income taxes deemed paid under sections 960(a) and (d).

* * * * *

(b) * * *

(5) * * *

(i) * * * CFC has current year taxes, all of which are eligible current year taxes, translated into U.S. dollars, of $740,000x that are allocated and apportioned as follows: $50,000x to subpart F income group 1; $240,000x to subpart F income group 2; and $450,000x to subpart F income group 3. * * *

(ii) * * *

(A) * * * Under paragraphs (b)(2) and (3) of this section, the amount of CFC's foreign income taxes that are properly attributable to items of income in subpart F income group 1 to which a subpart F inclusion is attributable equals USP's proportionate share of the eligible current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to subpart F income group 1, which is $40,000x ($50,000x × 800,000u/1,000,000u). Under paragraphs (b)(2) and (3) of this section, the amount of CFC's foreign income taxes that are properly attributable to items of income in subpart F income group 2 to which a subpart F inclusion is attributable equals USP's proportionate share of the eligible current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to subpart F income group 2, which is $192,000x ($240,000x × 1,920,000u/2,400,000u). * * *

(B) * * * Under paragraphs (b)(2) and (3) of this section, the amount of CFC's foreign income taxes that are properly attributable to items of income in subpart F income group 3 to which a subpart F inclusion is attributable equals USP's proportionate share of the eligible current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to subpart F income group 3, which is $360,000x ($450,000x × 1,440,000u/1,800,000u). CFC has no other subpart F income groups within the general category. * * *

* * * * *

(c) * * *

(7) * * *

(i) * * *

(A) * * * CFC1 has current year taxes, all of which are eligible current year taxes, translated into U.S. dollars, of $400x that are all allocated and apportioned to the tested income group. * * *

(B) * * * Under paragraph (c)(5) of this section, USP's proportionate share of the eligible current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to CFC1's tested income group is $400x ($400x × 2,000u/2,000u). Therefore, under paragraph (c)(4) of this section, the amount of foreign income taxes that are properly attributable to tested income taxes taken into account by USP under section 951A(a) and § 1.951A–1(b) is $400x. * * *

(ii) * * *

(A) * * *

(*1*) * * * CFC1 has current year taxes, all of which are eligible current year taxes, translated into U.S. dollars, of $100x that are all allocated and apportioned to CFC1's tested income group. * * * CFC2 has current year taxes, all of which are eligible current year taxes, translated into U.S. dollars, of $20x that are allocated and apportioned to CFC2's tested income group.

* * * * *

(B) * * *

(*1*) * * *

(*i*) * * * Under paragraphs (c)(5) and (6) of this section, US1's proportionate share of the eligible current year taxes that are allocated and apportioned under § 1.960–1(d)(3)(ii) to CFC1's tested income group is $95x ($100x × 285u/300u). Therefore, under paragraph (c)(4) of this section, the amount of the foreign income taxes that are properly attributable to tested income taxes taken into account by US1 under section 951A(a) and § 1.951A–1(b) is $95x. * * *

* * * * *

■ **Par. 35.** Section 1.960–7, as amended in FR Doc. 2020–21819, published elsewhere in this issue of the **Federal Register**, is further amended by revising paragraph (b) to read as follows:

§ 1.960–7 Applicability dates.

* * * * *

(b) Section 1.960–1(c)(2) and (d)(3)(ii) apply to taxable years of a foreign corporation beginning after December 31, 2019, and to each taxable year of a domestic corporation that is a United States shareholder of the foreign corporation in which or with which such taxable year of such foreign corporation ends. For taxable years of a foreign corporation that end on or after December 4, 2018, and also begin before January 1, 2020, see § 1.960–1(c)(2) and (d)(3)(ii) as in effect on December 17, 2019. Paragraphs (b)(4), (5), and (6), (c)(1)(ii), (iii), and (iv), and (d)(3)(ii)(A) and (B) of § 1.960–1, and paragraphs (b)(2), (b)(3)(i), (b)(5)(i), (b)(5)(iv)(A), and (c)(4), (5), and (7) of § 1.960–2, apply to taxable years of foreign corporations beginning on or after [date final regulations are filed in the **Federal Register**], and to each taxable year of a

domestic corporation that is a United States shareholder of the foreign corporation in which or with which such taxable year of such foreign corporation ends. For taxable years of foreign corporations beginning before [date final regulations are filed in the **Federal Register**], with respect to the paragraphs described in the preceding sentence, see §§ 1.960–1 and 1.960–2 as in effect on November 12, 2020.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2020–21818 Filed 11–2–20; 11:15 am]

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Part IV

Department of the Treasury

Internal Revenue Service

Department of Labor

Employee Benefits Security Administration

Department of Health and Human Services

26 CFR Part 54

29 CFR Part 2590

45 CFR Parts 147 and 158

Transparency in Coverage; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9929]

RIN 1545–BP47

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB93

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147 and 158

[CMS–9915–F]

RIN 0938–AU04

Transparency in Coverage

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The final rules set forth requirements for group health plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request to a participant, beneficiary, or enrollee (or his or her authorized representative), including an estimate of the individual's cost-sharing liability for covered items or services furnished by a particular provider. Under the final rules, plans and issuers are required to make this information available on an internet website and, if requested, in paper form, thereby allowing a participant, beneficiary, or enrollee (or his or her authorized representative) to obtain an estimate and understanding of the individual's out-of-pocket expenses and effectively shop for items and services. The final rules also require plans and issuers to disclose in-network provider negotiated rates, historical out-of-network allowed amounts, and drug pricing information through three machine-readable files posted on an internet website, thereby allowing the public to have access to health coverage information that can be used to understand health care pricing and potentially dampen the rise in health care spending. The Department of Health and Human Services (HHS) also finalizes amendments to its medical loss ratio (MLR) program rules to allow issuers offering group or individual health insurance coverage to receive credit in their MLR calculations for savings they share with enrollees that result from the enrollees shopping for, and receiving care from, lower-cost, higher-value providers.

DATES:

Effective date: The final rules are effective on January 11, 2021.

Applicability date: See the **SUPPLEMENTARY INFORMATION** section for information on the applicability dates.

FOR FURTHER INFORMATION CONTACT: Deborah Bryant, Centers for Medicare & Medicaid Services, (301) 492–4293. Christopher Dellana, Internal Revenue Service, (202) 317–5500. Matthew Litton or Frank Kolb, Employee Benefits Security Administration, (202) 693–8335.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor (DOL) concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1–866–444–EBSA (3272) or visit DOL's website (*http://www.dol.gov/ebsa*). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website (*www.cms.gov/cciio*) and information on health reform can be found at *http://www.healthcare.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The final rules require group health plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request, to a participant, beneficiary, or enrollee, which, unless otherwise indicated, for the purpose of the final rules includes an authorized representative, and require plans and issuers to disclose in-network provider rates, historical out-of-network allowed amounts and the associated billed charges, and negotiated rates for prescription drugs in 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 147. HHS also finalizes amendments to its MLR program rules in 45 CFR part 158.

A. Statutory Background and Enactment of PPACA

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010 (collectively, PPACA). As relevant here, PPACA reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service (PHS) Act relating to health coverage requirements for group health plans and health insurance issuers in the group and individual markets. The term group health plan includes both insured and self-insured group health plans.

PPACA also added section 715 to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815 to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act, PHS Act sections 2701 through 2728, into ERISA and the Code, making them applicable to group health plans, and health insurance issuers providing coverage in connection with group health plans.

1. Transparency in Coverage

Section 2715A of the PHS Act provides that group health plans and health insurance issuers offering group or individual health insurance coverage must comply with section 1311(e)(3) of PPACA, which addresses transparency in health coverage and imposes certain reporting and disclosure requirements for health plans that are seeking certification as qualified health plans (QHPs) that may be offered on an Exchange. A plan or coverage that is not offered through an Exchange (as defined by section 1311(b)(1) of PPACA) is required to submit the information required to the Secretary of HHS and the relevant state's insurance commissioner, and to make that information available to the public.

Paragraph (A) of section 1311(e)(3) of PPACA requires a plan seeking certification as a QHP to make the following information available to the public and submit it to state insurance regulators, the Secretary of HHS, and the Exchange:

- Claims payment policies and practices,
- periodic financial disclosures,
- data on enrollment,
- data on disenrollment,
- data on the number of claims that are denied,
- data on rating practices,
- information on cost-sharing and payments with respect to any out-of-network coverage, and
- information on enrollee and participant rights under Title I of PPACA.

Paragraph (A) also requires a plan seeking certification as a QHP to submit any ''[o]ther information as determined appropriate by the Secretary.''

Paragraph (C) of section 1311(e)(3) of PPACA requires plans, as a requirement of certification as a QHP, to permit individuals to learn the amount of cost sharing (including deductibles, copayments, and coinsurance) under the individual's coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by an in-network provider in a timely manner upon the request of the individual. Paragraph (C) specifies that, at a minimum, such information must be made available to the individual through an internet website and through other means for individuals without access to the internet.

Together these statutory provisions require the overriding majority of private health plans [1] to disseminate a substantial amount of information to provide transparency in coverage. The portions of the final rules that require plans and issuers to disclose cost-sharing information upon request, to a participant, beneficiary, or enrollee implement paragraph (C) of section 1311(e)(3) of PPACA. The portions of the final rules that require plans and issuers to disclose in-network provider rates, historical out-of-network allowed amounts and the associated billed charges, and negotiated rates for prescription drugs implement paragraph (A) of section 1311(e)(3) of PPACA. The requirements to disclose out-of-network allowed amounts specifically implements the requirement in section 1311(e)(3)(A)(vii) to provide information on ''payments with respect to any out-of-network coverage.'' In addition to payment information on out-of-network charges, the Secretary of HHS determined that payment information on in-network rates and prescription drugs is also appropriate information to require plans and issuers to disclose to provide transparency in coverage under section 1311(e)(3)(A)(ix).

PPACA's transparency in coverage requirements were enacted in coordination with a set of requirements that transformed the regulation of private market health plans and issuers. These requirements for the first time apply a comprehensive framework for regulating private health coverage through Federal law.[2] Prior to PPACA, Federal law relied on states to be the primary regulators of health insurance, but applied only a limited set of Federal requirements to govern private health coverage. Where Federal law regulated private health coverage, there was a substantial variation in how these regulations applied, depending on whether private health coverage was self-insured group coverage, large group insurance coverage, small group insurance coverage, or individual insurance coverage. To establish a comprehensive framework for regulating private health coverage, PPACA first set out a series of requirements on ''Improving Coverage'' that generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage.[3] These requirements ranged from the prohibition on lifetime or annual dollar limits in section 2711 of the PHS Act to the requirement to cover out-of-network emergency services in section 2719A of the PHS Act and include the transparency in coverage requirements in section 2715A of the PHS Act.[4] By including transparency in coverage in this set of requirements that apply to most private coverage, Congress established transparency as a key component to PPACA's comprehensive framework for regulating private health coverage.[5]

On March 27, 2012, HHS issued the Exchange Establishment final rule that implemented sections 1311(e)(3)(A) through (C) of PPACA at 45 CFR 155.1040(a) through (c) and 156.220.[6] The Exchange Establishment final rule created standards for QHP issuers to submit specific information related to transparency in coverage. QHPs are required to post and make data related to transparency in coverage available to the public in plain language and submit this same data to HHS, the Exchange, and the relevant state insurance commissioner. In the preamble to the Exchange Establishment final rule, HHS noted that ''health plan standards set forth under the final rules are, for the most part, strictly related to QHPs certified to be offered through the Exchange and not the entire individual and small group market. Such policies for the entire individual and small and large group markets have been, and will continue to be, addressed in separate rulemaking issued by HHS, and the Departments of Labor and the Treasury.''

2. Medical Loss Ratio

Section 2718(a) of the PHS Act, as added by PPACA, generally requires health insurance issuers offering group or individual health insurance coverage (including a grandfathered health insurance plan) to submit an annual report to the Secretary of HHS that details the percentage of premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under health coverage and on activities that improve health care quality. The proportion of premium revenue spent on clinical services and quality improvement activities is called the MLR. Section 2718(b) of the PHS Act requires an issuer to provide annual rebates to enrollees if its MLR falls below specified standards (generally 80 percent for the individual and small group markets, and 85 percent for the large group market). HHS published an interim final rule to implement the MLR program in the December 1, 2010 **Federal Register** (75 FR 74863). A final rule was published in the December 7, 2011 **Federal Register** (76 FR 76573). The MLR program requirements were amended in final rules published in the December 7, 2011 **Federal Register** (76 FR 76595), the May 16, 2012 **Federal Register** (77 FR 28790), the March 11, 2014 **Federal Register** (79 FR 13743),

[1] As of 2018, private, non-grandfathered health plans that must comply with these statutory provisions covered more than 92 percent of the almost 177 million people covered by private health coverage. The remaining 7.7 percent were covered by grandfathered health plans or were enrolled in short-term limited duration coverage or health care sharing ministries. *See* Kaiser Family Foundation, Health Insurance Coverage of the Total Population in 2018, *https://www.kff.org/other/state-indicator/total-population/?dataView=1&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D*, last accessed October 5, 2020.

[2] *See* Jost, T.S. ''Loopholes in the Affordable Care Act: Regulatory gaps and border crossing techniques and how to address them.'' St. Louis University Journal of Health Law and Policy, Washington & Lee Legal Studies Paper No. 2011–16. August 15, 2011 (explaining that ''[t]he Affordable Care Act was meant to regulate health care plans comprehensively'' and providing further details on the scope of PPACA). Available at: *https://scholarlycommons.law.wlu.edu/wlufac/265/*.

[3] Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119 (2010), section 1001.

[4] In addition to these requirements, PPACA's ''Improving Coverage'' requirements include, among other things: The prohibition on rescissions in section 2712 of the PHS Act; the requirement to cover preventive health services without cost sharing requirements in section 2713 of the PHS Act; the extension of coverage to dependents up to age 26 in section 2714 of the PHS Act; the requirement to provide a summary of benefits and coverage in section 2715 of the PHS Act; quality reporting requirements in section 2717 of the PHS Act; and appeals process requirements in section in 2719 of the PHS Act.

[5] Transparency was included as an important and transformative element in other leading comprehensive health reform proposals. *See* Porter, M. and Teisberg, E. *Redefining Health Care.* Harvard Business School Press. Boston, MA. 2006. (''Perhaps the most fundamental role of government in enabling value-based competition is to ensure that universal, high-quality information on provider outcomes and prices for every medical condition is collected and disseminated. This single step will have far-reaching and pervasive effects throughout the system . . . .'').

[6] 77 FR 18310 (Mar. 27, 2012).

the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), the April 17, 2018 **Federal Register** (83 FR 16930), the April 25, 2019 **Federal Register** (84 FR 17454), and the February 6, 2020 **Federal Register** (85 FR 7088).

B. Benefits of Transparency in Health Coverage and Past Efforts To Promote Transparency

PPACA's transparency in coverage requirements can help ensure the accurate and timely disclosure of information appropriate to support an efficient and competitive health care market. A well-functioning, competitive market depends on information being available to buyers and sellers.[7] As President Trump's ''Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First'' explains: ''To make fully informed decisions about their health care, patients must know the price and quality of a good or service in advance.'' Yet, as the Executive order then notes, ''patients often lack both access to useful price and quality information and the incentives to find low-cost, high-quality care.'' The lack of this information is widely understood to be one of the root problems causing dysfunction within America's health care system.

The Departments of Labor, HHS, and the Treasury (Departments) are of the view that transparency in health coverage requirements will strengthen America's health care system by giving health care consumers, researchers, regulators, lawmakers, health innovators, and other health care stakeholders the information they need to make, or assist others in making informed decisions about health care purchases. Health care consumers include various persons and entities that finance health care needs through the purchase of insurance. Health care consumers also include uninsured persons without health coverage who must pay out-of-pocket for health care items and services and uninsured persons who may be shopping for health coverage. Employers that sponsor health plans for their employees and government programs that provide health care services and benefits to consumers are also health care consumers.

By requiring the dissemination of price and benefit information directly to consumers and to the public, the transparency in coverage requirements will provide the following consumer benefits:

- Enables consumers to evaluate health care options and to make cost-conscious decisions;
- strengthens the support consumers receive from stakeholders that help protect and engage consumers;
- reduces potential surprises in relation to individual consumers' out-of-pocket costs for health care services;
- creates a competitive dynamic that may narrow price dispersion for the same items and services in the same health care markets; and
- puts downward pressure on prices which, in turn, potentially lowers overall health care costs.

The goal of the final rules is to deliver these benefits to all consumers and health care stakeholders through greater transparency in coverage.

Comments received in response to the proposed rules on transparency in coverage (discussed in more detail later in this preamble) have strengthened the Departments' view that this price transparency effort will equip the public with information to actively and effectively participate in the health care system as consumers.[8] The majority of commenters acknowledged the importance of the availability of health care pricing information and appropriate tools to assist consumers in health care decision-making and managing health care costs. For these reasons and those explained in more detail below in this preamble, the Departments continue to be of the view that price transparency efforts are crucial to providing consumers (individual and institutional) with meaningful and actionable pricing information in an effort to contain the growth of health care costs.

1. Transparency Provides Necessary Information for Consumers To Make More Informed Health Care Spending Decisions

As explained in the report, ''Reforming America's Healthcare System Through Choice and Competition,'' consumers have an important role to play in controlling costs, but consumers must have meaningful information in order to create the market forces necessary to achieve lower health care costs.[9] When consumers seek care, they do not typically know whether they could have received the same service from another provider at lower prices. Third-party payers negotiate prices on the consumer's behalf and reimburse costs directly to health care providers, concealing the actual price from the consumer at the point of care. After receiving care, consumers typically receive an Explanation of Benefits (EOB), which details the price charged by the provider, contracted or negotiated rate, and consumer cost sharing. Often, only after services are rendered is the cost of care disclosed to the consumer.

Historically, there has been little to no incentive for some consumers to consider price and seek lower-cost care.[10] Rapidly rising health care spending in the past 20 years, however, has led to consumers shouldering a greater portion of their health care costs through increases in out-of-pocket expenses.[11]

Since 1970, per capita out-of-pocket expenditures have nearly doubled due to a number of factors.[12] These factors include increased enrollment in high deductible health plans (HDHPs) and accompanying health savings accounts (HSAs), and increased plan and issuer reliance on payments towards deductibles comprising the proportion of total cost-sharing payments.[13] As explained in the preamble to the proposed rules, these shifts in plan design and enrollment are correlated with consumers bearing a greater share of their overall health care costs in the private health insurance market than in previous years.[14] From 2002 to the enactment of PPACA in 2010,

[7] Porter, M. and Teisberg, E. *Redefining Health Care.* Harvard Business School Press. Boston, MA. 2006, pg. 54. (''Information is fundamental to competition in any well-functioning market. It enables buyers to shop for the best value and allows sellers to compare themselves to rivals. Without relevant information, doctors cannot compare their results to best practice and to other providers. And without appropriate information, patient choice has little meaning.'').

[8] 84 FR 65464 (Nov. 27, 2019).

[9] Azar, A.M., Mnuchin, S.T., and Acosta, A. ''Reforming America's Healthcare System Through Choice and Competition.'' United States, Department of Health and Human Services. December 3, 2018. Available at: *https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.*

[10] *Id.*

[11] Claxton, G., Levitt, L., Long M. ''Payments for cost sharing increasing rapidly over time.'' Peterson-Kaiser Health System Tracker. April 2016. Available at: *https://www.healthsystemtracker.org/brief/payments-for-cost-sharing-increasing-rapidly-over-time/.*

[12] ''Out-of-pocket spending.'' Peterson-KFF Health System Tracker. May 2020. Available at: *https://www.healthsystemtracker.org/indicator/access-affordability/out-of-pocket-spending/.*

[13] HDHP as defined in section 223(c)(2) of the Code; *see also* Claxton, G., Levitt, L., Long, M. ''Payments for cost sharing increasing rapidly over time.'' Peterson-KFF Health System Tracker. April 2016. Available at: *https://www.healthsystemtracker.org/brief/payments-for-cost-sharing-increasing-rapidly-over-time/.*

[14] 84 FR 65464, 65465 (Nov. 27, 2019).

nationally, the percentage of private sector employees enrolled in a health plan with a deductible increased from 47.6 percent to 77.5 percent and continued to increase to 86.6 percent in 2019.[15] Average family deductibles for private sector employees grew from $958 in 2002 to $1,975 in 2010, and then to $3,655 in 2019—an 85 percent increase since the enactment of PPACA.[16] These changes represent a substantial increase in the amount that consumers must pay for health care before insurance begins to cover items or services.[17] Deductibles made up 52 percent of cost-sharing spending in 2016, up from 30 percent in 2006, while copays dropped from 43 percent to 17 percent of cost-sharing payments over the same period.[18] The gradual shift away from copayments, which are predictable to the consumer through their set dollar amounts for each covered item or service, to deductibles and coinsurance, has increased the need for consumers to know the negotiated price in order to plan ahead and budget for out-of-pocket costs. Over time, price disclosure can improve consumers' ability to better manage costs of utilized health care for a variety of health care plans. Increased enrollment in HDHPs and the shift to coinsurance across plan and benefit designs means that consumers have a vested interest in learning the costs of care prior to paying for items or services, as they are responsible for paying out-of-pocket expenditures, which are directly dependent on the negotiated or contractual price.

These trends in designing health plans have led to consumers bearing an increased share of their health care costs. The fact that more consumers are bearing greater financial responsibility for the cost of their health care provides an opportunity to establish a more consumer-directed and consumer-driven health care market. Eighty-eight percent of consumers support requirements for providers and issuers to disclose prices prior to care.[19] If consumers have better pricing information and can shop for health care items and services more efficiently, they can increase competition and demand for lower prices.[20] However, consumers generally have little information regarding negotiated rates or out-of-network costs until after services are rendered. There is also wide variability in health care prices for the same service.[21] As a result, it can be difficult for consumers to estimate potential out-of-pocket costs.

2. Transparency Strengthens Stakeholders' Ability To Support Consumers

Making price transparency information publicly available strengthens the work of other health care stakeholders that help provide care or promote access to care to consumers, or otherwise aim to protect consumers and their interests in the health care system. These entities include researchers, regulators, lawmakers, patient and consumer advocates, and businesses that provide consumer support tools and services. A key aspect of transparency in coverage is to make health care pricing information more accessible and useful to consumers by making the information available to persons and entities with the requisite experience and expertise to assist individual consumers and other health care purchasers to make informed health care decisions.

With information on pricing, these other health care stakeholders can better fulfill each of the unique roles they play to improve America's health care system for consumers. For instance, with pricing information researchers could better assess the cost-effectiveness of various treatments; state regulators could better review issuers' proposed rate increases; patient advocates could better help guide patients through care plans; employers could adopt incentives for consumers to choose more cost-effective care; and entrepreneurs could develop tools that help doctors better engage with patients.

3. Transparency Reduces the Potential for Surprise Billing

Making the price of care available to consumers before they receive care can reduce the potential for consumers to be surprised by the price of a health care item or service when they receive the bill after receiving care. However, accessible pricing information holds special value for insured consumers.[22] Surprise billing has become a substantial concern for insured consumers, in particular, consumers who receive a bill from an out-of-network provider when they thought an in-network provider was treating them. While price transparency alone is not a complete solution to this problem, the disclosure of pricing directly to consumers could help mitigate some unexpected health care costs. As just noted, making pricing information public can also strengthen other health care stakeholders' ability to protect consumers. In the case of surprise billing, public information on pricing for in-network and out-of-network services could allow stakeholders to develop better tools to help patients avoid surprises and improve oversight of health insurance issuers, plans, and providers.

4. Transparency Increases Competition and Contains Costs

Without transparency in pricing, market forces cannot drive competition. This lack of competition in many health care markets is demonstrated by significant, unexplained variations in prices for procedures, even within a single region.[23] For example, studies of price variation within California and nationally suggest that there is substantial opportunity for increased transparency to save money by shifting patients from high to lower-cost providers.[24] The Departments are of the

[15] *See* ''Medical Expenditure Panel Survey. Insurance Component National-Level Summary Tables.'' United States Department for Health and Human Services Agency for Healthcare Research and Quality. Available at: *https://www.meps.ahrq.gov/mepsweb/data_stats/quick_tables_search.jsp?component=2&subcomponent=1.*

[16] *Id.*

[17] McCarthy-Alfano, M., et al. ''Measuring the burden of health care costs for working families.'' Health Affairs. April 2, 2019. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20190327.999531/full/.*

[18] Claxton, G. et al. ''Increases in cost-sharing payments continue to outpace wage growth.'' Peterson-KFF Health System Tracker. June 15, 2018. Available at: *https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/.*

[19] ''Harvard CAPS Harris Poll.'' Harvard University. May 2019. Available at: *https://harvardharrispoll.com/wp-content/uploads/2019/06/HHP_May19_vF.pdf?utm_source=hs_email&utm_medium=email&_hsenc=p2ANqtz--NgSdTYggGUP4tWyR2IEQ7i8TCg1s3DcHuQyhErIgkX3KFUi3SFgl9OZKm4-JUOOi9tmMQ.*

[20] Azar, A.M., Mnuchin, S.T., and Acosta, A. ''Reforming America's Healthcare System Through Choice and Competition.'' United States, Department of Health and Human Services. December 3, 2018. Available at: *https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.*

[21] Cooper, Z., et al. ''The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured.'' *The Quarterly Journal of Economics,* Vol. 134. Issue 1. February 2019. September 4, 2018. Available at: *https://academic.oup.com/qje/article/134/1/51/5090426?searchresult=1.*

[22] *See* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Secretary of Health and Human Services' Report on: Addressing Surprise Medical Billing, at p. 3. July 2020. (recognizing that HHS regulatory action to encourage price transparency by insurers ''can serve as the backbone for a more comprehensive surprise billing solution''). Available at *https://aspe.hhs.gov/system/files/pdf/263871/Surprise-Medical-Billing.pdf.*

[23] *Id.*

[24] Boynton, A., Robinson, J. ''Appropriate Use of Reference Pricing Can Increase Value.'' Health Affairs Blog. July 7, 2015. Available at: *https://www.healthaffairs.org/do/10.1377/*

Continued

view that consumers will take advantage of increased transparency to shop for their health care if price transparency is put into place nationwide.[25] Many empirical studies have investigated the impact of price transparency on non-health care markets, with most research showing that ''price transparency leads to lower and more uniform prices, a view consistent with predictions of standard economic theory.'' [26] Studies suggest that consumers want and will use actionable pricing information to shop for more cost-effective care.[27] For example, when automobile prices were presented transparently on the internet, inclusive of the dealer invoice price, the consumers who did not like the traditional bargaining process were able to reduce spending overall by 1.5 percent.[28] Another study demonstrated the public display of life insurance prices for comparison led to a 5 percent decrease in the consumer price.[29] Price transparency also reduced price dispersion across other markets, such as the airline industry, which saw a reduction in price dispersion from 18 percent in 1997 narrowing to 0.3–2.2 percent in 2002 for fares available at multiple travel websites.[30] These lessons from other markets suggest that more thoroughly implementing price transparency across the health care industry could increase competition to provide lower costs and limit price variation.[31]

Despite the general absence of price transparency in the health care sector, there is research showing how price transparency leads to lower and more uniform pricing in health care markets. For instance, as noted in the preamble to the proposed rule, research shows patients saved $7.9 million and issuers saved $36 million on imaging services in New Hampshire after the state launched a website publishing health prices for most consumers with private health insurance.[32] One study found use of a telephone- and email-based tool to search for health care prices reduced the price paid by 10 to 17 percent and reduced the prices paid for care on average by 1.6 percent.[33] Another study of a program that provided health plan participants, beneficiaries, or enrollees with price and quality information to help select high-value imaging services found an increase in the use of lower-cost facilities.[34] This consumer behavior prompted higher-cost facilities to lower their prices, which resulted in a 30 percent reduction in the price variation between low- and high-cost facilities.[35] These studies, as well the numerous studies highlighted in subsequent sections of this rule, offer substantial evidence that price transparency in health care markets will result in consumer benefits similar to those that result from transparency in other markets.

5. The Final Rules Will Fill Gaps Left by State and Private Transparency Efforts

Currently, the information that consumers need to make informed decisions based on the prices of health care services is not readily available or is presented in a manner that makes it challenging to understand. As noted in the preamble to the proposed rules, the 2011 Government Accountability Office (GAO) report, ''Health Care Price Transparency: Meaningful Price Information is Difficult for Consumers to Obtain Prior to Receiving Care,'' found that the lack of transparency in health care prices, coupled with the wide pricing disparities for particular procedures within the same market, can make it difficult for consumers to understand health care prices and to shop effectively based on cost.[36] The report also explored various price transparency initiatives, including tools that consumers could use to generate price estimates before receiving a health care service. The report notes that pricing information displayed by tools varies across initiatives, in large part due to limits reported by the initiatives in their access or authority to collect certain necessary price data. In particular, the report notes the lack of public disclosure of rates negotiated between providers and third-party payers. The GAO report, therefore, recommended that HHS determine the feasibility of, and the next steps for, making estimates of out-of-pocket costs for health care services available to consumers.

States have been at the forefront of transparency initiatives and have adopted a variety of approaches to improve price transparency.[37] More than half of the states have passed legislation establishing price transparency websites or mandating that health plans, hospitals, or physicians make pricing information available to patients.[38] For example, as of September 2020, thirty one states have enacted laws that provide participants, beneficiaries, and enrollees with at least partial protection against the practice of ''balance billing.'' [39] At least eighteen states have All-Payer Claims Databases. However, state transparency requirements are generally not applicable to self-insured group health plans, which cover approximately 58.7

hblog20150707.049155/full/; *see also* Sinaiko, A., Rosenthal, M. ''Examining a Health Care Price Transparency Tool: Who Uses it, and How They Shop for Care.'' 35 Health Affairs 662. April 2016. Available at: *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.0746*.

[25] *See* Gordon, D., et al. ''Health Care Consumer Shopping Behaviors and Sentiment: Qualitative Study.'' Journal of Participatory Medicine. Volume 12. No. 2. 2020. Available at: *https://jopm.jmir.org/2020/2/e13924/* (study demonstrating that consumers already engage in ''behaviors related to seeking, comparing, or knowing the prices of care'' regardless of the presence of price transparency tools).

[26] Austin, D.A., and Gravelle, J.G. ''Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Health Sector.'' United States Congress Congressional Research Service. April 29, 2008. Available at: *https://crsreports.congress.gov/product/pdf/RL/RL34101*; *see also* Grennan, M., Swanson, A. ''Transparency and Negotiated Prices: The Value of Information in Hospital-Supplier Bargaining.'' 128 Journal of Political Economy. April 2020 (Citing research in consumer goods showing that information can help decision making when buyers have imperfect information on costs.). Available at: *https://www.nber.org/papers/w22039*; *see also* 84 FR 65464, 65466 (Nov. 27, 2019).

[27] Semigran, H.L., et al. ''Patients' Views on Price Shopping and Price Transparency.'' The American Journal of Managed Care. June 26, 2017. Available at: *https://www.ajmc.com/view/patients-views-on-price-shopping-and-price-transparency*.

[28] Zettlemeyer, F., Morton, F.S., and Silva-Risso, J. ''How the internet Lowers Prices: Evidence from Matched Survey and Automobile Transaction Data.'' Journal of Marketing Research. May 2006. Available at: *https://doi.org/10.1509%2Fjmkr.43.2.168*.

[29] Brown, J., and Goolsbee, A. ''Does the internet Make Markets More Competitive? Evidence from the Life Insurance Industry.'' Journal of Political Economy, vol. 110, June 2002, pp. 481–507.

[30] Clemons, E.K., Hann, I., and Hitt, L. ''Price Dispersion and Differentiation in Online Travel: An Empirical Investigation,'' Management Science, vol. 48, no. 4, 2001, pp. 521–39; *see also* ''Occupational Labor Statistics.'' United States Bureau of Labor Statistics. Available at: *https://www.bls.gov/oes/current/oes_stru.htm*.

[31] 84 FR 65464, 65466 (Nov. 27, 2019).

[32] *Id.*

[33] Lieber, E. ''Does It Pay to Know Prices in Health Care?'' American Economic Journal: Economic Policy. February 2017. Available at *https://pubs.aeaweb.org/doi/pdfplus/10.1257/pol.20150124*.

[34] Wu, S.J. et al. ''Price transparency for MRIs increased use of less costly providers and triggered provider competition.'' Health Affairs. August 2014. Available at: *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0168*.

[35] *Id.*

[36] 84 FR 65464, 65466–65467 (Nov. 27, 2019); *see also* GAO–11–791 at p. 28 (Sep. 2011).

[37] De Brantes, F., et al. ''Price Transparency & Physician Quality Report Card 2017.'' Catalyst for Payment Reform. Available at: *https://www.catalyze.org/product/2017-price-transparency-physician-quality-report-card/*.

[38] Frakt, A., and Mehrotra, A. ''What Type of Price Transparency Do We Need in Health Care?'' Annals of Internal Medicine. April 16, 2019. Available at: *https://www.acpjournals.org/doi/10.7326/M19*.

[39] Kona, M. ''State Balance-Billing Protections.'' The Commonwealth Fund. September 16, 2020. Available at: *https://www.commonwealthfund.org/publications/maps-and-interactives/2020/sep/state-balance-billing-protections*.

percent of private-sector workers.[40] As a result, the data collected under state law does not include data from self-insured plans, and a significant portion of consumers may not have access to information on their plans.

In response to state action and consumer demands for more information on health care pricing, and to align with increased price transparency in other markets, health insurance issuers and self-insured plans have moved to increase price transparency. For example, some plans are using price transparency tools to incentivize employees to make cost-conscious decisions when purchasing health care services. Most large issuers have comparative cost information, which includes rates that plans and issuers have negotiated with in-network providers and suppliers.

However, many existing tools are either insufficient in the amount of detail they provide or the level of accuracy available. In order to expand price transparency to all consumers, Federal action is therefore necessary to establish standards and universal access to this information. In preparation for writing the proposed rules, the Departments met with over 50 stakeholders including plans, issuers, and third-party tool developers. Several stakeholders provided demonstrations of their tools to the Departments. The Departments note that over 90 percent of plans offer some version of a price comparison tool.[41] However, many of the plans and issuers that the Departments met with, who did not have a tool serve large portions of participants, beneficiaries, and enrollees. It is therefore the Departments' understanding that there are still millions of insured Americans that do not have access to any type of health care pricing tool. Also based on these demonstrations, the Departments are of the view that many price transparency tools on the market only offer wide-range estimates or average estimates of pricing that use historical claims data and do not always take into account the accumulated amount a participant, beneficiary, or enrollee has paid toward their deductible or out-of-pocket limit (sometimes referred to as an ''accumulator''). The Departments are of the view that wide-range estimates are of limited value to consumers, given that they may not accurately reflect an individual's plan design and benefits, and that ranges should be replaced by actual estimated out-of-pocket costs, in order to allow the consumer to meaningfully predict costs. In addition, the inclusion of negotiated rates in these tools could help show the changes to a participant's, beneficiary's, or enrollee's costs if they have a future need for the same service, conditioned on the level of fulfillment of any cost-sharing responsibilities. This could help the consumer better understand the full value of the health care they are considering and how the cost may be different in the future when the participant's, beneficiary's, or enrollee's accumulator resets in a new plan year. Information on quality and results are also important for assessing the value of care.[42] Through this increased availability of information and consumer comprehension, transparent pricing can apply pressure on providers to demonstrate and improve quality and health care results. Providers may likely then be in the position of having to justify their costs relative to alternative options.

The Departments are of the view that existing price transparency tools often function in a way that makes them difficult for users to navigate. These tools often display information that makes it difficult to compare one plan against another, understand the scope of services covered and their costs, and interpret the terminology plans and issuers use. Consumers may be discouraged by these difficult user interfaces and may be less likely to make fully informed decisions with their healthcare choices. Research demonstrates that poor or confusing user interfaces will lead users to abandon engagement with the hosting website.[43] The Departments are of the view that it is important to establish a minimum set of standards regarding what is acceptable so that consumers can fully utilize all relevant information. Tools that provide consistent information to every consumer across all markets, and that base cost estimates on accurate and recent information, will be a significant improvement over all or most existing options. Accuracy and consistency are intended to give consumers confidence that the information presented by these tools will not change significantly from the prices they are ultimately charged. Reliability should assure consumers that information in these tools accurately reflects plans' and issuers' best estimates of consumer out-of-pocket costs. The availability of these tools across most private markets will ensure broad access for all participants, beneficiaries, or enrollees to the intended outcomes and potential benefits of the final rules. The Departments anticipate that participants, beneficiaries, and enrollees will become accustomed to having access to this standardized information, no matter what private market plan or coverage they choose, which will make them more comfortable with using this information in health care purchasing decisions. The Departments further anticipate and encourage plans and issuers to include additional functionality and innovation in existing price transparency tools, but a baseline is necessary to give participants, beneficiaries, and enrollees the confidence that, regardless of the tool they use, they can expect the same standard information and functionality.

C. Stakeholder Feedback and Prior Actions in Support of Transparency

In the HHS 2020 Notice of Benefit and Payment Parameters (2020 Payment Notice) proposed rule,[44] HHS sought input on ways to provide consumers with greater transparency regarding their own health care data, QHP offerings on the Federally-facilitated Exchanges (FFEs), and the cost of health care services.[45] Additionally, HHS sought comment on ways to further implement section 1311(e)(3) of PPACA, as implemented by 45 CFR 156.220(d), under which, upon the request of an enrollee, a QHP issuer must make available in a timely manner the amount of enrollee cost sharing under the enrollee's coverage for a specific service furnished by an in-network provider. HHS was particularly interested in what types of data would be most useful to improving consumers' abilities to make informed health care decisions, including decisions related to their coverage specifications and ways to

[40] ''Report to Congress: Self-Insured Health Benefit Plans 2019: Based on Filings through Statistical Year 2016.'' March, 2019. Available at: *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2019.pdf*; *see also* Fronstin, P. ''Self-Insured Health Plans: Recent Trends by Firm Size 1996–2018.'' Employee Benefit Research Institute. No. 488. August 1, 2019. Available at: *https://www.ebri.org/docs/default-source/ebri-issue-brief/ebri_ib_488_selfinsur-1aug19.pdf?sfvrsn=bd7e3c2f_6*.

[41] ''Study: Health Plans Implement Price Transparency Tools for Consumers.'' ACA International. April 2016. Available online at: *https://www.expressrecovery.com/file/86c228ef-245f-45cb-abd7-a30edbdec1f3*.

[42] See additional discussion of quality information in section II.C.1 of the preamble.

[43] Georgiou, M. ''User Experience Is the Most Important Metric You Aren't Measuring.'' Entrepreneur. March 1, 2018. Available at: *https://www.entrepreneur.com/article/309161*.

[44] 84 FR 227 (Jan. 24, 2019).

[45] The term ''Exchanges'' means American Health Benefit Exchanges established under section 1311 of PPACA. *See* section 2791(d)(21) of the PHS Act.

improve consumer access to information about health care costs.

Commenters on the 2020 Payment Notice overwhelmingly supported the idea of increased price transparency. Many commenters provided suggestions for defining the scope of price transparency requirements, such as providing costs for both in-network and out-of-network health care, and providing health care cost estimates that include an accounting for consumer-specific benefit information, like progress toward meeting deductibles and annual limitations on cost sharing, as well as remaining visits under visit limits. Commenters expressed support for implementing price transparency requirements across all private markets and for price transparency efforts to be a part of a larger payment reform effort and a provider empowerment and patient engagement strategy. Some commenters advised HHS to carefully consider how such policies should be implemented, warning against Federal duplication of state efforts and requirements that would result in plans and issuers passing along increased administrative costs to consumers and cautioning that the proprietary and competitive nature of payment data should be protected.

In the summer and fall of 2018, HHS hosted listening sessions related to the goal of empowering consumers by ensuring the availability of useable pricing information. The listening sessions included a wide representation of stakeholders including providers, issuers, researchers, and consumer and patient advocacy groups. Attendees noted that currently available pricing tools are underutilized, in part because consumers are often unaware that they exist,[46] and even when used, the tools sometimes convey inconsistent and inaccurate information.

Attendees also commented that tool development could be expensive, especially for smaller health plans, which tend to invest less in technology because of the limited return on investment. Attendees further commented that most tools developed to date do not allow for comparison shopping. Attendees stated that existing tools usually use historical claims data, which results in broad, sometimes regional, estimates, rather than accurate and individualized prices. In a national study, there was alignment among patients, employers, and providers in wanting to know and discuss the cost of care at the point of service.[47] However, attendees noted pricing tools are rarely available when and where consumers are likely to make health care decisions, for example, during interactions with providers. Thus, patients are not able to consider relevant cost issues when discussing referral options or the tradeoffs of various treatment options with referring providers. With access to patient-specific cost estimates for services furnished by particular providers, referring providers and their patients could take pricing information into account when considering clinically appropriate treatment options. Separately, CMS has met with members from several state Departments of Insurance to discuss the limits to state authority to require price transparency in a meaningful way and the benefits and drawbacks of All Payer Claims Databases (APCDs). During these discussions, it became clear that APCDs' reliance on historical claims data that is not necessarily linked to a specific plan or issuer limits the utility of such databases for consumers. These conversations helped clarify the types of price transparency information necessary to empower consumers.

CMS has pursued initiatives in addition to the final rules to improve access to the information necessary to empower consumers to make more informed decisions about their health care costs, including a multi-step effort to implement section 2718(e) of the PHS Act. Section 2718(e) of the PHS Act requires each hospital operating within the United States, for each year, to establish (and update) and make public (in accordance with guidelines developed by the Secretary of HHS) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act (SSA). In the Fiscal Year (FY) 2015 Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) proposed and final rules, CMS reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the PHS Act and provided guidelines for its implementation.[48] At that time, CMS required hospitals to either make public a list of their standard charges or their policies for allowing the public to view a list of those charges in response to an inquiry. In addition, CMS stated that it expected hospitals to update the information at least annually, or more often as appropriate, to reflect current charges. CMS also encouraged hospitals to undertake efforts to engage in consumer-friendly communication of their charges to enable consumers to compare charges for similar services across hospitals and to help them understand what their potential financial liability might be for items and services they obtain at the hospital.

In the FY 2019 IPPS/LTCH PPS proposed and final rules, CMS again reminded hospitals of their obligation to comply with section 2718(e) of the PHS Act and announced an update to its guidelines.[49] The updated guidelines, which have been effective since January 1, 2019, require hospitals to make available a list of their current standard charges (whether in the form of a ''chargemaster'' or another form of the hospital's choice) via the internet in a machine-readable format and to update this information at least annually, or more often as appropriate.

In response to stakeholder feedback and in accordance with Executive Order 13877, issued on June 24, 2019,[50] CMS took another important step toward improving health care value and increasing competition in the Calendar Year 2020 Hospital Outpatient Policy Payment System (OPPS) Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates: Price Transparency Requirements for Hospitals to Make Standard Charges Public final rule (Hospital Price Transparency final rule) by codifying regulatory requirements that implement section 2718(e) of the PHS Act, as well as a regulatory scheme under section 2718(b)(3) of the PHS Act that enables CMS to enforce those requirements.[51] The price transparency disclosure requirements that CMS finalized in the Hospital Price Transparency final rule will be effective on January 1, 2021, and they require hospitals to make publicly available, as applicable, their gross charges (as found in the hospital's chargemaster), payer-specific negotiated charges, discounted cash prices, and de-identified minimum and maximum negotiated charges for all items and services they provide through a single online machine-readable file that is updated at least once annually. Additionally, the Hospital Price

[46] Miller, S. ''Healthcare Shopping Tools Often Go Unused.'' Society for Human Resource Management. May 19, 2016. Available at: *https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/health-care-shopping.aspx.*

[47] ''Let's Talk About Money.'' University of Utah Health Home. Available at: *https://uofuhealth.utah.edu/value/lets-talk-about-money.php.*

[48] 79 FR 27978, 28169 (May 15, 2014) and 79 FR 49854, 50146 (Aug. 22, 2014), respectively.

[49] 83 FR 20164, 20548 (May 7, 2018) and 83 FR 41144, 41686 (Aug. 17, 2018), respectively.

[50] 84 FR 30849 (Jun. 27, 2019). The Executive order was issued on June 24, 2019 and was published in the **Federal Register** on June 27, 2019.

[51] 84 FR 65524 (Nov. 27, 2019).

Transparency final rule requires hospitals to display online in a consumer-friendly format, as applicable, the payer-specific negotiated charges, discounted cash prices (or, to the extent one does not exist for a shoppable service, the undiscounted gross charge) and de-identified minimum and maximum negotiated charges for as many of the 70 shoppable services selected by CMS that the hospital provides and as many additional hospital-selected shoppable services as are necessary for a combined total of at least 300 shoppable services (or if the hospital provides fewer than 300 shoppable services, then for as many as the hospital provides). The rule defines a shoppable service as a service that can be scheduled by a health care consumer in advance and further explains that a shoppable service is typically one that is routinely provided in non-urgent situations that does not require immediate action or attention to the patient, thus allowing patients to price shop and schedule such a service at a time that is convenient for them.[52]

In addition to making pricing information available for items and services provided by hospitals, the Administration has also been engaged in increasing transparency of prescription drug pricing and lowering the costs of prescription drugs. Four Executive orders direct CMS and other HHS agencies to develop and issue tools, models, and several regulations to increase competition and lower patients' drug costs.[53] The actions directed in these Executive orders supplement those CMS has already taken to increase drug-pricing transparency and lower drug costs. Through the Drug Spending Dashboard, CMS publishes data on Medicare and Medicaid spending for prescription drugs in an interactive web-based tool so researchers and consumers can easily sort the data to identify trends. Over the past four years, CMS has expanded this dashboard to include reporting on payments for prescription drugs in their first year on the market and information on the drugs' manufacturers.[54] Through the Part D Senior Savings model, beginning January 1, 2021, CMS is testing a change to the Manufacturer Coverage Gap Discount Program (the ''discount program'') to allow Part D sponsors to offer a Part D benefit design that includes predictable copays in the deductible, initial coverage, and coverage gap phases for a broad range of insulins included in the Model by offering supplemental benefits that apply after manufacturers provide a discounted price.[55]

CMS issued regulations addressing prescription drug transparency,[56] including a regulation implementing the statutory prohibition on pharmacist gag clauses,[57] helping to ensure patients have information on lower cost alternatives or that they can save money by paying cash. As part of the Calendar Year (CY) 2018 Medicare Physician Fee Schedule, CMS adopted a policy that all FDA-approved Part B biosimilars would be assigned their own HCPCS codes. Under this revised coding policy, CMS pays for separately payable Part B biosimilars based on its own Average Sales Price (ASP) plus 6 percent of the ASP of its reference product. This policy change was made to promote a stable and robust biosimilars market that drives competition and lowers prices.

In the CY 2019 Medicare Advantage and Part D final rule, CMS adopted a policy to allow for certain low-cost generic drugs to be substituted onto plan formularies at any point during the year, so beneficiaries immediately benefit and have lower cost sharing.[58] The Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses rule[59] finalized in May 2019 requires Part D plans to implement, no later than January 1, 2021, a real-time benefit tool that can be integrated into at least one prescriber's electronic prescribing or EHR system to provide patient-specific formulary and benefit information, including cost sharing.[60] The rule also requires that beginning January 2021, the Explanation of Benefits document that Part D enrollees receive each month must include information on drug price increases and lower-cost therapeutic alternatives. In June 2020, CMS proposed[61] further policy changes that would begin removing barriers to value-based purchasing arrangements between drug manufacturers and payers.[62] Value-based payments for prescription drugs has the potential to increase patient access to new medicines by holding prescription drug manufacturers accountable for outcomes their drug achieves, as well as creating alternatives to traditional cost controls that may impede patient access.[63]

As part of its effort to incentivize states to pursue innovative responses to rising drug prices, CMS approved nine states' (and the District of Columbia's) plan amendment proposals to negotiate supplemental rebate agreements involving value-based purchasing arrangements with drug manufacturers.[64] These supplemental rebate agreements allow states to link payment for prescription drugs to the value delivered to patients. Increasing states' flexibility empowers them to develop policies that are effective and responsive to local conditions and price ''hot spots'' that lower costs, increase

[52] 84 FR 65524, 65564 (Nov. 27, 2019).

[53] ''Trump Administration Announces Historic Action to Lower Drug Prices for Americans.'' United States Department of Health and Human Services. July 24, 2020. Available at: *https://www.hhs.gov/about/news/2020/07/24/trump-administration-announces-historic-action-lower-drug-prices-americans.html*.

[54] ''CMS Releases Enhanced Drug Dashboards Updated with Data for 2018.'' Centers for Medicare & Medicaid Services.'' December 19, 2019. Available at: *https://www.cms.gov/newsroom/press-releases/cms-releases-enhanced-drug-dashboards-updated-data-2018*; *see also* ''CMS Updates Drug Dashboards with Prescription Drug Pricing and Spending Data.'' Centers for Medicare & Medicaid Services. March 14, 2019. Available at: *https://www.cms.gov/newsroom/press-releases/cms-updates-drug-dashboards-prescription-drug-pricing-and-spending-data*.

[55] ''Part D Senior Savings Model.'' Centers for Medicare & Medicaid Services. Available online at: *https://innovation.cms.gov/innovation-models/part-d-savings-model*.

[56] *See* 84 FR 23832 (May 23, 2019) (HHS final rule finalizing policies that aimed to ''increase transparency of drug pricing and drug price increases, giv[e] beneficiaries and prescribers tools to help improve adherence, lower prescription drug costs, and minimize beneficiary out-of-pocket costs''); *see, for example,* 42 CFR 423.128 (requiring additional information in Part D explanations of benefits to increase transparency); 42 CFR 423.160 (requiring adoption of e-prescribing standards to increase transparency).

[57] 42 CFR 423.120(a)(8)(iii); *see also* Verma, S. ''Memorandum to All Part D Plan Sponsors: Unacceptable Pharmacy Gag Clauses.'' Centers for Medicare & Medicaid Services. May 17, 2018. Available at: *https://downloads.cms.gov/files/2018-05-17.pdf*.

[58] ''CMS lowers the cost of prescription drugs for Medicare beneficiaries.'' Centers for Medicare & Medicaid Services. April 2, 2018. Available at: *https://www.cms.gov/newsroom/press-releases/cms-lowers-cost-prescription-drugs-medicare-beneficiaries*.

[59] 84 FR 23832 (May 23, 2019).

[60] ''CMS Takes Action to Lower Prescription Drug Prices and Increase Transparency.'' Centers for Medicare & Medicaid Services. May 16, 2019. Available at: *https://www.cms.gov/newsroom/press-releases/cms-takes-action-lower-prescription-drug-prices-and-increase-transparency*.

[61] ''Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS 2482–P) Fact Sheet. Centers for Medicare & Medicaid Services. June 17, 2020. Available at: *https://www.cms.gov/newsroom/fact-sheets/establishing-minimum-standards-medicaid-state-drug-utilization-review-dur-and-supporting-value-based*.

[62] 85 FR 37286 (Jun. 19, 2020).

[63] Verma, S. ''CMS's Proposed Rule On Value-Based Purchasing For Prescription Drugs: New Tools For Negotiating Price For The Next Generation Of Therapies.'' Health Affairs. June 17, 2020. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20200617.728496/full/*.

[64] ''Medicaid State Plan Amendments.'' Centers for Medicare & Medicaid Services. Available online at: *https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments/index.html*.

the predictability of expenses, and improve access for patients.

As it currently stands, and despite ongoing Federal efforts to improve price transparency, there continues to be a lack of standardized pricing information to assist consumers in the private market when shopping for health care items and services. While there are several efforts across states, 33 still do not have comprehensive statewide price transparency initiatives,[65] and as noted earlier, sometimes cannot legally require private market plans and issuers to provide real-time, out-of-pocket cost estimates to participants, beneficiaries, and enrollees.

The Departments have concluded that the Hospital Price Transparency final rule and the other efforts described earlier in this section cannot result in enrollees receiving complete price estimates for health care items and services because, as the GAO concluded, complete price estimates require pricing information from both providers and health insurance issuers.[66] In other words, this rule complements existing State, Federal, and private sector price transparency efforts by ensuring that pricing information is available from both hospitals and payers in both the public and private markets and by expanding transparency to pricing information for health care items and services provided outside of a hospital setting. As a result of these rules, regardless of where a consumer seeks information, be it their plan or issuer, or their hospital, they will have guaranteed access to up to date and accurate pricing information. In addition, because section 2718(e) of the PHS Act applies only to items and services provided by hospitals the Hospital Price Transparency final rule does not address price transparency with respect to items and services provided by other health care providers. Accordingly, the Departments have concluded that additional price transparency efforts are necessary and required under the statute to empower a more price-conscious and responsible health care consumer, promote competition in the health care industry, and lower the overall rate of growth in health care spending.[67]

The Departments are of the view that the disclosures required under the final rules are necessary and appropriate to more fully implement section 2715A of the PHS Act and section 1311(e)(3)(C) of PPACA to ensure that consumers have ready access to the information they need to estimate their potential out-of-pocket costs for health care items and services before that service is rendered or that item is delivered. The final rules are also intended to empower consumers by incentivizing market innovators to help consumers understand how their plan or coverage pays for health care and to shop for health care items and services based on price, which is a fundamental factor in any purchasing decision.

D. Executive Order

On June 24, 2019, President Trump issued Executive Order 13877, ''Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First.'' Section 3(b) of Executive Order 13877 directed the Secretaries of the Departments to issue an advance notice of proposed rulemaking (ANPRM), consistent with applicable law, soliciting comment on a proposal to require health care providers, health insurance issuers, and self-insured group health plans to provide or facilitate access to information about expected out-of-pocket costs for items or services to patients before they receive care. The Departments considered the issue, including by consulting with stakeholders, and determined that an NPRM, rather than an ANPRM, would allow for more specific and useful feedback from commenters, who would be able to respond to specific proposals.

E. Proposed Rules

In response to Executive Order 13877 and to also implement legislative mandates under sections 1311(e)(3) of PPACA and section 2715A of the PHS Act, the Departments published an NPRM entitled ''Transparency in Coverage'' on November 27, 2019 (to be codified at 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 147) (the proposed rules) with comments requested by January 14, 2020.[68] In response to requests from stakeholders, the Departments extended the comment period 15 days, to January 29, 2020.[69] The proposed rules set forth proposed requirements for group health plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request to a participant, beneficiary, or enrollee, including an estimate of an individual's cost-sharing liability for covered items or services furnished by a particular provider. The Departments proposed that plans and issuers be required to make such information available on an internet website and, if requested, through non-internet means, thereby allowing a participant, beneficiary, or enrollee to obtain an estimate and understanding of the individual's out-of-pocket expenses and effectively shop for items and services. The proposed rules also included proposals to require plans and issuers to disclose in-network provider negotiated rates, and historical out-of-network allowed amounts through two machine-readable files posted on an internet website, thereby allowing the public to have access to health coverage information that can be used to understand health care pricing and potentially dampen the rise in health care spending.

The proposed rules also included requests for information (RFIs) on topics closely related to the rulemaking. Due to the design and capability differences among the information technology (IT) systems of plans and issuers, as well as difficulties consumers experience in deciphering information relevant to health care and health insurance, the Departments sought comment on additional price transparency requirements that could supplement the proposed requirements for disclosing cost-sharing information to participants, beneficiaries, or enrollees and the proposed requirements for public disclosure of negotiated rates and historical allowed amount data for covered items and services from out-of-network providers. Specifically, the Departments sought comment on whether plans and issuers should be required to disclose information necessary to calculate a participant's, beneficiary's, or enrollee's cost-sharing liability through a publicly-available, standards-based application programming interface (API).

Such a requirement would build off a final rule, ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare

[65] LaPointe, J. ''Few States Have Robust Healthcare Transparency Laws.'' RevCycle Intelligence. May 11, 2020. Available at: *https://revcycleintelligence.com/news/few-states-have-robust-healthcare-price-transparency-laws*.

[66] GAO–11–791 (Sep. 2011).

[67] This view is consistent with the legislative history of PPACA. As initially introduced in the Senate on November 19, 2009, PPACA included only the requirement on hospitals to disclose standard charges included in section 2718. On December 1, 2009, in comments supporting the hospital transparency requirement, Sen. Max Baucus noted, ''I think the same should also apply to physicians so people have a better idea what they will pay or their insurance company will pay for these procedures.'' *https://www.congress.gov/111/crec/2009/12/08/CREC-2009-12-08.pdf*. Sections 2715A and 1311(e)(3)(C) were then amended to PPACA on December 19 in the final managers amendment before passage in the Senate. Available at: *https://www.congress.gov/111/crec/2009/12/19/CREC-2009-12-19.pdf*.

[68] 84 FR 65464 (Nov. 27, 2019).

[69] 85 FR 276 (Jan. 3, 2020).

Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and Chip Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers'' (CMS Interoperability & Patient Access final rule), that CMS published on May 1, 2020.[70] That rule requires Medicare Advantage organizations, Medicaid and CHIP Fee-for-Service programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in the FFEs to provide enrollees with access to select data, including claims data, through a standards-based API that conforms to the technical standards adopted in the Office of the National Coordinator for Health Information Technology (ONC) 21st Century Cures Act final rule at 45 CFR 170.215. The CMS Interoperability & Patient Access final rule requires certain entities, such as FFE QHP issuers, to provide certain data through a standards-based API. The Departments appreciate the comments received in response to the API RFI and will use the comments to inform the need for future rulemaking regarding whether plans and issuers should be required to disclose information necessary to calculate cost-sharing liability through a publicly-available, standards-based API. HHS will also monitor the implementation of the CMS Interoperability & Patient Access final rule to inform any such future rulemaking.

The proposed rule also included RFIs on how provider quality measurements and reporting in the private health insurance market may be used to complement cost-sharing information for plans and issuers in the private health insurance market. The Departments sought comment on how existing quality data on health care provider items and services could be leveraged to complement the proposals in the proposed rules. The primary goal of the proposed and final rules is making information available to address the absence of price transparency in the health care market; the final rules do not address health care quality at this time.

HHS also proposed to amend its MLR program rules using the authority under section 2718(c) of the PHS Act, under which the standardized methodologies for calculating measures of the activities reported under section 2718(a) of the PHS Act shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans. Specifically, HHS proposed to recognize the special circumstances of a different and newer type of plan for purposes of MLR reporting and calculations for plans that share savings with consumers who choose lower-cost, higher-value providers. HHS proposed to amend 45 CFR 158.221 to add a new paragraph (b)(9) to allow any such ''shared savings'' payments made by an issuer to an enrollee as a result of the enrollee choosing to obtain health care from a lower-cost, higher-value provider, to be factored into an issuer's MLR numerator, beginning with the 2020 MLR reporting year (for reports filed by July 31, 2021).

The Departments requested comments on all aspects of the proposed rules, as well as a number of specific issues. The Departments received over 25,000 comments in response to the proposed rules from a range of stakeholders, including plans and issuers, health care providers, prescription drug companies, employers, state regulators, health IT companies, health care policy organizations and think tanks, and individuals. No requests for a public hearing were received. The Departments received a number of comments and suggestions that were outside the scope of the proposed rules that are not addressed in the final rules (for example, regarding hospital prices, other methods for reducing health care and prescription drug costs, consumer education and provider directories). After careful consideration of the comments, the Departments are finalizing the proposed rules with certain modifications made in response to comments. These modifications are discussed later in this preamble.

F. Legal Authority

Several commenters questioned the Departments' legal authority regarding various aspects of the proposed rules. The Departments are of the view that the legal authorities identified earlier in this preamble are sufficient to support the final rules.

1. Statutory Authority Under Section 1311(e)(3) of PPACA

Several commenters contended that section 1311(e)(3)(A)(ix) of PPACA does not give the Departments statutory authority to require that plans and issuers make the rates they have negotiated with providers and out-of-network allowed amounts publicly available. The commenters noted that section 1311(e)(3)(A) of PPACA enumerates eight specific categories of information subject to the transparency in coverage mandate followed by a ninth ''catchall'' category consisting of ''other information as determined appropriate by the Secretary.''[71] These commenters maintained that the Secretary of HHS's authority under section 1311(e)(3)(A)(ix) of PPACA is insufficient to support a requirement to publicize negotiated rates because they are not sufficiently similar to the other categories of information identified under section 1311(e)(3)(A) of PPACA.

The Departments disagree with these comments and are of the view that the information required to be disclosed under this rule fits squarely within the scope of information that plans and issuers may be required to disclose under section 1311(e)(3)(A)(ix) of PPACA and section 2715A of the PHS Act. Section 1311(e)(3)(A)(i) to (viii) of PPACA outlines specific information and data that must be submitted to the Exchange, the Secretary of HHS, the relevant State insurance commissioner, and the public on an accurate and timely basis. In addition, section 1311(e)(3)(A)(ix) of PPACA requires health plans to submit ''other information as determined appropriate by the Secretary.'' Under established principles of statutory construction, when a general term follows a list of specific terms in a statute, the general term is construed to encompass subjects of a similar character to the specific terms. The principle of *ejusdem generis* guides courts in evaluating a catch-all at the end of a list. Therefore, when a statute allows an implementing agency to exercise its discretion by adding additional items to a list, the implementing agency is empowered to add additional items as long as those items are of similar character to the items enumerated in the statute.[72] In this case, the statutory list includes information and data useful to evaluate the coverage offered by plans and issuers with an emphasis on business practices, financial stability, and consumer experience. The list also includes information useful to regulators and the public in general to evaluate plans' and issuers' business practices and activity in the market. Given that the list includes some disclosures that are more immediately useful to individual consumers and others that are more immediately useful to regulators, the catchall provision is reasonably and best read as Congress' recognition that the Secretary of HHS (and, therefore, the Departments, by virtue of their joint authority under section 2715A of the PHS Act) would need broad flexibility to require the

[70] 85 FR 25510 (May 1, 2020).

[71] *See* section 1311(e)(3)(A)(i) through (viii) of PPACA.

[72] *See Norfolk & Western R. Co.* v. *Train Dispatchers,* 499 U.S. 117, 128–29 (1991).

disclosure of information as appropriate to deliver the transparency necessary for consumers to understand their coverage options and for regulators to hold plans and issuers accountable.

It is important to note that Congress considered one amendment that would have only required public disclosure at least annually of in-network allowed charges and expected allowed charges for out of network without allowing the Secretary discretion to add to the content of the required disclosure.[73] Instead of adopting this prescriptive approach, Congress required public disclosure of a broader set of information that similarly included payments for out-of-network services, as well as providing the Secretary discretion to require disclosure of other information. While Congress did not specifically include in-network allowed charges in the provision enacted, the discretion they provided suggests they understood that the Secretary might later find that requiring the disclosure of additional information, including information considered by Congress, might be useful and appropriate. That Congress considered and rejected a more prescriptive approach strongly suggests Congress intended that the Secretary have the ability to mandate more particularized disclosures in the future, including the disclosure of in-network negotiated rates.[74]

A plan's or issuer's negotiated rates provide important information to help consumers both evaluate their options before buying coverage and, after choosing coverage, evaluate how to use their coverage when they need care. Those shopping for coverage will benefit from knowing how effectively a plan or issuer negotiates rates; for example, by comparing the rates one plan or issuer pays a provider for a particular item or service that this consumer knows they, or their family, will need in the future, which can then allow them to shop and compare which plans and issuers offer the most value. Once coverage is obtained, knowing negotiated rates upfront will ensure consumers covered under a variety of plan designs and coverage options to, in each case, have access to the information they need to obtain health care services in an efficient, cost-effective manner, when considering available options for a shoppable service. As discussed earlier in this preamble, making negotiated rates public also strengthens other health care stakeholders' ability to support consumers. Because negotiated rates provide important information to help people—including consumers, regulators and the general public—evaluate the coverage offered by a plan or issuer, it clearly falls within the scope of information already required under section 1311(e)(3)(A) of PPACA. As discussed in more detail later in this section, out-of-network allowed amounts likewise provide vital information to help evaluate coverage.

Out-of-network allowed charges also provide consumers with important information. Consumers may opt for out-of-network services for numerous reasons, such as the unavailability of an in-network provider who can meet certain medical needs, an existing relationship with an out-of-network provider, the recommendation of another provider, or personal convenience. Disclosure of estimates of out-of-network allowed amounts is essential to the ability of consumers considering out-of-network services to form an estimate of their potential liability. Limiting transparency in pricing requirements to only providers under contract with a carrier would prevent transparency for all such services, contrary to the plain language of the statute.[75] Indeed, the language of the statute (for example, the requirement of section 1311(e)(3)(B) of PPACA that the intended audience, including individuals with limited English proficiency, can readily understand and use because that language is concise, well-organized, and follows other best practices of plain language writing) indicates an intention to assist consumers by enhancing their ability to make cost-conscious decisions; this is an essential component of establishing and maintaining robust market competition with costs that are reasonable and plausibly tethered to standard market discipline. As the preamble to the proposed rules observed, there is substantial evidence that increased price transparency provides consumers and the public at large with the information that is necessary to improve market efficiency.[76] For these reasons, the Departments are of the view that requiring disclosure of estimates of out-of-network allowed amounts, which reflect out-of-network benefits under a plan, is well within both the text and spirit of the statute and its aims to assist consumers in selecting providers, evaluating market options, increasing competition, and reducing market disparities. The Departments have identified these requirements as beneficial to the ongoing efforts of employers and regulators to aid consumers, and as consistent with the goals of the statute; thus, the Departments reject the assertion of commenters that these purposes are beyond the scope of the statute.

Several commenters asserted that the specific justifications the Departments cite as support for mandating the disclosure of negotiated rates are unrelated to the purposes authorized by statute. They asserted that those purposes—assisting consumers in selecting health care providers, assisting consumers in evaluating options in the market, increasing competition and reducing disparities in the market, assisting employers, and assisting state regulators—have no relationship to the statutory purpose of providing transparency in coverage for consumers. Moreover, commenters stated that the statute does not authorize the use of price transparency mechanisms to affect issuer and provider rate negotiations or health care costs generally, to assist employers in negotiations, or to aid state regulators in their duties. The Departments, however, find ample support in PPACA evidencing the relationship between the purposes intended to be served by this final rule, the overall purposes of PPACA, and the PPACA's price transparency measures, including section 1311(e)(3).

The purposes underlying the final rule's requirement to disclose negotiated rates are directly tied to providing transparency in coverage to consumers. The negotiated rate information that the final rules require to be disclosed pursuant to the Departments' authority under section 1311(e)(3)(A)(ix) of PPACA, and section 2715A of the PHS Act, is directly relevant to providing consumers with transparent pricing information sufficient to allow them to assess, in advance of receiving services, their liability under a health plan or

[73] Congressional Record 155: 183 (December 8, 2009) p. S12716. Available at: *https://www.congress.gov/111/crec/2009/12/08/CREC-2009-12-08-senate.pdf.*

[74] *See, for example, Lehman* v. *Nakshian,* 453 U.S. 156, 167–8 (1981) (citing a rejected amendment to a Federal statute as evidence of Congressional intent).

[75] Section 1311(e)(3)(A)(vii) of PPACA.

[76] 84 FR 65464, 65489, 65495 (Nov. 27, 2019); *see also* Austin, D.A., and Gravelle, J.G. ''Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector.'' United States Congress Congressional Research Service. July 24, 2007. Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf; see also* Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 100 Rev. Econ. & Stat. 1 (2018). Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf; see also* Enthoven, A. Market Forces and Efficient Health Care Systems. Health Affairs, Vol. 23, No. 2. Available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.23.2.25.*

health coverage in the numerous instances in the course of any plan year in which the negotiated rate will determine all or a portion of a consumer's liability. This is important information that helps consumers under a wide variety of plan designs and cost-sharing arrangements in both choosing and using coverage. The Departments are requiring the disclosure of cost information to further the goal of price transparency and are doing so under the authority of section 1311(e)(3) of PPACA.

Two commenters suggested that the proposal to require the release of negotiated rates in machine-readable format is not authorized under the statute. The statute mandates that transparency in coverage information ''shall be provided in plain language . . . that the intended audience, including individuals with limited English proficiency, can readily understand and use because it is concise, well-organized, and follows best practices of plain writing.'' [77] These commenters contended that machine-readable information is not plain language that is accessible or understandable to the typical consumer, and is therefore not within the scope of information authorized for public disclosure under section 1311(e)(3)(B) of PPACA.

The Departments disagree with this assertion. Consistent with the statute, the final rules require the machine-readable files to include a plain language description for each billing code. The proposed requirement that two data files be provided in ''machine-readable format''—one containing negotiated rates and the other containing out-of-network allowed amounts—is a purely operational consideration intended to ensure that the file data can be imported or read by a computer system directly, without altering the data, and without reliance on proprietary software.[78] Under section 1311(e)(3)(B) of PPACA, the ''plain language'' requirement concerns information to be made available to the public, the ''intended audience,'' per the statute. The Departments require the publication of data in machine-readable files so that the required information may be presented to all members of the intended audience in a concise, well-organized manner that follows best practices of plain writing relevant to the intended audience.

The Departments explain elsewhere in the preamble that the intended audience for the information required to be published under the final rules includes all consumers and purchasers of health care items and services, including individual consumers, employers, and government health care programs. The intended audience also includes health care stakeholders such as researchers, legislators, and regulators, as well as application developers who could make the information usable and easily understood by laypersons. Accordingly, application developers will be able to access the data in a format that is easily used and understood using skills common to application developers. This same expertise allows such innovators to incorporate large data sets into easy-to-use internet-based tools and mobile applications that will present information to laypersons in easy-to-understand, plain language that is sufficiently concise and well-organized. The Departments are of the view that providing the files in machine-readable format is an effective and necessary mechanism to ensure that price transparency information be made available to all members of the intended audience in a consistent, understandable, plain language format, as the statute requires.

One commenter suggested that the disclosures to the public required under section 1311(e)(3)(A) of PPACA consist of aggregated data only and do not contemplate or allow public disclosure of specific rate and price information. The Departments disagree. While it is true that several of the data elements listed under section 1311(e)(3)(A) of PPACA are general in nature, such as financial disclosures and enrollment data, this fact does not compel the conclusion that all elements listed must be construed as requiring aggregated information. As noted above, the list encompasses information and data useful to the evaluation of plans and issuers by all varieties of health care consumer, including individuals, employers, and government programs. Certain elements provide information specific to the benefits and protections a plan or issuer's coverage provides to an individual, including claims payment policies and information on enrollee rights under the law. In particular, the data element listed at section 1311(e)(3)(A)(vii) of PPACA encompasses ''information on cost sharing and payments with respect to any out-of-network coverage,'' which, by its plain terms, does not contemplate general or cumulative information.

The final rules specify the nature of the information that must be made available pursuant to sections 1311(e)(3)(A)(vii) and (ix) of PPACA, and the manner in which it is to be made available to fully implement the goals and purposes of the statute. Section 1311(e)(3)(C) of PPACA concerns disclosures to participants, beneficiaries, and enrollees receiving services from participating providers only, whereas section 1311(e)(3)(A) of PPACA concerns disclosures to the public generally and incorporates out-of-network payment information as well. Taken together, and as implemented under the final rules, the statute and regulatory schemes cover all persons seeking health pricing information in a given market, and advance the purposes of enhancing competition, reducing price disparities, and ultimately lowering costs through transparency in coverage.

Ultimately, by adding section 2715A of the PHS Act and section 1311(e)(3) of PPACA through the manager's amendment prior to passing PPACA in the Senate, Congress made transparency a key component of the PPACA's comprehensive framework for regulating private health coverage through Federal law. Notably, in contrast to the amendment rejected by Congress discussed earlier in this preamble, the transparency in coverage provisions signed into law provide a far more comprehensive and expansive approach toward providing transparency. The law covers nearly all private health plans, requires disclosure by plans through an internet website, requires disclosures to more entities, requires a broader set of information disclosures, and provides additional discretion to expand information disclosures. By taking this approach, Congress recognized both the importance and the complexity of requiring transparency. The discretion provided under the statute ensures that the Departments can accommodate changes in technology and health care markets, as well as build on the information disclosures specifically itemized in the statute.

A commenter also contended that the proposal to require issuers to make estimates of out-of-network allowed amounts available through the internet-based self-service tool is not authorized by the statute. This commenter asserted that section 1311(e)(3)(C) of PPACA only authorizes a requirement that payers make available information concerning cost-sharing obligations with respect to items or services furnished by a participating provider, not by out-of-network providers.

The Departments disagree and are of the view that the statute fully supports a requirement that plans and issuers make available information concerning cost-sharing obligations with respect to

[77] Section 1311(e)(3)(B) of PPACA.

[78] 84 FR 65464, 65481 (Nov 27. 2019).

items or services furnished by out-of-network providers. The information to be made available under section 1311(e)(3) specifically includes ''[i]nformation on cost sharing and payments with respect to any out-of-network coverage,'' as well as ''[o]ther information as determined appropriate by the Secretary.'' [79] While section 1311(e)(3)(C) of PPACA focuses primarily on providing information to enrollees, section 1311(e)(3)(A) of PPACA authorizes the Departments to make certain out-of-network information available to the public, which includes participants, beneficiaries, and enrollees. Thus the Departments reasonably determined that section 1311(e)(3)(A) and (C), together, authorize the requirement that plans and issuers provide cost estimates for covered items and services provided by out-of-network providers.

2. Constitutional Concerns

Several commenters asserted that requiring issuers to make rates they have negotiated with providers available to the public constitutes compelled commercial speech in violation of the First Amendment to the Constitution, and an unlawful taking of trade secrets without just compensation in violation of the Fifth Amendment. Commenters cited various reasons for their belief that the requirement in the proposed rules to disclose negotiated rates to the public could not survive constitutional scrutiny.

Several commenters contended that the proposed requirement constituted compelled commercial speech, and that the rationale the Departments articulated to justify the proposed requirement failed to meet the legal standard necessary to justify such action. One commenter asserted that a standard of constitutional scrutiny higher than that relevant to compelled commercial speech applies to the requirement to publish negotiated rates because, the commenter contended, the disclosure of negotiated rates does not propose a future commercial transaction. Some commenters challenged the proposed rules on the basis that negotiated rates have little or no relevance or value to consumers attempting to ascertain their potential liability for a particular service at a given point in time in the future because negotiated rates do not reflect the terms of different plan designs or the status of the individual consumer at a given point in time in relation to cost-sharing obligations, in particular any annual deductible.

Two commenters asserted that the requirement to publicly disclose negotiated rates would go well beyond the stated goal of providing notice to participants, beneficiaries, and enrollees of cost-sharing liability for covered services because it calls for negotiated rates to be available to the public generally, not just to enrolled consumers inquiring about their coverage. They also claimed that disclosure of negotiated rates would be extremely burdensome because fulfilling the mandate would require the disclosure of millions, or even billions, of data points. One commenter asserted that because the requirement to publish negotiated rates would not be useful to consumers in all situations, the requirements in the proposed rules were not narrowly tailored enough to survive constitutional scrutiny.

Some commenters also contended that the Departments' other stated interests in mandating the publication of negotiated rates, including lowering prices, increasing competition, and informing decision-making in the market generally, are not authorized under relevant statute; therefore, the breadth of these requirements is overly burdensome and inclusive of information not necessary to advance the goals of the statute. These commenters concluded that, to the extent the mandated publication of negotiated rates is calculated to advance those purposes, they are not sufficiently tailored to statutory goals to survive constitutional scrutiny.

a. First Amendment Compelled Speech

The Departments disagree that the proposed rules and the final rules run afoul of the First Amendment and would not survive constitutional scrutiny. As the United States Supreme Court recognized in *Zauderer* v. *Office of Disciplinary Counsel,* 471 U.S. 626 (1985) and recently confirmed in *National Institute of Family and Life Advocates* v. *Becerra,* 138 S. Ct. 2361, 2372, 2376 (2018) (''*NIFLA*''), required disclosures of factual, uncontroversial information in commercial speech are subject to more deferential First Amendment scrutiny. Under the approach articulated in *Zauderer,* courts have upheld required disclosures of factual information in the realm of commercial speech where the disclosure requirement reasonably relates to a government interest and is not unjustified or unduly burdensome such that it would chill protected speech. *See, e.g., Am. Meat Inst.* v. *U.S. Dept. of Agric.,* 760 F.3d 18, 27 (D.C. Cir. 2014); *Mass. Ass'n of Private Career Sch.* v. *Healey,* 159 F. Supp. 3d 173, 201 (D. Mass. 2016).

The Departments articulated substantial governmental interests in proposing these requirements: Assisting consumers of health care services in understanding the costs for which they will be liable for covered services prior to the delivery of the services; assisting other consumers of health care, such as employers and government health benefits programs, in evaluating and negotiating coverage options and obtaining the most value for health care dollars; and supporting a market-driven health care economy that is sustainable. The preamble to the proposed rules also explained how the information required to be disclosed under the proposed rules is of substantial value to consumers, including health plan participants, beneficiaries, and enrollees who have and have not satisfied their annual deductible or reached their maximum out-of-pocket limit, and that remains true under the final rules. For such consumers who have not met their deductibles, knowledge of negotiated rates is necessary for estimating their out-of-pocket costs because these consumers generally will be responsible for paying the full negotiated rate for health care items and services until they reach their deductible (or the maximum annual limit on cost sharing).

As the Departments noted earlier in the preamble, between the enactment of PPACA and 2019, average family deductibles for private sector employees increased by 85 percent, up to $3,655 in 2019.[80] Consumers in the private health insurance market are increasingly responsible for a greater share of their health care costs through higher deductibles and shifts from copayments to coinsurance.[81] The final rules will give health care consumers and stakeholders information vital to their roles in creating and supporting a sustainable market-driven health care economy.

[79] Section 1311(e)(3)(A) of PPACA; *see also* Section 1311(e)(3)(A)(vii) and (ix) of PPACA.

[80] *See* ''Medical Expenditure Panel Survey. Insurance Component National-Level Summary Tables.'' United States Department for Health and Human Services Agency for Healthcare Research and Quality. Available at: *https://www.meps.ahrq.gov/mepsweb/data_stats/quick_tables_search.jsp?component=2&subcomponent=1.*

[81] The preamble to the proposed rules contains a detailed discussion regarding increases in deductibles. *See* 84 FR 65464, 65465 (Nov. 27, 2019) (citing Ray, M., Copeland, R., Cox, C. ''Tracking the rise in premium contributions and cost-sharing for families with large employer coverage,'' Peterson-Kaiser Health System Tracker. August 14, 2019. Available at: *https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributionsand-cost-sharing-for-families-with-large-employercoverage/.*).

The final rules also will provide critical information to consumers who have satisfied their deductibles or reached their out-of-pocket limit. These consumers may wish to base their health care spending decisions on underlying prices to avoid excess spending by their issuer or employer that could lead to premium increases, increased out-of-pocket obligations, or lower employer contributions toward employer-sponsored coverage. Knowing the rates negotiated by other issuers in their geographic market will assist consumers during open enrollment, as they search for a plan that may lower their out-of-pocket costs in the coming year.

The government also has a substantial interest in assisting other health care spenders, such as employers and government benefits programs, to make coverage choices that drive value for the public. Given the size and scope of the country's health care market and the fact that choices made by employers and benefits programs operate at scale to direct health care spending, the government can increase the value of health care expenditures by ensuring those entities have access to accurate information. Providing employers and government benefit programs with actionable data may also help drive down total health care spending, as issuers compete to offer higher-value programs.

The government's interest in promoting a sustainable health care economy driven by market forces is substantial, as reflected in section 1311(e) of PPACA. As of 2018, U.S. health care spending had reached $3.6 trillion, or $11,172 per person and accounted for 17.7 percent of the nation's Gross Domestic Product.[82] Given the scope of the market and the earlier-discussed data suggesting that price transparency and market forces can drive down health care costs, the government's interest in increasing price transparency is substantial.

Each of the three interests identified above is furthered by the final rules. For individuals, the data provided will permit them to compare prices for health care items and services and allocate their funds accordingly. For benefit plans and employers, the information provided will guide decision-making about which coverage options to offer, and which providers or third parties, like pharmacy benefit managers (PBMs), to contract with. For the health care economy as a whole, the Departments are of the view (based on available data) that transparency and market forces will drive savings and reduce expenditures. Accordingly, the Departments continue to hold the view that the final rules serve substantial government interests.

Furthermore, the requirement to provide these disclosures does not unduly burden plan or issuer speech because nothing in the final rules would ''drown out [a plans' or issuers'] own message'' or ''effectively rule out'' any mode of communication. *See NIFLA,* 138 S. Ct. at 2378. Plans and issuers remain free to communicate with consumers using methods and media they have always used or may choose to use in the future.

The Departments further disagree that the final rules would be subject to a standard of constitutional scrutiny higher than that applied to compelled commercial speech. For First Amendment purposes, commercial speech is speech ''related solely to the economic interests of the speaker and its audience.'' *Cent. Hudson Gas & Electric Corp.* v. *Pub. Serv. Comm'n of N.Y.,* 447 U.S. 557, 561 (1980). Price information concerning the cost of health services is related solely to the economic interests of providers and the consumers who seek their services. The speech in question here, therefore, is commercial speech.

Furthermore, the disclosure of negotiated rates is one concerning ''purely factual and uncontroversial information about the terms [*i.e.,* the price] under which services are available.'' *See Zauderer,* 471 U.S. at 651; *see also Am. Meat Inst.* v. *U.S. Dept. of Agric.,* 760 F.3d 18, 27 (D.C. Cir. 2014). Therefore, the imposition on commercial speech by the final rules need only be ''reasonably related'' to the government's stated interest. For the reasons discussed above, the Departments are of the view that making available negotiated rates to consumers is reasonably related to the government's stated interests in providing greater cost information to consumers and benefit plans, as well as increasing price transparency in the health care market more broadly. While the Departments disagree that the stricter constitutional scrutiny under *Central Hudson* would apply to the final rules for the reasons discussed above, the Departments also are of the view that the government interests described above are ''substantial,'' and the regulations, for the reasons described above, directly advance that governmental interest and are not more extensive than necessary to serve that interest. None of the alternatives considered by the Departments would provide the full panoply of information necessary to achieve the identified interests. Specifically, the only way to provide information concerning a consumer's personal liability for health care services when the negotiated rate is all or any portion of that liability is by disclosing those rates.

The Departments disagree that the rules are excessively burdensome and are invalid because they purportedly exceed the statute's goal of providing notice of cost-sharing liability. The Departments are of the view that, in addition to providing participants, beneficiaries, and enrollees with notice of cost-sharing liability, the final rules are intended to advance a number of concurrent goals, as described earlier in this preamble. These goals are consistent with the full text of section 1311(e)(3) of PPACA and section 2715A of the PHS Act. They include the overarching goal of facilitating a market-driven heath care system by giving consumers of health care services data that will enable consumers to make fully informed, cost-conscious decisions when choosing health care. These transparency requirements will support the creation of a competitive dynamic in health care markets that leads to narrower price differentials for the same services, fosters innovation, and potentially lowers overall health care costs over time.[83] These goals are consistent with the statutory mandate to promote transparency in coverage by making available to the public accurate and timely health care information, including cost-sharing information, and other information as deemed appropriate by the Departments.

The Departments also disagree with any notion that, because published negotiated rates would not be useful to all consumers in all situations, the final rules are not sufficiently tailored to survive constitutional scrutiny. Consumers seeking in-network items or services must have access to negotiated rate information to calculate out-of-pocket costs under the majority of health care payment models. These negotiated rates determine the price they will be obliged to pay, up to the applicable out-of-pocket limit. Thus, disclosing the negotiated rate is important to the consumer's ability to reasonably estimate his or her personal financial liability in advance of receiving services. In particular, and as explained earlier in this preamble, annual deductibles for plans and issuers

[82] ''Historical National Health Expenditure Data.'' Centers for Medicare and Medicare Services. Available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.*

[83] 84 FR 65465 (Nov. 27, 2019).

now routinely obligate consumers to pay several thousand dollars before the plan or issuer pays any benefits. The requirement to disclose negotiated rates to consumers is, therefore, crucial to providing meaningful transparency in health care markets.

b. Fifth Amendment Taking

The Departments also disagree that the requirement to disclose negotiated rates in the final rules constitutes an unlawful taking without just compensation under the Fifth Amendment. As an initial matter, the subject of any ''taking'' is a cognizable property interest. Commenters asserted that their negotiated rates constitute property because they are trade secrets. The Departments disagree. In order for a piece of information to qualify as a trade secret, it must be the subject of efforts to maintain its secrecy that are reasonable under the circumstances. Under most circumstances, if a piece of information is disclosed to third parties who have no obligation to keep it a secret, it does not qualify for trade secrets protection. Negotiated rates for health care items and services are routinely disclosed in EOBs provided to participants, beneficiaries, and enrollees. Participants, beneficiaries, and enrollees have no obligation to keep the information contained in their EOBs secret; some patients provide them to journalists or upload them to crowd-sourcing websites.[84] The Departments are of the view that this routine disclosure of negotiated rate information is sufficient to defeat any asserted trade-secret protection, and, therefore, the issuers have no proprietary interest in the negotiated rates that could be the subject of a constitutional ''taking.''

Moreover, plans' and issuers' expectations of confidentiality in information provided as a condition of participation in a highly regulated industry (for example, health insurance) are substantially diminished by the highly regulated nature of the industry. *See, e.g., Ruckelshaus* v. *Monsanto Co.,* 467 U.S. 986, 1007 (1984) (noting that expectations are necessarily adjusted in areas that ''ha[ve] long been the source of public concern and the subject of government regulation''); *Me. Educ. Ass'n Benefits Trust* v. *Cioppa,* 695 F.3d 145 (1st Cir. 2012) (discussing a Maine law requiring health issuers to disclose loss information); *Franklin Mem'l Hosp.* v. *Harvey,* 575 F.3d 121, 128 (1st Cir. 2009) (holding that a claimant's investment-backed expectations were ''tempered by the fact that it operate[d] in the highly regulated hospital industry'').[85] Plans and issuers are already subject to extensive regulation under Federal and state law. As noted by the 1st Circuit in *Pharmacy Care* v. *Rowe:*

> If [regulated parties] truly assumed that they would be free from disclosure requirements . . . this would be more wishful thinking than reasonable expectation. Whether or not the law strikes the right economic balance between competing producer and consumer interests, it is no more a taking than the requirement that public corporations disclose private corporate information about financial prospects to the public through regular SEC filings.

Pharm. Care Mgmt. Ass'n v. *Rowe,* 429 F.3d 294, 316 (1st Cir. 2005) (joint concurring opinion representing the opinion of the court). The Court further stated: ''Given the absence of a full-scale taking and the presence of a traditional regulatory interest, it is enough to defeat the takings claim that no reasonable investment-backed expectation is present at all.'' *Id.* at 315; *see also Good* v. *United States,* 189 F.3d 1355, 1363 (Fed. Cir. 1999) (''We have previously held that the government is entitled to summary judgment on a regulatory takings claim where the plaintiffs lacked reasonable, investment-backed expectations. . . .'').

Even if there were some property interest in negotiated rates, the Departments are of the view that this regulation is not a taking. The Supreme Court ''has identified several factors that should be taken into account when determining whether a governmental action has gone beyond 'regulation' and effects a 'taking.' '' *Monsanto,* 467 U.S. at 1005. Among those factors are ''the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations.'' *Id.* (citing *PruneYard Shopping Ctr.* v. *Robins,* 447 U.S. 74, 83 (1980)); *see also Kaiser Aetna* v. *United States,* 444 U.S. 164, 175 (1979); *Penn Cent. Transp. Co.* v. *City of N.Y.,* 438 U.S. 104, 124 (1978).

In requiring disclosure under the final rules, the government does not do so with the intention that the information is primarily and explicitly for the government's own use, or that any such potential impact is the purpose for requiring the disclosure. Instead, the final rules are intended to, and will, enable consumers to access information needed to make informed decisions on health care services. Under *Penn Central,* ''[a] 'taking' may more readily be found when the interference with property can be characterized as a physical invasion by government than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common good.'' *Penn Central,* 438 U.S. at 124 (citation omitted). The final rules clearly fall on the other end of the spectrum, arising from statutory provisions, section 1311(e)(3) of PPACA and section 2175A of the PHS Act, that ''adjust[t] the benefits and burdens of economic life to promote the common good.'' *Connolly* v. *Pension Benefit Guar. Corp.,* 475 U.S. 211, 212 (1986).

3. Protections for Proprietary, Confidential Business Information, and Trade Secrets

Several commenters objected to the proposed rules on grounds that the requirement that issuers make public negotiated rates with providers would require the disclosure of allegedly confidential, proprietary business information, and trade secrets that are expressly protected from disclosure by a variety of Federal and state laws, and the statute does not in any way purport to abrogate those protections. Several commenters pointed to the Defend Trade Secrets Act (DTSA), which protects the property rights of trade secret holders,[86] and the Freedom of Information Act (FOIA),[87] which protects confidential, proprietary business information, and trade secrets from public disclosure, as examples of Congress' intent that such information be protected.

The Departments disagree. As discussed above, the Departments are of the view that the routine disclosure of negotiated rate information to third parties via EOBs means that the rate information is not a trade secret, and the DTSA, therefore, does not apply. Even if it did, there can be no meaningful sense in which the disclosure of this information pursuant to the final rules would constitute a misappropriation by

[84] Kliff, S. ''Why I'm Obsessed With Patients' Medical Bills, New York Times. August 7, 2020. Available at *https://www.nytimes.com/2020/08/07/insider/coronavirus-medical-bills.html*; *see also* Cerullo, M. ''As medical costs soar, more Americans turn to crowdfunding.'' CBS News. February 21, 2020. Available at: *https://www.cbsnews.com/news/health-care-costs-crowdfunding-medical-bills/.*

[85] PBMs serve as intermediaries between pharmacies and health benefit plans, including plans covered by ERISA. PBMs contract with pharmacies to establish pharmacy networks and contract with health benefit plans to provide access to those pharmacy networks. When a participant in a health benefit plan fills a drug prescription at a network pharmacy, the PBM pays the pharmacy at the rate negotiated in the contract between the PBM and the pharmacy (less any copayment by the participant), and the health benefit plan then reimburses the PBM at the rate negotiated in the contract between the PBM and the health benefit plan.

[86] 18 U.S.C. 1836(b).

[87] 5 U.S.C. 552.

improper means prohibited by the DTSA. The disclosures in question would be made pursuant to a regulatory mandate authorized by law, to effectuate policy priorities enacted by Congress: Namely, transparency in health care. These disclosures cannot reasonably be construed as ''theft, bribery, or misrepresentation.'' [88]

The disclosures required under the final rules would also not constitute a breach or inducement of a breach of a duty to maintain secrecy, as the final rules apply prospectively in a regulatory environment in which all parties to provider agreements, and all affected plans and issuers, are being placed on notice and should be aware in advance of the requirements of the final rules. All parties to these contracts are therefore positioned to modify contractual arrangements, or similar policies, practices, or expectations relating to privacy or trade secrets to conform to the final rules. Otherwise, the final rules will supersede these arrangements to the extent necessary to implement these rules.

FOIA is also not relevant to the disclosure that would be required by the final rules.[89] FOIA is a public information law that applies to Federal agencies, and generally enables the public to obtain records in possession of an agency.[90] Under the final rules, by contrast, negotiated rate information and out-of-network allowed amount information would be made available for the express purpose of making the information broadly available to the public, consistent with the authority Congress vested in the Departments. FOIA does not apply to disclosures by private entities such as the plans and issuers that would be subject to the disclosure requirements in the final rules. The exemptions found in the FOIA statute apply to disclosures by the government; that a piece of information might be subject to a FOIA exemption does not mean it is entitled to a heightened protection from disclosure when held by a private party.

Neither does FOIA apply to information maintained by private entities and not by an agency or government contractor, as that information would not constitute an agency record. To be an agency record subject to FOIA, an agency must have created or obtained the materials and must be in control of the materials. *U.S. Dep't of Justice* v. *Tax Analysts,* 492 U.S. 136, 145 (1989). Regardless of whether the negotiated rates and allowed amounts would constitute trade secrets or commercial information under FOIA, a requirement that private entities make certain information public does not implicate FOIA.

One commenter contended that the proposed disclosure of negotiated rates does not concern trade secrets, and is therefore not prohibited for that reason. The commenter asserted that the proposed disclosures concern end prices, which are comparable to the ''sticker price'' of a medical service or device. The commenter stated that those prices are not themselves trade secrets, which the commenter contended consist of negotiating tactics which the proposed rules would not require issuers to make available to the public. As indicated above in relation to the DTSA, the Departments agree that the final rules do not implicate trade secrets.

In support of the proposition that Congress could not have intended to undermine existing protections for confidential or proprietary business information and trade secrets when it enacted section 1311(e)(3) of PPACA, one commenter noted that elsewhere in PPACA, where Congress mandated pricing-related disclosures, it included language or arrangements that protected individual negotiated rates and pricing information from disclosure. A provision relating to the disclosure of drug cost information mandates release of only aggregated information and includes a specific designation of the information as confidential and protected from publication except in specific formats and for limited purposes that protect the identity of the parties to particular pricing arrangements.[91] Another provision mandates that hospitals make public a list of standard charges for items and services, not negotiated rates, on an annual basis only.[92] Both of these provisions, the commenter suggested, indicate Congressional intent to protect proprietary business information that is contrary to the requirements of the proposed rule.

The Departments are aware that Congress included provisions preventing or limiting disclosures of health care information in other sections of PPACA but note that Congress did not include such provisions in section 1311(e)(3)(A) of PPACA, indicating no intention that such restrictions apply in this context.[93]

Several commenters also pointed to the Sherman Antitrust Act, and specific applications of antitrust principles relating to the disclosure of trade secrets, including negotiated rates between issuers and providers in the health care context. They contend that Congress could not have intended to indirectly undermine these long-standing standards and policies when it enacted section 1311(e)(3) of PPACA. Several commenters also cited interpretive communications and similar guidance from the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice for the proposition that public disclosure of negotiated prices can have anticompetitive effects and harm consumers, contrary to long standing principles of antitrust law. One commenter recommended that any plan to make public privately negotiated rates should include requirements to aggregate information to ensure that arrangements of specific market participants remain confidential, and that a time lag also should be applied to any released data to ensure current information is not compromised.

The Departments disagree with the notion that the final rules will lead to anticompetitive behavior by plans, issuers, and providers. The Sherman Antitrust Act prohibits any contract, combination, or conspiracy in restraint of trade or commerce.[94] Specifically, the law prohibits any ''person'' from entering into any such contract, trust, or similar arrangement.[95] ''The primary purpose of the antitrust laws is to protect interbrand competition.'' *State Oil Co.* v. *Khan,* 522 U.S. 3, 15 (1997) (citing *Bus. Elec. Corp.* v. *Sharp Elec. Corp.,* 485 U.S. 717, 726 (1988)). The Departments are not of the view that publication of plans' and issuers' negotiated rates with providers is likely to spur plans and issuers (''persons'') to violate the law by colluding to fix their prices in a manner that restrains trade. Rather, while the publication of price information sometimes facilitates tacit collusion, based on public comments and the many empirical studies that have investigated the impact of price transparency on other, non-health care markets, the Departments are of the

[88] 18 U.S.C. 1839(5)–(6).

[89] 5 U.S.C. 552.

[90] 5 U.S.C. 552(b)(4).

[91] 42 U.S.C. 1320b–23(c).

[92] 42 U.S.C. 300gg(18)(e).

[93] *See, for example, Keene Corp.* v. *United States,* 508 U.S. 200, 208 (1993) (''[W]here Congress includes particular language in one section of a statute but omits it in another . . . it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'').

[94] 15 U.S.C. 1.

[95] *Id.* ''Person'' or ''persons'' are defined at 15 U.S.C. 12(a) (''[P]erson'' or ''persons'' wherever used in this Act shall be deemed to include corporations and associations existing under or authorized by the laws of either the United States, the laws of any of the Territories, the laws of any State, or the laws of any foreign country'').

view that transparency of negotiated rates will likely motivate plans, issuers, and providers to reassess the competitiveness of their prices in order to continue to successfully compete with lower premiums, deductibles, and other cost-sharing responsibilities, and lower priced health care items and services. As stated in the preamble of the Hospital Price Transparency Final Rule, many empirical studies have investigated the impact of price transparency on markets, with most research, consistent with predictions of standard economic theory, showing that price transparency leads to lower and more uniform prices.[96] Traditional economic analysis suggests that if consumers were to have better pricing information for health care services, providers would face pressure to lower prices and provide better quality care. Falling prices may, in turn, expand consumers' access to health care.[97]

By disclosing negotiated rates, the Departments are of the view that the public (including patients, employers, clinicians, and other third parties) will have the information necessary to make more informed decisions about their care. The Departments expect that the impact of more expansive transparency in pricing information will increase market competition and may ultimately drive down the cost of health care services, making care more affordable for all consumers.

Although the Departments appreciate that regulated entities could seek to engage in unlawful behavior in restraint of trade, antitrust law does not proscribe or limit action by the Federal Government to address chronic issues in the nation's health care markets. Such actions include new, innovative measures that, based on evidence and research, are likely to improve competition and lower costs to consumers. The Departments also are of the view that the statute and the final rules do not constitute an abrogation of antitrust law. Nothing under the final rules creates, compels, or endorses agreements or conspiracies between or among persons to form illegal arrangements or trusts in restraint of trade or commerce. To the contrary, antitrust law enforcement remains an important tool to protect these markets from anticompetitive behavior.

The Departments are of the view that the disclosure of negotiated rates would serve a greater public interest and that ''concealing negotiated price information serves little purpose other than protecting dominant providers' ability to charge above-market prices. . . .'' [98] For example, in Maine, one state official indicated that ''to date, there is no evidence that the release of [Maine Health Data Organization] claims data has resulted in an anticompetitive market. Similarly, disclosure of claims data in New Hampshire has resulted increased competition and reduced prices for health care.[99]

For the reasons set forth in this preamble, the Departments are of the view that the final rules will enhance competition, improve markets, and benefit all consumers of health care, including individuals, employers, and government health care programs. Under the final rules, disclosure of the negotiated rate is critical to the ability of consumers, including those who have not met their annual deductible obligation, to be able to reasonably estimate in advance their personal liability for covered services from participating providers. It is also critical in estimating coinsurance liabilities that are calculated as a percentage of provider charges. In addition, the Departments are of the view that accessible pricing information improves market efficiency.[100]

4. Administrative Procedure Act (APA) and Arbitrary and Capricious Agency Action

Some commenters asserted that the proposed rules were arbitrary and capricious and thus violate the APA. Two commenters contended that the Departments' rationale is entirely speculative. They also contended that the Departments have not quantified in a reliable way the costs or anticipated benefits of the proposed rules, examined relevant data, or articulated a satisfactory explanation for the proposed rules. One commenter held the opposite position and asserted that the proposed rules were fully consonant with APA requirements. The commenter believed the Departments are implementing PPACA appropriately, and that the interpretation of the authorities underlying the proposed rules was reasonable and rationally explained by the Departments.

The Departments are also of the view that the final rules are consistent with the APA. Section 1311(e)(3) of PPACA and section 2715A of the PHS Act are designed to assist consumers by enhancing their ability to make cost-conscious decisions, which is essential to establish and maintain the level of market competition necessary to ensure that health care costs are rational, reasonable, and governed by standard market discipline. As the preamble to the proposed rules observed, there is substantial evidence that increased price transparency improves market efficiency.[101] For these reasons, it is within the scope of the statute to assist consumers with selecting providers, evaluating market options, increasing competition, and reducing market disparities. The carefully targeted information is essential to the goals of price transparency, and there is no other means of making cost-sharing liability information available to consumers whose personal liability is determined in whole or in part by reference to negotiated rates or allowed amounts. The Departments further hold the view that the Departments have made reasonable efforts to quantify all aspects of the final rules, and their potential effects, for which data is available. The Departments also note that efforts have been made to qualitatively address those areas where the Departments are unable to adequately derive quantitative assessments. Responses to additional comments are discussed later in the Regulatory Impact Analysis (RIA) and Regulatory Alternatives Considered sections of this preamble.

This preamble (as well as the preamble to the proposed rules) cites substantial research indicating that increased price transparency increases competition and lowers costs, leads to

[96] 84 FR 65464, 65524 (Nov. 27, 2019).

[97] Austin, A. D., and Gravelle, J. G. ''Congressional Research Service Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector''. April 29, 2008. Available at: *https://crsreports.congress.gov/product/pdf/RL/RL34101*.

[98] Catalyst for Payment Reform. ''Report Card on State Price Transparency Laws.'' July 2015. Available at: *https://www.catalyze.org/wp-content/uploads/woocommerce_uploads/2017/04/2015-Report-Card-on-State-Price-Transparency-Laws.pdf*.

[99] Brown Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 101 Rev. of Econ. & Stat. 699 (2019). Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf*.

[100] Austin, D.A., and Gravelle, J.G. ''CRS Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector.'' July 24, 2007. Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf*.

[101] 84 FR 65464, 65489; 65495 (Nov. 27, 2019); *see also* Austin, A.D., and Gravelle, J.G. ''Congressional Research Service Report to Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector.'' July 24, 2007. Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf; see also* Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 100 Rev. Econ. & Stat. 1. Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf*; *see also* Enthoven, A. ''Market Forces and Efficient Health Care Systems.'' Health Affairs, Vol. 23, No. 2. Available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.23.2.25*.

more uniform pricing within markets, and increases overall market efficiency.[102] This preamble also cites an abundance of evidence indicating that industry and other stakeholders believe that increased price transparency will enhance competition and benefit consumers. As stated earlier in this preamble in relation to comments regarding the First Amendment, the information the final rules require to be disclosed is clearly identified and has a direct nexus to the government's legitimate and substantial interest in ensuring that consumers have sufficient information to calculate out of pocket costs for health care items and services and ultimately assess whether the payment terms of plans and coverages are fair, reasonable, or advantageous to the consumer. Furthermore, in the Impact Estimates of the Transparency in Coverage Provisions and Accounting Table section later in this preamble, the Departments identify ranges of relevant factors and categories of information that the Departments have attempted to quantify, as well as those factors and categories that the Departments cannot quantify at this time. Nevertheless, the Departments are of the view that those determinations are reasonable and sufficiently thorough, and that the Departments' expectations regarding the impacts of the final rules are not speculative.

5. Other Legal Concerns

Several commenters asserted that requiring issuers to make negotiated prices public could violate various state laws, principles of common law, and tort laws concerned with the protection of trade secrets and proprietary business information. Several commenters specifically stated that the proposal would violate the Uniform Trade Secrets Act (UTSA) [103] as adopted by several states.

The Departments understand these concerns and appreciate that States have passed laws and regulations that may address the same or similar information the final rules require to be publicly disclosed, or disclosed to participants, beneficiaries, or enrollees. The final rules will preempt these laws, to the extent they conflict with Federal law and would prevent application of Federal requirements, as required under section 1321(d) of PPACA and section 2724(a) of the PHS Act. The Departments discuss this issue in more detail later in this preamble in the context of addressing federalism considerations.

Moreover, the Departments are also of the view that negotiated rates do not constitute trade secrets as defined under the UTSA and under principles of tort law. A trade secret under the UTSA is ''information, including a formula, pattern, compilation, program, device, method, technique, or process'' that ''derives independent economic value. . . from not being generally known [or] readily ascertainable by proper means by . . . other persons who can obtain economic value from its disclosure [and] is the subject of efforts to . . . maintain its secrecy.'' [104] Critically, and as discussed earlier, negotiated rates are routinely disclosed to beneficiaries in EOBs.

To the extent the final rules require disclosure of trade secrets, the activity that supports a cause of action under tort law includes obtaining the information by improper means or a breach of confidence.[105] No such scenario is implicated where the disclosure is made pursuant to a regulatory mandate authorized by statute. In this context, the disclosure is a legal obligation, and so the disclosure is by definition proper and made in the absence of any duty of confidence.

Finally, even if negotiated rates could constitute trade secrets under a state's law, state law cannot invalidate the authority Congress granted to the Departments under section 1311(e)(3) of PPACA to require disclosure of negotiated rates and other information that the Departments determine appropriate to create a level of transparency in coverage sufficient to address chronic issues in American health care markets, including rising health care prices.

Several commenters asserted that making negotiated rates public would violate contractual arrangements between virtually all issuers and providers, in particular contractual provisions that prohibit disclosure of negotiated rates. One commenter noted that this would, at a minimum, require a considerable effort to amend many existing contracts.

The Departments understand that changes in applicable laws and regulations may necessitate changes to certain business and contractual relationships over time. The Departments are of the view, however, that the final rules are necessary to advance the interests of consumers and to fulfill the goals of the relevant statutes. The Departments also anticipate that in most cases, affected contracts include clauses that specifically anticipate the possibility of future changes to applicable law or regulations. Additionally, even if a contract between a provider and a payer includes a provision prohibiting the public disclosure of its terms, it is the Departments' understanding that such contracts typically include exceptions if a particular disclosure is required by Federal law. Finally, as the Supreme Court has found, ''[c]ontracts, however express, cannot fetter the constitutional authority of Congress. Contracts may create rights of property, but when contracts deal with a subject matter which lies within the control of Congress, they have a congenital infirmity. Parties cannot remove their transactions from the reach of dominant constitutional power by making contracts about them.'' *Norman* v. *Balt. & Ohio R.R. Co.,* 294 U.S. 240, 307–08 (1935) (''If the regulatory statute is otherwise within the powers of Congress . . . its application may not be defeated by private contractual provisions.''); *see also Connolly,* 475 U.S. at 224.

Several commenters contended that the proposed rules would be inconsistent with certain Executive orders. One commenter contended that Executive Order 13877, which the Departments cited as the impetus for the proposed rules, directs the agencies to ''require . . . health insurance issuers . . . to provide or facilitate access to information about expected out-of-pocket costs for items or services to patients before they receive care.'' The commenter asserted that this directive does not rationally encompass a requirement that issuers make public all negotiated rates and allowed amounts.

[102] 84 FR 65464, 65466–67 (Nov. 27, 2019).

[103] The Uniform Trade Secrets Act is a model statute that a majority of states have adopted in some form. The UTSA is promulgated by the Uniform Law Commission. *See generally,* Uniform Trade Secrets Act with 1985 Amendments, Nat'l Conference of Commissioners on Uniform State Laws, August 1985. UTSA has been adopted in some form by 48 states. New York and North Carolina are the exceptions. *See* ''Trade Secrets Act.'' Uniform Laws Commission. Available at: *https://www.uniformlaws.org/committees/community-home?CommunityKey=3a2538fb-e030-4e2d-a9e2-90373dc05792.*

[104] *See* Uniform Trade Secrets Act with 1985 Amendments, Nat'l Conference of Commissioners on Uniform State Laws, August, 1985; Restatement (First) of Torts section 757 (1939).

[105] Restatement (First) of Torts section 757 (1939) (''*GENERAL PRINCIPLE.* One who discloses or uses another's trade secret, without a privilege to do so, is liable to the other if (a) he discovered the secret by improper means, or (b) his disclosure or use constitutes a breach of confidence reposed in him by the other in disclosing the secret to him, or (c) he learned the secret from a third person with notice of the facts that it was a secret and that the third person discovered it by improper means or that the third person's disclosure of it was otherwise a breach of his duty to the other, or (d) he learned the secret with notice of the facts that it was a secret and that its disclosure was made to him by mistake.'').

The commenter also asserted that the proposed rules are incompatible with section 3(b) of Executive Order 13877, which provides that any rulemaking be ''consistent with applicable law,'' in that the proposed rules run contrary to antitrust law as well as prohibitions against disclosing trade secrets.

The Departments disagree with these comments. First, Executive Order 13877 clearly states that it is ''not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.'' Executive Order 13877, Sec. 8(c). Thus, an Executive order cannot form the basis of a challenge to a rulemaking. Second, for all the reasons detailed earlier in this preamble, the Departments are of the view that the final rules are necessary and appropriate measures that are sufficiently narrowly tailored to meet the stated goals of the Executive order. Making public the negotiated rates and out-of-network allowed amounts is essential for consumers to obtain useful information about out-of-pocket costs they are likely to incur before receiving services. Due to the prevalence of high deductibles throughout markets nationwide, this information will be crucial for a significant cohort of persons enrolled in health plans to be able to anticipate costs in advance of each plan year. For the public, access to information concerning allowed amounts is essential to obtain reliable advance estimates of personal liability to facilitate cost-conscious choices that enhance competition and lower overall costs. Finally, as described later in this preamble, the Departments considered many alternatives to the proposed and final rules. The Departments are of the view that the final rules are a straightforward implementation of the mandate of section 1311(e)(3) of PPACA, and that the choices taken in particular instances are well calculated to effectively and fully implement the goals of the authorizing statutes. Moreover, the regulations provide tools and information to consumers that are critical to their ability to access meaningful price information, including the personal liability associated with a substantial portion of health care services. This directly facilitates the meaningful engagement of consumers with their own health care and protects patients from the likelihood of unanticipated health care costs. As such, the regulations fulfill the mandate of Executive Order 13877.

For the foregoing reasons, the final rules adopt the majority of the provisions in the proposed rules, with certain modifications, as described in detail in the following sections of this preamble.

II. Overview of the Final Rules Regarding Transparency—the Departments of the Treasury, Labor, and Health and Human Services

The Departments are finalizing price transparency requirements set forth in the final rules in 26 CFR 54.9815–2715A1, 54.9815–2715A2, and 54.9815–2715A3, 29 CFR 2590.715–2715A1, 2590.715–2715A2, and 2590.715–2715A3, and 45 CFR 147.210, 147.211, and 147.212. The final rules separate the proposed regulations all contained in 26 CFR 54.9815–2715A, 29 CFR 2590.715–2715A, and 45 CFR 147.210, into three separate regulations for each of the Departments. The regulations set forth the scope and relevant definitions in 26 CFR 54.9815–2715A1, 29 CFR 2590.715–2715A1, and 45 CFR 147.210 (which correspond with paragraph (a) of the proposed regulations). The regulations at 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and, 45 CFR 147.211 (which correspond with paragraph (b) of the proposed regulations) include: (1) A requirement that group health plans and health insurance issuers in the individual and group markets disclose to participants, beneficiaries, or enrollees upon request, through a self-service tool made available by the plan or issuer on an internet website, cost-sharing information for a covered item or service from a particular provider or providers, and (2) a requirement that plans and issuers make such information available in paper form, upon request. As explained in more detail later in this preamble, the final rules adopt a three-year, phased-in approach with respect to the scope of the requirement to disclose cost-sharing information. Plans and issuers must make cost-sharing information available for 500 items and services identified by the Departments for plan years (in the individual market, for policy years) beginning on or after January 1, 2023, and must make cost-sharing information available for all items and services for plan years (in the individual market, for policy years) beginning on or after January 1, 2024.

The regulations at 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 (at paragraph (c) of the proposed regulations) require that plans and issuers disclose pricing information to the public through three machine-readable files. One file requires disclosure of payment rates negotiated between plans or issuers and providers for all covered items and services. The second file will disclose the unique amounts a plan or issuer allowed, as well as associated billed charges, for covered items or services furnished by out-of-network providers during a specified time period. To reduce the complexity and burden of including prescription drug information in the negotiated rate machine-readable file, the final rules require a third file that will include pricing information for prescription drugs. The final rules modify the applicability date for these provisions to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

The provisions proposed at paragraph (d) of the proposed regulations are finalized in 26 CFR 54.9815–2715A2 and 54.9815–2715A3, 29 CFR 2590.715–2715A2 and 2590.715–2715A3, and 45 CFR 147.211 and 147.212 with non-substantive editorial changes for increased readability, and with effective dates reflecting the phased approach to implementation mentioned earlier and discussed in more detail later in this preamble.

In addition to splitting the final rules into three separate regulations for each Department, the Departments have added severability clauses to the final rules to emphasize the Departments' intent that, to the extent a reviewing court holds that any provision of the final rules is unlawful, the remaining rules should take effect and be given the maximum effect permitted by law. The final rules provide that any provision held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from the relevant section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

To streamline the final rules, the Departments have removed definitions of terms that are defined in the applicable statute or elsewhere in such statutes' implementing regulations and have revised certain definitions to provide more clarity. Finally, based on comments received, the Departments have reassessed the associated burden estimates in the Economic Impact Analysis and Paperwork Burden section of this preamble.

A. Definitions

The final regulations at 26 CFR 54.9815–2715A1(a), 29 CFR 2590.715–2715A1(a), and 45 CFR 147.210(a) (paragraph (a) of the proposed regulations) set forth definitions that are applicable to the regulations at 26 CFR 54.9815–2715A2, 29 CFR 2590.715–

2715A2, and 45 CFR 147.211 (paragraph (b) of the proposed regulations) and 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, 45 CFR 147.212 (paragraph (c) of the proposed regulations). The Departments have revised the proposed definitions of some terms and included new defined terms in order to clarify the final requirements of 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211, and 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212. Comments on the definitions in the proposed rule focused on concerns regarding consistency of definitions across related government programs, the general need for increased clarity in relation to some proposed definitions, and the need for resolution of perceived ambiguities in the proposed definitions. In response to these comments, the Departments are not finalizing certain proposed definitions that are already defined in existing, pertinent regulations. The Departments are finalizing revised versions of other proposed definitions to clarify their meaning, as well as the policies and requirements adopted in the final rules.

Commenters recommended aligning definitions in the proposed regulations with those in other existing regulations to avoid conflicts. In light of these recommendations, the Departments are not finalizing the proposed definition of ''participant'' under 26 CFR 54.9815–2715A1, 29 CFR 2590.715–2715A1, or 45 CFR 147.210 because the term is already defined in the Departments' regulations at 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103. Likewise, the Departments are not finalizing the proposed definition of ''beneficiary'' under proposed 45 CFR 145.210 and 29 CFR 2590.715–2715A1, because the term is already defined under HHS regulation at 45 CFR 144.103 and in statute at ERISA section 3(8). The Departments, however, are finalizing the definition of ''beneficiary'' proposed under 26 CFR 54.9815–2715A(a) (now at 26 CFR 54.9815–2715A1), because the term is not otherwise defined in Treasury Regulations or the Code. Finally, the Departments are not finalizing the proposed definition for ''qualified health plan'' at 45 CFR 145.210 since the term is not used in the regulation text.

Some commenters requested clarification of the terms ''participants'' and ''beneficiaries'' because the proposed rules' definitions of these terms included individuals who may become eligible for a plan or coverage, and as the proposed rules envisioned personalized feedback to ''participants'' and ''enrollees'' it would be impossible to provide such information to an individual not currently enrolled in a plan or coverage. The Departments agree. However, instead of modifying existing, applicable definitions for ''participants'' and ''beneficiaries,'' the final rules, at 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211, and this preamble below clarify to whom these disclosures are required.

One commenter recommended the Departments define the term ''in-network provider'' in the final rules to clearly exclude device suppliers and manufacturers that, the commenter suggested, have not traditionally been considered in-network providers and whose price information is of limited value to consumers. The Departments do not agree that device suppliers and manufacturers should be excluded. Based on the numerous public comments from individuals who support broad price transparency for all covered items and services, the Departments are of the view that pricing information for all covered items and services should be available, including pricing for durable medical equipment (DME) or other medical devices that are supplied to a participant, beneficiary, or enrollee by a provider under a contract with a plan or issuer. To clarify, the final rules define in-network provider to mean any provider of items and services with which the plan or issuer, or a third-party for a plan or issuer, has a contract setting forth the terms under which a covered item or service may be provided to a participant, beneficiary, or enrollee. The Departments broadened this definition to clarify that even where a provider and a plan or issuer have a limited rate agreement of some kind, or a rate agreement covering DME, those providers should be considered in-network providers for purposes of the final rules. Additionally, if a plan or issuer enters into a contract or has such payment arrangements, then the pricing information for the specific covered items or services subject to that contract or payment arrangement are required to be disclosed as part of the internet self-service tool and machine-readable files.

The proposed regulations included a definition for ''negotiated rate'' to mean the amount a group health plan or health insurance issuer, or a third party on behalf of a plan or issuer, has contractually agreed to pay an in-network provider for covered items and services, pursuant to the terms of an agreement between the provider and the plan or issuer, or a third-party on behalf of a plan or issuer. Consistent with the proposed and final definitions of ''items and services,'' plans and issuers are required to disclose ''negotiated rates'' for encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees) to participants, beneficiaries, and enrollees through the internet-based self-service tool (and in paper form) as well as to the public through a machine-readable file. One commenter requested the Departments clarify the meaning of ''negotiated rate'' for prescription drugs, noting that they assumed the Departments expected plans and issuers to provide the drug price negotiated by a PBM on behalf of the plan. Another commenter asserted that the ''negotiated rate'' of prescription drugs for disclosure should be the price patients will see at the point-of-sale, meaning the undiscounted price of the drug, plus dispensing fees. Conversely, another commenter stated that dispensing fees are not paid by enrollees or used in determining cost-sharing liability. Other commenters suggested that the Departments grant plans and issuers flexibility in determining the appropriate rate for disclosure, as plans and issuers use a variety of different benchmarks, such as the Average Wholesale Price (AWP), or Wholesale Acquisition Cost (WAC) which may be considered as the ''negotiated rate'' for the purpose of determining cost-sharing liability under the plan or coverage.

In the final rules, the Departments have revised the definition of ''negotiated rate'' to mean the amount a plan or issuer has contractually agreed to pay for a covered item or service, whether directly or indirectly through a third party administrator (TPA) or PBM, to an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items or services. The final rules adopt the proposed definition with two key modifications. First, the term ''third party'' from the proposed definition is expanded in the final rules to explicitly refer to ''third-party administrator or pharmacy benefit manager.'' Second, the final definition of ''negotiated rate'' specifically notes that the term in-network provider includes an in-network pharmacy or other prescription drug dispenser. The purpose of these modifications is to confirm the commenter's inference that in the case of prescription drugs, the plan or issuer should include the price negotiated for that plan or issuer by a PBM. Furthermore, the ''negotiated rate'' in the final rules is intended to be broad enough to account for different plan

designs and benchmarks for determining negotiated rates.

The final rules also add definitions for the following terms that were not included in the proposed regulations: ''billed charge,'' ''copayment assistance,'' ''derived amount,'' ''historic net price,'' ''national drug code,'' and ''underlying fee schedule.'' The addition of these definitions is discussed later in this preamble.

One commenter noted that the Departments have proposed definitions for ''accumulated amounts,'' ''cost-sharing liability,'' and ''cost-sharing information'' that are unique to the proposed rules and, in some cases, differ from definitions of similar terms used in other related regulations. In particular, this commenter recommended that all definitions should explicitly recognize that cost sharing can be paid by or on behalf of an enrollee, participant, or beneficiary, since that is how cost sharing is defined by HHS regulation. The commenter also requested that the Departments clarify the proposed definition of ''accumulated amounts'' and suggested revising the definition to state clearly that accumulated amounts are the ''amount of financial responsibility a participant, beneficiary, or enrollee has incurred, whether satisfied by or on behalf of the participant, beneficiary, or enrollee. . . .''

The Departments recognize that cost sharing may be paid by a third-party on behalf of an enrollee, participant, or beneficiary. However, the Departments are of the view that some plans and issuers do not count cost-sharing liability payments made by a third-party towards a participant's, beneficiary's, or enrollee's accumulated amounts, and modifying the definitions as suggested by the commenter could cause confusion in the context of the final rules.

The Departments have added disclosure requirements that are discussed in detail elsewhere in this preamble to address this concern. The definitions being finalized also include non-substantive editorial changes from the proposed regulations for readability to the following terms; ''accumulated amounts,'' ''billing code,'' ''bundled payment arrangement,'' ''cost-sharing liability,'' ''cost-sharing information,'' ''covered items or services,'' ''item or services,'' and ''out-of-network allowed amount.''

The definitions identified as new or substantively modified in this section, as well as those that are being finalized as proposed, are discussed further in relation to the requirements of 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211 and 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212 throughout this preamble.

B. Requirements for Disclosing Cost-Sharing Information to Participants, Beneficiaries, and Enrollees

The final rules are intended to enable participants, beneficiaries, and enrollees to obtain an estimate of their potential cost-sharing liability for covered items and services they might receive from a particular health care provider, consistent with the requirements of section 2715A of the PHS Act and section 1311(e)(3)(C) of PPACA. Accordingly, the Departments proposed in paragraph (b) of the proposed regulations to require group health plans and health insurance issuers to disclose certain information relevant to a determination of a consumer's out-of-pocket costs for a particular health care item or service in accordance with specific method and format requirements, upon the request of a participant, beneficiary, or enrollee.

A majority of commenters supported the Departments' proposal and urged the Departments to finalize this section of the proposed rules. Many commenters were supportive of being able to know their costs before receiving care in order to make informed shopping decisions. Some commenters agreed that consumers should have access to cost information in advance of receiving care, but suggested modifications to the proposed requirements. The final rules adopt the requirement that plans and issuers disclose certain cost-sharing information for a particular health care item or service, generally as set forth in the proposed rules, but with certain modifications and clarifications explained later in this section of this preamble.

1. Information Required To Be Disclosed to Participants, Beneficiaries, or Enrollees

Based on significant research and review of public comments, the Departments concluded that requiring group health plans and health insurance issuers to disclose to participants, beneficiaries, or enrollees cost-sharing information in the manner most familiar to them is the best means to empower individuals to understand their potential cost-sharing liability for covered items and services furnished by particular providers. The Departments, therefore, modeled the proposed price transparency requirements on existing notice requirements.

Specifically, section 2719 of the PHS Act (incorporated into the Code by section 9815 of the Code and into ERISA by section 715 of ERISA) requires non-grandfathered plans and issuers offering non-grandfathered coverage in the individual or group markets to provide a notice of adverse benefit determination (typically satisfied by the EOB) to participants, beneficiaries, or enrollees after health care items or services are furnished and claims for benefits are adjudicated. EOBs typically include the amount billed by a provider for items and services, negotiated rates or underlying fee schedules with in-network providers or allowed amounts for out-of-network providers, the amount the plan paid to the provider, and the individual's obligation for deductibles, copayments, coinsurance, and any other balance under the provider's bill. Consumers are accustomed to seeing cost-sharing information as it is presented in an EOB. The proposed rules were intended to similarly require plans and issuers to provide the specific price and benefit information on which an individual's cost-sharing liability is based. Based on comments, the Departments are of the view that participants, beneficiaries, and enrollees would also benefit from understanding the price of items and services, even in circumstances when their cost-sharing liability is not based upon a negotiated rate or underlying fee schedule rate. Given this primary goal of overall price transparency, the Departments are requiring disclosure of the negotiated rate, even if it is not the amount used as the basis for cost-sharing liability.

The proposed rules set forth seven content elements that a plan or issuer must disclose, upon request, to a participant, beneficiary, or enrollee for a covered item or service: estimated cost-sharing liability, accumulated amounts, negotiated rates, out-of-network allowed amounts, a list of items and services subject to bundled payment arrangements, a notice of prerequisites, if applicable, and a disclosure notice. These seven content elements generally reflect the same information that is included in an EOB after health care services are provided. The Departments determined that each of the seven content elements, as well as two additional content elements, are necessary and appropriate to implement the mandates of section 2715A of the PHS Act and section 1311(e)(3)(C) of PPACA by permitting individuals to learn the amount of their cost-sharing liability and understand the price for specific items or services under a plan

or coverage from a particular provider. The final rules adopt the requirement that plans and issuers must satisfy these elements through disclosure of actual data relevant to an individual's cost-sharing liability that is accurate at the time the request is made. The Departments acknowledge that plans and issuers may not have processed all of an individual's outstanding claims when the individual requests the information; therefore, plans and issuers would not be required to account for outstanding claims that have not yet been fully processed. As set forth in 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211 this cost-sharing information must be disclosed upon request in two ways: (1) Through a self-service tool that meets certain standards and is available on an internet website, and (2) in paper form, if requested by the participant, beneficiary, or enrollee.

Furthermore, under the final rules, the cost-sharing information must be disclosed to the participant, beneficiary, or enrollee in plain language. The final rules define ''plain language'' to mean written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee. Determining whether this standard has been satisfied requires an exercise of considered judgment and discretion, taking into account such factors as the level of comprehension and education of typical participants, beneficiaries, or enrollees in the plan or coverage and the complexity of the terms of the plan or coverage. Accounting for these factors would likely require limiting or eliminating the use of technical jargon and long, complex sentences, so that the information provided will not have the effect of misleading, misinforming, or failing to inform participants, beneficiaries, or enrollees.

Several commenters agreed that the information found in an EOB is a good basis for informing individuals of their cost-sharing liability and will effectively further coverage transparency efforts. One commenter stated that information found in an advance EOB is neither a trade secret, nor proprietary, as it is routinely disclosed following care. Other commenters expressed concern about this concept of an advance EOB, stating that most plans and issuers do not have access to all the information necessary to provide beneficiaries with an upfront adjudication of the beneficiary's claim, and that the vast majority of data provided via online tools now rely on estimated costs drawn from publicly available sources rather than personal information and circumstances.

Many commenters expressed concerns that the elements and methods of disclosure proposed by the Departments are overly prescriptive, hindering health plan innovation and requiring potentially significant reworking of existing transparency tools, as well as requiring massive IT and resource investments by all commercial plans and issuers to develop, build or modify, test, and implement tools that meet the new standards. Several commenters recommended providing plans and issuers with flexibility to build upon current systems. Another commenter urged the Departments to evaluate the individualized tools currently available, and that if requirements for cost-estimator tools are adopted, they should give carriers and TPAs maximum flexibility in designing their tools. One commenter felt a better approach would be to educate consumers about the online tools that are currently available and assist employers to encourage their use. Several commenters opposed the requirement to provide the tool and suggested the Departments remove this requirement from the final rules altogether. These commenters stated that price estimator tools should not be required, citing studies showing low tool utilization by consumers and plan participants, beneficiaries, or enrollees. These commenters stated that the administration should instead focus on educating consumers about the online tools that are currently available and assisting employers and plans in encouraging their use.

The Departments are of the view that modeling the pricing disclosures on the elements provided within an EOB is both reasonable and appropriate. The Departments acknowledge the potential burden of updating existing tools to comply with the final rules, but the Departments think that the potential burden is outweighed by the importance of all enrollees, beneficiaries, and participants having access to self-service tools that provide a baseline of accurate pricing elements. The Departments also acknowledge that, historically, there has been low utilization of existing tools; however, the Departments are of the view that by creating minimum uniform standards, consumers will have access to more reliable, personalized estimates and will be more likely to use the tools.

As described earlier in this preamble, through independent examination and engagement with stakeholders, the Departments are of the view that existing tools vary widely in usability and reliability due to the lack of minimum standards.[106] The Departments received thousands of supportive comments from individuals eager for access to transparent pricing information, indicating that the current tools available are inadequate in practice. Furthermore, as discussed in great detail throughout this preamble, as consumers increasingly become financially responsible for a greater proportion of the cost of their care (through deductible and coinsurance requirements, for example) they have a vested interest in comparing prices of potential providers and such items as prescription drugs. As such, it is likely in the best interest of plans, issuers, and providers to promote and educate their consumers on the benefits of these shopping tools, and the Departments encourage them to do so. The Departments do not agree with the commenter who stated that educating consumers regarding existing tools and encouraging their use would be a better approach than requiring the self-service tool as proposed. While the Departments agree that educating consumers on existing self-service tools is important, it does not replace the benefits of making reliable self-service tools available to most participants, beneficiaries, and enrollees in private market plans and coverages. The Departments are of the view that minimum consistent requirements for all plans and issuers may lead to an increase in health literacy and drive consumerism as participants, beneficiaries, and enrollees become more familiar with how plans and issuers calculate cost-sharing liability. Furthermore, the final rules adopt a phased implementation approach to these requirements as a mechanism to help mitigate the associated implementation burdens.

Some commenters requested that the Departments confirm that the intent of the proposed rules is that only participants and beneficiaries enrolled in the plan would have access to the tool, noting that the proposed regulations used the ERISA definitions of ''participant'' and ''beneficiary,''

[106] ''Are healthcare's cost estimate tools making matters worse for patients?'' Becker's Hospital CFO Report, November 2015. Available at: *https://www.beckershospitalreview.com/finance/are-healthcare-s-cost-estimate-tools-making-matters-worse-for-patients.html. Citing* Gordon, E. ''Patients Want to Price-Shop For Care, But Online Tools Unreliable.'' NPR. November 30, 2015, Available at *https://www.npr.org/sections/health-shots/2015/11/30/453087857/patients-want-to-price-shop-for-care-but-online-tools-unreliable.* (''Some estimators reflect a combined range of possible costs, while others are based off historical pricing or claims data from various sources. Many online estimate tools are restricted in the types of procedures they include. . .'').

which include individuals who may become eligible for the plan. Many commenters encouraged the Departments to also require that plans and issuers make cost-sharing information easily accessible to authorized representatives—which may include health care providers—so that they can better respond to patient inquiries. These commenters suggested that patients reasonably turn to providers for this information when contemplating or scheduling health care services, but providers often face barriers in accessing the necessary details from issuers to provide a timely, accurate estimate. Commenters suggested that plans and issuers should be required to give providers access to their patients' specific benefit information via a secure website, subject to patient consent. One commenter recommended that the tool be made applicable for the public while they are in the shopping and plan selection phase, not just after someone is enrolled in a plan. This commenter suggested that true cost transparency would not be possible if this information was not made available in advance.

The final rules clarify that disclosures of cost-sharing information are only required to individuals who are enrolled in the plan or coverage; no disclosures are required to be made to a ''participant'' or ''beneficiary'' solely because they might become eligible for the plan in the future. This is reflected by a revision to the proposed language being finalized at 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b) to refer to plans and issuers providing cost-sharing information to a participant, beneficiary, or enrollee who is enrolled in a plan or coverage. The Departments understand the value in provider access to cost-sharing information required under the final rules. However, this rulemaking focuses on implementing the statutory obligation for plans to make this information available to participants, beneficiaries, and enrollees. A participant, beneficiary, or enrollee may choose to share information regarding their personal cost-sharing liability with a provider for the purposes of making health care decisions. The final rules also require that this information must be provided to a participant's, beneficiary's, or enrollee's authorized representative. Under other applicable regulations, participants, beneficiaries, or enrollees may appoint a health care provider as their authorized representative.[107]

Regarding whether other types of information should be required to be disclosed in the self-service tool, several commenters expressed concern that information regarding cost without accompanying provider quality information could have a detrimental effect on overall health care cost and delivery of value-based care. One commenter stated that shifting care to a lower-cost provider could have unintended consequences of higher costs associated with unnecessary or improper care. Commenters recommended that a quality metric be included and that quality information be allowed to be included alongside price.

As discussed in the background section of this preamble and later in this preamble, the Departments acknowledge that quality information could be a valuable addition to a self-service tool. However, the Departments did not propose to require disclosure of quality information. Rather, the Departments sought comments regarding quality information in the proposed rules and plan to take those comments into consideration for future action. The Departments encourage plans and issuers to further innovate around the baseline standards outlined above and include quality information and other metrics not required by the final rules that would assist in consumer decision-making.

Several commenters suggested that plans and issuers should be required to disclose information not directly related to cost sharing. One commenter urged the Departments to include an additional requirement in the final rules for plans and issuers to provide consumers with information they need to fully understand their cost-sharing obligations for emergency services at the time they obtain their coverage, and recommended plans and issuers also update this information on an annual basis or when major changes occur that would impact their access to, and overall cost of, emergency care, such as changes to their provider. Another commenter recommended that when consumers enter a search for a primary service or treatment, that they also be provided with an ''alert'' that additional services, such as anesthesia, pathology, or laboratory tests, likely will be involved and will entail additional costs, which should also be disclosed. Another commenter requested that the Departments add the ''type of plan'' (for example, ERISA-covered group health plan, a QHP, a Medicare Advantage plan, a Medicaid MCO plan, an individual health plan, or a plan that is grandfathered from PPACA requirements) and in what state the plan is providing coverage as disclosure content elements that health plans would be required to post on the proposed internet-based self-service tool, so that the information is readily available.

The Departments recognize the benefit of providing information for emergency services at the time consumers obtain their coverage. The Departments are of the view, however, that existing rules governing summaries of benefits and coverage are designed to provide such information to consumers at the time they obtain coverage. As such, the Departments are not inclined to duplicate existing requirements in the final rules. The Departments also acknowledge that alerting consumers to additional services associated with a service or treatment for which they searched could be beneficial. For this reason, the final rules provide plans and issuers flexibility to give disclaimers that can address the likelihood that services in addition to the one for which a consumer searched will be necessary. The final rules also require that plans and issuers outline individual services when a consumer requests an estimate for a service that, per the agreement between a payer and a provider, will be provided and billed as a bundle. Plans and issuers are also free to provide such information in any way they so choose, including through an alert. The Departments are also of the view that participants, beneficiaries, and enrollees are generally aware of the type of plan they are enrolled in or can reasonably access this information by contacting their plan or issuer and therefore decline to require this information as part of the final rules.

Scope of Items and Services

Many commenters stated that the requirement to disclose the price of all covered items and services was overly broad and overly burdensome, and instead suggested the Departments limit disclosure to a core set of ''shoppable services'' that are commonly searched for in existing cost-estimator tools. Many commenters referenced the recently finalized definition of a shoppable service that was included in the Hospital Price Transparency final rule as ''a service that can be scheduled by a health care consumer in

[107] 29 CFR 2560.503–1(b)(4); *see also* 26 CFR 54.9815–2719(b)(2)(i), 29 CFR 2590.715–2719(b)(2)(ii), and 45 CFR 147.136(b)(2)(ii).

advance.''[108] Two commenters recommended no more than 300 shoppable items and services, while another suggested a limit of 200. As a way to reduce the cost burden, one commenter suggested that the requirements under the rules be limited to services that are priced above a certain threshold and provided $5,000 as an example. One commenter said the Departments should permit health plans and issuers to tailor their tools to best meet their enrollees' and providers' demonstrated needs and priorities, including selection of the items and services for which estimates are most useful and meaningful for participants, beneficiaries, and enrollees. Another commenter recommended that the cost-sharing requirement be limited to items and services where the estimated out-of-pocket price is frequently the same as the final price. Another recommended the tool not require data on those items/services with volatile prices or low volume.

One commenter, representing many plans and issuers, provided a list of 421 items and services that they recommended including under this disclosure requirement. The recommended list of 421 items and services are a result of an analysis the commenter performed which compared member feedback, claims frequency, operational feasibility, and state mandates and regulations, as well as variability of cost and search frequency. All 421 items and services were included by, at the minimum, a subset of issuers, indicating confidence that the covered items and services were shoppable. This commenter also noted that their survey of existing tools found a median of 526 services available to consumers enrolled in commercial coverage.

A few commenters recommended that the Departments limit the list of items and services to only major medical services. One commenter recommended the Departments not include cost sharing for DME. Several commenters suggested that a Technical Expert Panel (TEP) was needed to review data and input from stakeholders, advise on research the Departments should undertake, and determine which items and services and functional requirements would be suitable to include in the future.

Many individual commenters expressed their desire for dental, vision, and other excepted benefits to be included under the requirements of the final rules or in the near future. Further, a majority of individual commenters encouraged the Departments to require the inclusion of all items and services, stating that consumers have a right to know this information for all items and services in advance. Several commenters recommended that the rules be implemented in a more gradual phased-in timeline, by requiring the tool to cover a narrower data set of the most common shoppable services first and then broadened to eventually include all items and services. Another commenter stated that to the extent that the services include non-medical estimates like pharmacy and dental costs, those costs could likely only be included by allowing third parties that fulfill those benefits to provide separate transparency tools that integrate with a plan's tool.

The Departments agree with commenters who stated that consumers should be given price estimates in advance, and the Departments understand that what is considered useful and meaningful pricing information is likely to be unique to an individual's circumstances. For these reasons, and the rationale for this rulemaking described throughout this preamble, the Departments decline to accept suggestions related to limiting the number or types of items and services included under this requirement. However, the Departments acknowledge the potential burden of incorporating all items and services into a self-service tool immediately and are therefore finalizing a phased-in implementation timeline. Under the final rules, plans and issuers are required to provide estimates for the 500 items and services identified in Table 1 for plan years (in the individual market, for policy years) beginning on or after January 1, 2023. However, plans and issuers will be required to disclose pricing information with respect to all items and services for plan years (in the individual market, for policy years) beginning on or after January 1, 2024. Given that pricing estimates for all items and services will ultimately be required, the Departments do not find it necessary to convene a TEP to determine which items and services and functional requirements would be suitable to include in the future.

Further, in finalizing the provision that plans and issuers disclose cost-sharing liability information for all covered items and services, the Departments are clarifying that cost-sharing information must also be provided for covered prescription drugs and DME. As discussed later in this preamble, a plan or issuer will be considered compliant with this requirement if it offers its participants, beneficiaries, or enrollees access to the pricing information that is required under 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211, through a third-party tool, such as a PBM tool. As discussed elsewhere in this preamble, the Departments clarify that excepted benefits, such as limited-scope dental benefits offered under a separate policy, certificate, or contract of insurance that are not an integral part of a group health plan or health insurance coverage, are not subject to the requirements established under the final rules.

In developing the list of 500 items and services that are required to be included in the self-service tool during the first year of implementation, the Departments considered the recommendations made by the commenters to include shoppable items and services that are commonly used in existing tools. As mentioned above, in a survey of existing price transparency tools currently in use, one commenter found that the median number of items and services in existing tools is 526. Table 1 lists 500 items and services that will be required to be included in the first phase of implementation of the internet-based self-service tool. The Departments will publish a copy of this list on a publicly available website. The majority of these items and services (416) are based on the recommendation of several stakeholders. The Departments have determined not to include five of the recommended codes because they have since been retired. The Departments augmented the list with 84 additional services. These 84 services reflect some of the most frequently found services in External Data Gathering Environment (EDGE)[109] data, which are representative of services commonly provided in the individual and small group (or merged) markets. The Departments also examined the aggregate claims costs associated with these services nationally and concluded that these services could

[108] 84 FR 65524 (Nov. 27, 2019) (codified at 45 CFR 180.20).

[109] CMS began collecting enrollee-level data from issuers' EDGE servers beginning with the 2016 benefit year. See the HHS Notice of Benefit and Payment Parameters for 2018; Final Rule, 81 FR 94058, 94101–94103 (Dec. 22, 2016). The enrollee-level EDGE data collected by CMS includes an enrollment file, a medical claims file, a pharmacy claims file, and a supplemental diagnosis file for risk adjustment-covered plans in the states where HHS operates the risk adjustment program. CMS does not collect enrollee-identifiable elements to safeguard enrollee privacy and issuers' proprietary information. *See,* for example, 45 CFR 153.720.

have significant cost variability, ranging from the 25th percentile to the 75th percentile of costs, depending on service.

TABLE 1—500 ITEMS AND SERVICES LIST

Code	Description	Plain language description
J0702	BETAMETHASONE ACET&SOD PHOSP	Injection to treat reaction to a drug.
J1745	INFLIXIMAB NOT BIOSIMIL 10MG	A biologic medication.
G0102	Prostate cancer screening; digital rectal examination	
G0103	Prostate cancer screening; prostate specific antigen test (psa).	
G2061	Qualified non physician healthcare professional online assessment; 5–10 minutes.	Qualified non physician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes.
G2062	Qualified non physician healthcare professional online assessment service; 11–20 minutes.	Qualified non physician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes.
G2063	Qualified non physician qualified healthcare professional assessment service; 21+ minutes.	Qualified non physician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes.
G0206	Diagnostic mammography, including computer-aided detection (cad) when performed; unilateral.	
G0204	Diagnostic mammography, including computer-aided detection (cad) when performed; bilateral.	
G0121	Colon ca scrn; not hi risk ind	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk.
G0105	Colorectal ca scrn; hi risk ind	Colorectal cancer screening; colonoscopy on individual at high risk.
S0285	Cnslt before screen colonosc	Colonoscopy consultation performed prior to a screening colonoscopy procedure.
G0289	Arthro, loose body + chondro	Arthroscopy, knee, surgical, for removal of loose body, foreign body, debridement/shaving of articular cartilage (chondroplasty) at the time of other surgical knee arthroscopy in a different compartment of the same knee.
G0120	Colon ca scrn; barium enema	Colorectal cancer screening; alternative to g0105, screening colonoscopy, barium enema.
460	SPINAL FUSION (POSTERIOR)	Spinal fusion except cervical.
470	KNEE REPLACEMENT	Major joint replacement or reattachment of lower extremity.
473	SPINAL FUSION (ANTERIOR)	Cervical spinal fusion.
743	HYSTERECTOMY	Uterine and adnexa procedures for non-malignancy.
1960	Anesthesia for vaginal delivery	
1961	Anesthesia for cesarean delivery	
1967	Anesthesia for labor during planned vaginal delivery	
1968	Anesthesia for cesarean delivery following labor	
10005	FNA W IMAGE	Fine needle aspiration biopsy, including ultrasound guidance; first lesion.
10021	FNA W/O IMAGE	Fine Needle Aspiration Biopsy without imaging.
10040	ACNE SURGERY	Incision and Drainage Procedures on the Skin, Subcutaneous and Accessory Structures.
10060	DRAINAGE OF SKIN ABSCESS	Incision and drainage of abscess; simple or single and complex or multiple.
10140	DRAINAGE OF HEMATOMA/FLUID	Incision and drainage of hematoma, seroma or fluid collection.
10160	PUNCTURE DRAINAGE OF LESION	Puncture aspiration of abscess, hematoma, bulla, or cyst.
11000	DEBRIDE INFECTED SKIN	Removal of infected skin.
11056	TRIM SKIN LESIONS 2 TO 4	Paring or cutting of benign hyperkeratotic lesion.
11102	BIOPSY SKIN LESION	Tangential biopsy of skin (for example, shave, scoop, saucerize, curette); single lesion.
11103	BIOPSY SKIN ADD–ON	Tangential biopsy of skin (for example, shave, scoop, saucerize, curette); each separate/additional lesion.
11200	REMOVAL OF SKIN TAGS <W/15	Removal of skin tags, multiple fibrocutaneous tags, any area.
11401	EXC TR–EXT B9+MARG 0.6–1 CM	Under Excision-Benign Lesions Procedures on the Skin 0.6–1 CM.
11422	EXC H–F–NK–SP B9+MARG 1.1–2	Under Excision-Benign Lesions Procedures on the Skin 1.1–2 CM.
11602	EXC TR–EXT MAL+MARG 1.1–2 CM	Excision-Malignant Lesions.
11721	DEBRIDE NAIL 6 OR MORE	Removal of 6 or more nails.
11730	REMOVAL OF NAIL PLATE	Separation and removal of the entire nail plate or a portion of nail plate.
11900	INJECT SKIN LESIONS </W7	Injections to remove up to 7 lesions on the skin.
12001	RPR S/N/AX/GEN/TRNK 2.5CM/<	Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities.
12011	RPR F/E/E/N/L/M 2.5 CM/<	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes.
17000	DESTRUCT PREMALG LESION	Destruction of pre-cancerous lesion.
17003	DESTRUCT PREMALG LES 2–14	Destruction of 2–14 pre-cancerous lesions.
17110	DESTRUCT B9 LESION 1–14	Destruction of 1–14 common or plantar warts.
17111	DESTRUCT LESION 15 OR MORE	Destruction of >15 common or plantar warts.
17250	CHEM CAUT OF GRANLTJ TISSUE	Chemical destruction of pre-cancerous lesions of the skin.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
17311	MOHS 1 STAGE H/N/HF/G	Micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens.
19120	REMOVAL OF BREAST LESION	
20550	INJ TENDON SHEATH/LIGAMENT	Injection of medication into a tendon or ligament.
20551	INJ TENDON ORIGIN/INSERTION	Injection of medication into the tendon/ligament origin.
20553	INJECT TRIGGER POINTS 3/>	Injection of medication into an area that triggers pain.
20600	DRAIN/INJ JOINT/BURSA W/O US	Draining or injecting medication into a small joint/bursa without ultrasound.
20605	DRAIN/INJ JOINT/BURSA W/O US	Draining or injecting medication into a large joint/bursa without ultrasound.
20610	DRAIN/INJ JOINT/BURSA W/O US	Draining or injecting medication into a major joint/bursa without ultrasound.
20612	ASPIRATE/INJ GANGLION CYST	Removal of fluid or injection of medication into a ganglion cyst.
27440	Revision of knee joint	Repair of knee joint.
27441	Revision of knee joint	Repair of knee joint.
27442	Revision of knee joint	Repair of knee joint.
27443	Revision of knee joint	Repair of knee joint.
27445	Revision of knee joint	Repair of knee joint with hinged prosthesis.
27446	Revision of knee joint	Repair of knee joint.
28296	CORRECTION HALLUX VALGUS	Under Repair, Revision, and/or Reconstruction Procedures on the Foot and Toes.
29826	Subacromial Decompression	Shaving of shoulder bone using an endoscope.
29848	WRIST ENDOSCOPY/SURGERY	Carpal tunnel release.
29880	KNEE ARTHROSCOPY/SURGERY	Surgery to remove of all or part of a torn meniscus in both medial and lateral compartments.
29881	KNEE ARTHROSCOPY/SURGERY	Surgery to remove of all or part of a torn meniscus in one compartment.
29888	KNEE ARTHROSCOPY/SURGERY	ACL reconstruction.
30520	REPAIR OF NASAL SEPTUM	Repair procedures of the nose.
31231	NASAL ENDOSCOPY DX	Nasal endoscopy, diagnostic, unilateral or bilateral.
31237	NASAL/SINUS ENDOSCOPY SURG	Surgical nasal/sinus endoscopy with biopsy, polypectomy or debridement.
31575	DIAGNOSTIC LARYNGOSCOPY	Flexible, fiberoptic diagnostic laryngoscopy.
36415	ROUTINE VENIPUNCTURE	Collection of venous blood by venipuncture.
36471	NJX SCLRSNT MLT INCMPTNT VN	Injections to remove spider veins on the limbs or trunk.
36475	ENDOVENOUS RF 1ST VEIN	Ablation of incompetent vein.
36478	ENDOVENOUS LASER 1ST VEIN	Laser removal of incompetent vein.
42820	REMOVE TONSILS AND ADENOIDS	Removal of tonsils and adenoid glands patient younger than age 12.
42826	REMOVAL OF TONSILS	Primary or secondary removal of tonsils.
42830	REMOVAL OF ADENOIDS	Primary removal of the adenoids.
43235	EGD DIAGNOSTIC BRUSH WASH	Diagnostic examination of esophagus, stomach, and/or upper small bowel using an endoscope.
43239	EGD BIOPSY SINGLE/MULTIPLE	Biopsy of the esophagus, stomach, and/or upper small bowel using an endoscope.
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption.	Surgical procedure used for weight loss resulting in a partial removal of stomach.
44388	Colonoscopy thru stoma spx	Diagnostic examination of large bowel using an endoscope which is inserted through abdominal opening.
44389	Colonoscopy with biopsy	Biopsies of large bowel using an endoscope which is inserted through abdominal opening.
44394	Colonoscopy w/snare	Removal of large bowel polyps or growths using an endoscope.
45378	DIAGNOSTIC COLONOSCOPY	Diagnostic examination of large bowel using an endoscope.
45379	Colonoscopy w/fb removal	Removal of foreign bodies in large bowel using an endoscope.
45380	COLONOSCOPY AND BIOPSY	Biopsy of large bowel using an endoscope.
45381	Colonoscopy submucous njx	Injections of large bowel using an endoscope.
45382	Colonoscopy w/control bleed	Control of bleeding in large bowel using an endoscope.
45384	Colonoscopy w/lesion removal	Removal of polyps or growths in large bowel using an endoscope.
45385	COLONOSCOPY W/LESION REMOVAL	Removal of polyps or growths of large bowel using an endoscope.
45386	Colonoscopy w/balloon dilat	Balloon dilation of large bowel using an endoscope.
45388	Colonoscopy w/ablation	Destruction of large bowel growths using an endoscope.
45390	Colonoscopy w/resection	Removal of large bowel tissue using an endoscope.
45391	Colonoscopy w/endoscope us	Ultrasound examination of lower large bowel using an endoscope.
45392	Colonoscopy w/endoscopic fnb	Ultrasound guided needle aspiration or biopsy of lower large bowel using an endoscope.
45398	Colonoscopy w/band ligation	Tying of large bowel using an endoscope.
47562	LAPAROSCOPIC CHOLECYSTECTOMY	Removal of gallbladder using an endoscope.
47563	LAPARO CHOLECYSTECTOMY/GRAPH	Gallbladder removal with use of an x-ray exam of the bile ducts.
49505	PRP I/HERN INIT REDUC >5 YR	Repair of groin hernia patient age 5 years or older.
49585	RPR UMBIL HERN REDUC > 5 YR	Repair of umbilical hernia in patients over 5 years old.
49650	LAP ING HERNIA REPAIR INIT	Inguinal hernia repair done by laparoscope.
50590	FRAGMENTING OF KIDNEY STONE	Surgical procedures on the kidney to break up and remove kidney stones.
51741	ELECTRO–UROFLOWMETRY FIRST	A diagnostic test used to measure the flow of urine.
51798	US URINE CAPACITY MEASURE	Ultrasound of bladder to measure urine capacity.
52000	CYSTOSCOPY	Procedure on the bladder.
52310	CYSTOSCOPY AND TREATMENT	Removing an indwelling ureteral stent by cystoscopy.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
52332	CYSTOSCOPY AND TREATMENT	Ureteral stents inserted internally between the bladder and the kidney and will remain within the patient for a defined period of time.
55250	EXCISION PROCEDURES ON THE VAS DEFERENS	Removal of sperm duct(s).
55700	Prostate biopsy	Biopsy of prostate gland.
55866	Surgical Procedures on the Prostate	Surgical removal of prostate and surrounding lymph nodes using an endoscope.
57022	Incision and drainage of vaginal blood accumulation following delivery.	
57288	REPAIR BLADDER DEFECT	Replacement of sling to support the bladder.
57454	BX/CURETT OF CERVIX W/SCOPE	Biopsy of cervix or uterus.
58100	EXCISION PROCEDURES ON THE CORPUS UTERI	Biopsy of the lining of the uterus.
58558	HYSTEROSCOPY BIOPSY	Surgical hysteroscopy with biopsy.
58563	HYSTEROSCOPY ABLATION	Surgical procedure used to treat premenopausal abnormal uterine bleeding.
58565	HYSTEROSCOPY STERILIZATION	Laparoscopic/Hysteroscopic Procedures on the uterus.
58571	TLH W/T/O 250 G OR LESS	Laparoscopic hysterectomy.
58661	LAPAROSCOPY REMOVE ADNEXA	Removal of either benign or malignant tissue from the uterus, ovaries, fallopian tubes, or any of the surrounding tissues using a laparoscope.
58662	LAPAROSCOPY EXCISE LESIONS	Removal of lesions of the ovary, pelvic viscera, or peritoneal surface.
58671	LAPAROSCOPY TUBAL BLOCK	Laparoscopic tubal sterilization is surgery to block the fallopian tubes to prevent pregnancy.
59000	AMNIOCENTESIS DIAGNOSTIC	Removal of amniotic fluid from the uterus for diagnostic purposes.
59025	FETAL NON–STRESS TEST	A common prenatal test used to check on a baby's health.
59400	OBSTETRICAL CARE	Obstetrical pre- and postpartum care and vaginal delivery.
59409	Vaginal delivery	
59410	Vaginal delivery with post-delivery care	
59414	Vaginal delivery of placenta	
59425	Pre-delivery care 4–6 visits	
59426	Pre-delivery care 7 or more visits	
59510	CESAREAN DELIVERY	Cesarean delivery with pre- and post-delivery care.
59514	Cesarean delivery	
59515	Cesarean delivery with post-delivery care	
59610	VBAC DELIVERY	Vaginal delivery after prior cesarean delivery.
59612	Vaginal delivery after prior cesarean delivery	
59614	Vaginal delivery after prior cesarean delivery with post-delivery care.	
62322	SPINAL INJECTION FOR PAIN MANAGEMENT	Injection of substance into spinal canal of lower back or sacrum using imaging guidance.
62323	Injection of substance into spinal canal of lower back or sacrum using imaging guidance.	
63030	LOW BACK DISK SURGERY	Surgical procedure to decompress a herniated vertebra.
64483	Transforaminal Epidural Injection	Injections of anesthetic and/or steroid drug into lower or sacral spine nerve root using imaging guidance.
64493	INJ PARAVERT F JNT L/S 1 LEV	Injection into lower back of nerve block using imaging guidance.
64721	CARPAL TUNNEL SURGERY	Release of the transverse carpal ligament.
66821	YAG capusulotomy surgery	Removal of recurring cataract in lens capsule using laser.
66984	CATARACT SURG W/IOL 1 STAGE	Removal of cataract with insertion of lens.
67028	INJECTION EYE DRUG	Injection of a pharmaceutical agent into the eye.
69210	REMOVE IMPACTED EAR WAX	Removal of ear wax from one or both ears.
69436	CREATE EARDRUM OPENING	Insertion of tubes into one or both ears.
70450	CT HEAD/BRAIN W/O DYE	CT scan head or brain without dye.
70486	CT MAXILLOFACIAL W/O DYE	CT Scan of the face and jaw without dye.
70491	CT SOFT TISSUE NECK W/DYE	CT scan of neck with dye.
70551	MRI BRAIN STEM W/O DYE	MRI of brain stem without dye.
70553	MRI BRAIN STEM W/O & W/DYE	MRI scan of brain before and after contrast.
71045	CHEST X–RAY	Single view.
71046	CHEST X–RAY	2 views, front and back.
71047	CHEST X–RAY	3 views.
71048	CHEST X–RAY	4 or more views.
71101	X–RAY EXAM UNILAT RIBS/CHEST	Radiologic examination of one side of the chest/ribs.
71250	CT THORAX W/O DYE	CT scan of the thorax without dye.
71260	CT THORAX W/DYE	CT scan of the thorax with dye.
71275	CT ANGIOGRAPHY CHEST	Diagnostic Radiology (Diagnostic Imaging) Procedures of the Chest.
72040	X–RAY EXAM NECK SPINE 2–3 VW	Radiologic examination of the neck/spine, 2–3 views.
72050	X–RAY EXAM NECK SPINE 4/5VWS	Radiologic examination of the neck/spine, 4–5 views.
72070	X–RAY EXAM THORAC SPINE 2VWS	Radiologic examination of the middle spine, 2 views.
72072	X–RAY EXAM THORAC SPINE 3VWS	Radiologic examination of the middle spine, 3 views.
72100	X–RAY EXAM L–S SPINE 2/3 VWS	X-ray of the lower spine 2–3 views.
72110	X–RAY EXAM L–2 SPINE 4/>VWS	X-ray of lower and sacral spine, minimum of 4 views.
72131	CT LUMBAR SPINE W/O DYE	CT scan of lower spine without dye.
72141	MRI NECK SPINE W/O DYE	MRI of the neck or spine without dye.
72146	MRI CHEST SPINE W/O DYE	MRI of chest and spine without dye.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
72148	MRI LUMBAR SPINE W/O DYE	MRI scan of lower spinal canal.
72156	MRI NECK SPINE W/O & W/DYE	MRI of neck/spine with and without dye.
72157	MRI CHEST SPINE W/O & W/DYE	MRI of chest and spine with and without dye.
72158	MRI LUMBAR SPINE W/O & W/DYE	MRI of lower back with and without dye.
72170	X–RAY EXAM OF PELVIS	Radiologic examination of the pelvis.
72192	CT PELVIS W/O DYE	CT of pelvis without dye.
72193	CT PELVIS W/DYE	CT scan, pelvis, with contrast.
72195	MRI PELVIS W/O DYE	MRI of pelvis without dye.
72197	MRI PELVIS W/O & W/DYE	MRI of pelvis before and after dye.
73000	X–RAY EXAM OF COLLAR BONE	Radiologic examination of the collar bone.
73030	X–RAY EXAM OF SHOULDER	Radiologic examination of the shoulder.
73070	X–RAY EXAM OF ELBOW	Radiologic examination, elbow; 2 views.
73080	X–RAY EXAM OF ELBOW	Radiologic examination, elbow; 3 or more views.
73090	X–RAY EXAM OF FOREARM	Radiologic examination of the forearm.
73100	X–RAY EXAM OF WRIST	3 or more views.
73110	X–RAY EXAM OF WRIST	Up to 3 views.
73120	X–RAY EXAM OF HAND	X-ray of the hand with 2 views.
73130	X–RAY EXAM OF HAND	X-ray of the hand with 3 or more views.
73140	X–RAY EXAM OF FINGER(S)	Radiologic examination of the finger(s).
73221	MRI JOINT UPR EXTREM W/O DYE	MRI of upper extremity without dye.
73560	X–RAY EXAM OF KNEE 1 OR 2	Radiologic examination of the knee with 1 or 2 views.
73562	X–RAY EXAM OF KNEE 3	Radiologic examination of the knee with 3 views.
73564	X–RAY EXAM KNEE 4 OR MORE	Radiologic examination of the knee with 4 or more views.
73565	X–RAY EXAM OF KNEES	Radiologic examination of both knees.
73590	X–RAY EXAM OF LOWER LEG	Radiologic examination of the lower leg.
73600	X–RAY EXAM OF ANKLE	Radiologic examination of the ankle with 2 views.
73610	X–RAY EXAM OF ANKLE	Radiologic examination of the ankle with 3 views.
73620	X–RAY EXAM OF FOOT	Radiologic examination, foot; 2 views.
73630	X–RAY EXAM OF FOOT	Radiologic examination of the foot with 3 or more views.
73650	X–RAY EXAM OF HEEL	Radiologic examination of the heel.
73660	X–RAY EXAM OF TOE(S)	Radiologic examination of the toe(s).
73700	CT LOWER EXTREMITY W/O DYE	CT scan of leg without dye.
73718	MRI LOWER EXTREMITY W/O DYE	MRI of leg without dye.
73721	MRI JNT OF LWR EXTRE W/O DYE	MRI of lower extremity joint (knee/ankle) without dye.
73722	MRI JOINT OF LWR EXTR W/DYE	MRI of lower extremity joint (knee/ankle) with dye.
73723	MRI JOINT LWR EXTR W/O&W/DYE	MRI of lower extremity joint (knee/ankle) with and without dye.
74022	X–RAY EXAM SERIES ABDOMEN	Serial radiologic examination of the abdomen.
74150	CT ABDOMEN W/O DYE	CT of abdomen without dye.
74160	CT ABDOMEN W/DYE	CT of abdomen with dye.
74170	CT ABDOMEN W/O & W/DYE	CT of abdomen with and without dye.
74176	CT ABD & PELVIS W/O CONTRAST	CT of abdomen and pelvis without dye.
74177	CT ABD & PELV W/CONTRAST	CT scan of abdomen and pelvis with contrast.
74178	CT ABD & PELV 1/> REGNS	Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions.
74181	MRI ABDOMEN W/O DYE	MRI of abdomen without dye.
74183	MRI ABDOMEN W/O & W/DYE	MRI of abdomen without and with dye.
76000	CHEST X–RAY	Flouroscopy, or x-ray "movie" that takes less than an hour.
76001	CHEST X–RAY	Flouroscopy, or x-ray "movie" that takes more than an hour.
76512	OPHTH US B W/NON–QUANT A	Ultrasound of the eye.
76514	ECHO EXAM OF EYE THICKNESS	A diagnostic procedure that allows a provider to see the organs and other structures in the abdomen.
76536	US EXAM OF HEAD AND NECK	Ultrasound of head and neck.
76642	ULTRASOUND BREAST LIMITED	Limited ultrasound of the breast.
76700	US EXAM ABDOM COMPLETE	Ultrasound of abdomen with all areas scanned.
76705	ECHO EXAM OF ABDOMEN	A diagnostic procedure that allows a provider to see the organs and other structures in the abdomen.
76770	US EXAM ABDO BACK WALL COMP	Ultrasound of back wall of the abdomen with all areas viewed.
76775	US EXAM ABDO BACK WALL LIM	Ultrasound of back wall of the abdomen with limited areas viewed.
76801	OB US < 14 WKS SINGLE FETUS	Abdominal ultrasound of pregnant uterus (less than 14 weeks) single or first fetus.
76805	OB US >/= 14 WKS SNGL FETUS	Abdominal ultrasound of pregnant uterus (greater or equal to 14 weeks 0 days) single or first fetus.
76811	OB US DETAILED SNGL FETUS	Ultrasound of single fetus.
76813	OB US NUCHAL MEAS 1 GEST	Evaluation through measurement of fetal nuchal translucency.
76815	OB US LIMITED FETUS(S)	Ultrasound of fetus with limited views.
76817	TRANSVAGINAL US OBSTETRIC	Transvaginal ultrasound of uterus.
76818	FETAL BIOPHYS PROFILE W/NST	Fetal biophysical profile with non-stress test.
76819	FETAL BIOPHYS PROFIL W/O NST	Fetal biophysical profile without non-stress test.
76830	TRANSVAGINAL US NON–OB	Ultrasound of the pelvis through vagina.
76831	ECHO EXAM UTERUS	A diagnostic procedure that allows a provider to see the uterus.
76856	US EXAM PELVIC COMPLETE	Complete ultrasound of the pelvis.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
76857	US EXAM PELVIC LIMITED	Limited ultrasound of the pelvis.
76870	US EXAM SCROTUM	Ultrasound of the scrotum.
76872	US TRANSRECTAL	Transrectal ultrasound.
76882	US LMTD JT/NONVASC XTR STRUX	Diagnostic ultrasound of an extremity excluding the bone, joints or vessels.
77047	MRI BOTH BREASTS	Magnetic resonance imaging, breasts, without contrast material; bilateral.
77065	DX MAMMO INCL CAD UNI	Mammography of one breast.
77066	DX MAMMO INCL CAD BI	Mammography of both breasts.
77067	SCR MAMMO BI INCL CAD	Mammography of both breasts-2 or more views.
77080	BONE DENSITY STUDY OF SPINE OR PELVIS	Scan to measure bone mineral density (BMD) at the spine and hip.
77385	Ntsty modul rad tx dlvr smpl	Radiation therapy delivery.
77386	Ntsty modul rad tx dlvr cplx	Radiation therapy delivery.
77387	Guidance for radia tx dlvr	Guidance for localization of target delivery of radiation treatment delivery.
77412	Radiation treatment delivery	Radiation treatment delivery.
78014	THYROID IMAGING W/BLOOD FLOW	Scan using a radioactive medication (radiopharmaceutical) to take pictures or images of the thyroid gland.
78306	BONE IMAGING WHOLE BODY	A procedure most commonly ordered to detect areas of abnormal bone growth due to fractures, tumors, infection, or other bone issues.
78452	HT MUSCLE IMAGE SPECT MULT	Image of the heart to assess perfusion.
78815	PET IMAGE W/CT SKULL–THIGH	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization.
80048	METABOLIC PANEL TOTAL CA	Basic metabolic panel.
80050	GENERAL HEALTH PANEL	General health panel.
80051	Blood test panel for electrolytes (sodium potassium, chloride, carbon dioxide).	.
80053	COMPREHEN METABOLIC PANEL	Blood test, comprehensive group of blood chemicals.
80055	OBSTETRIC PANEL	Obstetric blood test panel.
80061	LIPID PANEL	Blood test, lipids (cholesterol and triglycerides).
80069	RENAL FUNCTION PANEL	Kidney function panel test.
80074	ACUTE HEPATITIS PANEL	Acute hepatitis panel.
80076	HEPATIC FUNCTION PANEL	Liver function blood test panel.
80081	Blood test panel for obstetrics (cbc, differential wbc count, hepatitis b, hiv, rubella, syphilis, antibody screening, rbc, blood typing).	.
80197	ASSAY OF TACROLIMUS	Test is used to measure the amount of the drug in the blood to determine whether the concentration has reached a therapeutic level and is below the toxic level.
80307	Drug test prsmv chem anlyzr	Testing for presence of drug.
81000	URINALYSIS NONAUTO W/SCOPE	Manual urinalysis test with examination using microscope.
81001	URINALYSIS; MANUAL OR AUTO WITH OR WITHOUT MICROSCOPY.	Manual urinalysis test with examination with or without using microscope.
81002	URINALYSIS NONAUTO W/O SCOPE	Manual urinalysis test with examination without using microscope.
81003	URINALYSIS; MANUAL OR AUTO WITH OR WITHOUT MICROSCOPY.	Automated urinalysis test.
81025	URINE PREGNANCY TEST	Urine pregnancy test.
82043	UR ALBUMIN QUANTITATIVE	Urine test to measure albumin.
82044	UR ALBUMIN SEMIQUANTITATIVE	Urine test to measure albumin-semiquantitative.
82248	BILIRUBIN DIRECT	Measurement of direct bilirubin.
82306	VITAMIN D 25 HYDROXY	Blood test to monitor vitamin D levels.
82553	CREATINE MB FRACTION	Blood test to detect heart enzymes.
82570	ASSAY OF URINE CREATININE	Test to measure creatinine in the urine.
82607	VITAMIN B–12	Blood test to measure B–12.
82627	DEHYDROEPIANDROSTERONE	Blood test to measure an enzyme in the blood.
82670	ASSAY OF ESTRADIOL	Blood test to measure a type of estrogen in the blood.
82728	ASSAY OF FERRITIN	Test to determine level of iron in the blood.
82784	ASSAY IGA/IGD/IGG/IGM EACH	Test to determine levels of immunoglobulins in the blood.
82803	BLOOD GASES ANY COMBINATION	Test to measure arterial blood gases.
82947	ASSAY GLUCOSE BLOOD QUANT	Quantitative measure of glucose build up in the blood over time.
82950	GLUCOSE TEST	Test of glucose level in the blood.
82951	GLUCOSE TOLERANCE TEST	Test to predict likelihood of gestational diabetes.
83001	ASSAY OF GONADOTROPIN (FSH)	Test of hormone in the blood.
83002	ASSAY OF GONADOTROPIN (LH)	Test of hormone in the blood.
83013	H PYLORI (C–13) BREATH	Test of breath for a stomach bacterium.
83036	GLYCOSYLATED HEMOGLOBIN TEST	Blood test to measure average blood glucose levels for past 2–3 months.
83516	IMMUNOASSAY NONANTIBODY	Chemical test of the blood to measure presence or concentration of a substance in the blood.
83540	ASSAY OF IRON	Blood test to measure the amount of iron that is in transit in the body.
83550	IRON BINDING TEST	Blood test that measures the amount of iron carried in the blood.
83655	ASSAY OF LEAD	Blood test to determine the concentration of lead in the blood.
83718	ASSAY OF LIPOPROTEIN	Blood test to measure the level of lipoproteins in the blood.
83880	ASSAY OF NATRIURETIC PEPTIDE	Blood test used to diagnose heart failure.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
84134	ASSAY OF PREALBUMIN	Blood test to measure level of prealbumin.
84153	ASSAY OF PSA TOTAL	PSA (prostate specific antigen).
84154	PSA (prostate specific antigen) measurement	.
84436	ASSAY OF TOTAL THYROXINE	Blood test to measure a type of thyroid hormone.
84439	ASSAY OF FREE THYROXINE	Blood test to evaluate thyroid function.
84443	ASSAY THYROID STIM HORMONE	Blood test, thyroid stimulating hormone (TSH).
84460	ALANINE AMINO (ALT) (SGPT)	Blood test to evaluate liver function.
84480	ASSAY TRIIODOTHYRONINE (T3)	Blood test to evaluate thyroid function.
84484	ASSAY OF TROPONIN QUANT	Blood test to measure a certain protein in the blood to determine heart muscle damage.
84703	CHORIONIC GONADOTROPIN ASSAY	Blood test to assess for pregnancy.
85007	BL SMEAR W/DIFF WBC COUNT	Blood test to assess for infection.
85018	HEMOGLOBIN	Blood test to measure levels of hemoglobin.
85025	COMPLETE CBC W/AUTO DIFF WBC	Complete blood cell count, with differential white blood cells, automated.
85027	COMPLETE CBC AUTOMATED	Complete blood count, automated.
85610	PROTHROMBIN TIME	Blood test, clotting time.
85730	THROMBOPLASTIN TIME PARTIAL	Coagulation assessment blood test.
86039	ANTINUCLEAR ANTIBODIES (ANA)	Blood test to determine autoimmune disorders.
86147	CARDIOLIPIN ANTIBODY EA IG	Blood test to determine cause of inappropriate blood clot formation.
86200	CCP ANTIBODY	Blood test to diagnose rheumatoid arthritis.
86300	IMMUNOASSAY TUMOR CA 15–3	Blood test to monitor breast cancer.
86304	IMMUNOASSAY TUMOR CA 125	Blood test to monitor for cancer.
86336	INHIBIN A	Blood test to monitor for cancer in the ovaries or testis.
86592	SYPHILIS TEST NON–TREP QUAL	Blood test to screen for syphilis.
86644	CMV ANTIBODY	Blood test to monitor for cytomegalovirus.
86665	EPSTEIN–BARR CAPSID VCA	Blood test to diagnose mononucleosis.
86677	HELICOBACTER PYLORI ANTIBODY	Blood test to if peptic ulcers are caused by a certain bacterium.
86703	HIV–1/HIV–2 1 RESULT ANTBDY	Blood test to diagnose HIV.
86704	HEP B CORE ANTIBODY TOTAL	Blood test indicating infection with Hepatitis B.
86708	HEPATITIS A ANTIBODY	Blood test indicating infection with Hepatitis A.
86762	RUBELLA ANTIBODY	Blood test to determine if antibodies exist for rubella.
86765	RUBEOLA ANTIBODY	Blood test to determine if antibodies exist for measles.
86780	TREPONEMA PALLIDUM	Blood test to determine existence of certain bacterium that causes syphilis.
86803	HEPATITIS C AB TEST	Blood test to determine infection with Hepatitis C.
86850	RBC ANTIBODY SCREEN	Blood test to screen for antibodies that could harm red blood cells.
87040	BLOOD CULTURE FOR BACTERIA	Blood test to screen for bacteria in the blood.
87046	STOOL CULTR AEROBIC BACT EA	Blood test to identify bacteria that may be contributing to symptoms in the gastrointestinal tract.
87070	CULTURE OTHR SPECIMN AEROBIC	Test of body fluid other than blood to assess for bacteria.
87077	CULTURE AEROBIC IDENTIFY	Test of a wound for type of bacterial infection.
87081	CULTURE SCREEN ONLY	Medical test to find an infection.
87086	URINE CULTURE/COLONY COUNT	Culture of the urine to determine number of bacteria.
87088	URINE BACTERIA CULTURE	Culture of the urine to determine bacterial infection.
87101	SKIN FUNGI CULTURE	A procedure used to determine if fungi are present in an area of the body.
87186	MICROBE SUSCEPTIBLE MIC	A test used to determine which medications work on bacteria for fungi.
87205	SMEAR GRAM STAIN	A lab test used to detect bacteria or fungi in a sample taken from the site of a suspected infection.
87210	SMEAR WET MOUNT SALINE/INK	A lab test to screen for evidence of vaginal infection.
87324	CLOSTRIDIUM AG IA	A test of the stool to diagnose Clostridium difficile (C. diff) infection.
87389	HIV–1 AG W/HIV–1 & HIV–2 AB	Test for HIV.
87491	CHYLMD TRACH DNA AMP PROBE	Test that detects Chlamydia.
87510	GARDNER VAG DNA DIR PROBE	Blood test for vaginitis.
87591	N.GONORRHOEAE DNA AMP PROB	Blood test for an STD.
87624	Hpv high-risk types	Detection test for human papillomavirus (hpv).
87653	STREP B DNA AMP PROBE	Blood test for strep infection.
87661	TRICHOMONAS VAGINALIS AMPLIF	Blood test for an STD.
87801	DETECT AGNT MULT DNA AMPLI	Blood test to determine genetic material of certain infectious agents.
87804	INFLUENZA ASSAY W/OPTIC	Flu test.
87807	RSV ASSAY W/OPTIC	Test for RSV.
87880	STREP A ASSAY W/OPTIC	Test for strep A.
88112	CYTOPATH CELL ENHANCE TECH	Urine test.
88141	CYTOPATH C/V INTERPRET	Cervical cancer screening test with interpretation.
88142	CYTOPATH C/V THIN LAYER	PAP smear.
88150	CYTOPATH C/V MANUAL	Cervical cancer screening test done manually.
88175	CYTOPATH C/V AUTO FLUID REDO	PAP smear.
88305	TISSUE EXAM BY PATHOLOGIST	Test of tissues for diagnosis of abnormalities.
88312	SPECIAL STAINS GROUP 1	Blood test to assist with diagnosis.
88313	SPECIAL STAINS GROUP 2	Blood test to assist with diagnosis.
88342	IMMUNOHISTO ANTB 1ST STAIN	Pathology test.
90460	IM ADMIN 1ST/ONLY COMPONENT	Immunization administration in children <18.
90471	IMMUNIZATION ADMIN	Immunization administration by a medical assistant or nurse.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
90474	IMMUNE ADMIN ORAL/NASAL ADDL	Immunization administered orally or nasally.
90632	HEPA VACCINE ADULT IM	Hepatitis A vaccination for adults.
90633	HEPA VACC PED/ADOL 2 DOSE IM	Hepatitis A vaccination for adolescents and children.
90649	4VHPV VACCINE 3 DOSE IM	3-dose HPV vaccination.
90656	IIV3 VACC NO PRSV 0.5 ML IM	Flu shot-high dose for 2019–2020 flu season given by injection.
90658	IIV3 VACCINE SPLT 0.5 ML IM	Preservative free flu vaccine.
90672	LAIV4 VACCINE INTRANASAL	Nasal flu vaccine.
90681	RV1 VACC 2 DOSE LIVE ORAL	Rotavirus vaccination.
90686	IIV4 VACC NO PRSV 0.5 ML IM	Flu shot-high dose for 2019–2020 flu season given by injection for people >65.
90707	MMR VACCINE SC	Measles, mumps, and rubella vaccine.
90710	MMRV VACCINE SC	Measles, mumps, rubella, and varicella vaccine.
90715	TDAP VACCINE 7 YRS/> IM	Diphtheria, tetanus acellular, and pertussis vaccine for adults.
90716	VAR VACCINE LIVE SUBQ	Varicella vaccine.
90732	PPSV23 VACC 2 YRS+ SUBQ/IM	pneumococcal vaccine.
90734	MENACWYD/MENACWYCRM VACC IM	meningococcal conjugate vaccine.
90736	HZV VACCINE LIVE SUBQ	Shingles vaccine.
90746	HEPB VACCINE 3 DOSE ADULT IM	Hepatitis B vaccine.
90791	PSYCH DIAGNOSTIC EVALUATION	A diagnostic tool employed by a psychiatrist to diagnose problems with memory, thought processes, and behaviors.
90792	PSYCH DIAG EVAL W/MED SRVCS	A diagnostic tool employed by a psychiatrist to determine if medications are needed.
90832	PSYTX W PT 30 MINUTES	Psychotherapy, 30 min.
90833	PSYTX W PT W E/M 30 MIN	Psychotherapy, 30 minutes with patient when performed with an evaluation and management service.
90834	PSYTX W PT 45 MINUTES	Psychotherapy, 45 min.
90836	PSYTX W PT W E/M 45 MIN	Psychotherapy, 45 minutes with patient when performed with an evaluation and management service.
90837	PSYTX W PT 60 MINUTES	Psychotherapy, 60 min.
90838	Psychotherapy, 60 minutes	
90839	Psychotherapy for crisis, first 60 minutes	
90840	Psychotherapy for crisis	
90846	Family psychotherapy, 50 minutes	Family psychotherapy, not including patient, 50 min.
90847	FAMILY PSYTX W/PT 50 MIN	Family psychotherapy, including patient, 50 min.
90853	GROUP PSYCHOTHERAPY	Group psychotherapy.
92002	EYE EXAM NEW PATIENT	Intermediate exam.
92004	EYE EXAM NEW PATIENT	Complete exam.
92012	EYE EXAM ESTABLISH PATIENT	Eye exam on an established patient.
92014	EYE EXAM&TX ESTAB PT 1/>VST	Eye exam and treatment for established patient.
92083	VISUAL FIELD EXAMINATION(S)	An eye examination that can detect dysfunction in central and peripheral vision.
92133	CMPTR OPHTH IMG OPTIC NERVE	Optic nerve imaging.
92507	SPEECH/HEARING THERAPY	Therapy for speech or hearing.
92523	SPEECH SOUND LANG COMPREHEN	Evaluation of speech sound production with evaluation of language comprehension.
92552	PURE TONE AUDIOMETRY AIR	Type of hearing test.
93000	ELECTROCARDIOGRAM COMPLETE	Routine EKG using at least 12 leads including interpretation and report.
93015	CARDIOVASCULAR STRESS TEST	Test to determine heart abnormalities.
93303	ECHO TRANSTHORACIC	Test to screen the heart for abnormalities.
93306	Tte w/doppler complete	Ultrasound examination of heart including color-depicted blood flow rate, direction, and valve function.
93307	TTE W/O DOPPLER COMPLETE	Echo without doppler study.
93320	DOPPLER ECHO EXAM HEART	Echo with doppler.
93350	STRESS TTE ONLY	Stress test with echocardiogram.
93452	Cardiac Catheterization	Insertion of catheter into left heart for diagnosis.
93798	CARDIAC REHAB/MONITOR	Use of EKG to monitor cardiac rehabilitation.
93880	EXTRACRANIAL BILAT STUDY	Study of vessels on both sides of the head and neck.
93922	UPR/L XTREMITY ART 2 LEVELS	Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries.
93970	EXTREMITY STUDY	Complete bilateral study of the extremities.
93971	EXTREMITY STUDY	One sided or limited bilateral study.
94010	BREATHING CAPACITY TEST	Test to determine how well oxygen moves from the lungs to the blood stream.
94060	EVALUATION OF WHEEZING	Test to determine if wheezing is present.
94375	RESPIRATORY FLOW VOLUME LOOP	Graphical representation of inspiration and expiration.
94726	PULM FUNCT TST PLETHYSMOGRAP	Measures how much air is in the lungs after taking a deep breath.
94727	PULM FUNCTION TEST BY GAS	Measure of lung function and gas exchange.
94729	CO/MEMBANE DIFFUSE CAPACITY	Test to measure how well gases diffuse across lung surfaces.
95004	PERCUT ALLERGY SKIN TESTS	Allergy test.
95115	IMMUNOTHERAPY ONE INJECTION	Allergy shot-1 shot.
95117	IMMUNOTHERAPY INJECTIONS	Multiple allergy shots.
95810	POLYSOM 6/> YRS 4/> PARAM	Sleep monitoring of patient (6 years or older) in sleep lab.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
95811	POLYSOM 6/>YRS CPAP 4/> PARM	Sleep monitoring of patient (6 years or older) in sleep lab using CPAP.
95860	MUSCLE TEST ONE LIMB	Test to measure electrical activity of muscles or nerves in 1 limb.
95861	MUSCLE TEST 2 LIMBS	Test to measure electrical activity of muscles or nerves in 2 limb.
95886	MUSC TEST DONE W/N TEST COMP	Test to assess for nerve damage.
96110	DEVELOPMENTAL SCREEN W/SCORE	Childhood test to screen for developmental disabilities.
96365	THER/PROPH/DIAG IV INF INIT	Intravenous infusion, for therapy, prophylaxis, or diagnosis-initial infusion.
96366	THER/PROPH/DIAG IV INF ADDON	Intravenous infusion, for therapy, prophylaxis, or diagnosis-additional infusions.
96374	THER/PROPH/DIAG INJ IV PUSH	Intravenous infusion, for therapy, prophylaxis, or diagnosis-IV push.
96375	TX/PRO/DX INJ NEW DRUG ADDON	Intravenous infusion, for treatment, prophylaxis, or diagnosis-new drug add on.
96376	TX/PRO/DX INJ SAME DRUG ADON	Intravenous infusion, for treatment, prophylaxis, or diagnosis-same drug add on.
96415	CHEMO IV INFUSION ADDL HR	Chemotherapy infusion-each additional hour.
96417	CHEMO IV INFUS EACH ADDL SEQ	Chemotherapy infusion-additional IV pushes of the same medication.
97010	HOT OR COLD PACKS THERAPY	Use of external hot or cold packs.
97012	MECHANICAL TRACTION THERAPY	Form of decompression therapy of the spine.
97014	ELECTRIC STIMULATION THERAPY	One time use unattended.
97016	VASOPNEUMATIC DEVICE THERAPY	Machines designed to pump cold water into an inflatable wrap or brace, compressing the enveloped area of the body.
97026	INFRARED THERAPY	Light-based method to treat pain and inflammation.
97032	ELECTRICAL STIMULATION	Repeated application to one or more parts of the body.
97033	ELECTRIC CURRENT THERAPY	Psychiatric treatment in which seizures are electrically induced in patients to provide relief from mental disorders.
97035	ULTRASOUND THERAPY	Use of sound waves to treat medical problems, especially musculoskeletal problems like inflammation from injuries.
97110	THERAPEUTIC EXERCISES	Therapeutic exercise to develop strength, endurance, range of motion, and flexibility, each 15 minutes.
97112	NEUROMUSCULAR REEDUCATION	A technique used by physical therapists to restore normal body movement patterns.
97113	AQUATIC THERAPY/EXERCISES	Use of water for therapy/exercises.
97116	GAIT TRAINING THERAPY	A type of physical therapy.
97124	MASSAGE THERAPY	Use of massage.
97140	MANUAL THERAPY 1/> REGIONS	Manipulation of 1 or more regions of the body.
97530	THERAPEUTIC ACTIVITIES	Incorporates the use of multiple parameters, such as balance, strength, and range of motion, for a functional activity.
97535	SELF CARE MNGMENT TRAINING	Occupational therapy.
97597	RMVL DEVITAL TIS 20 CM/<	Debridement (for example, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel, and forceps).
97811	ACUPUNCT W/O STIMUL ADDL 15M	Acupuncture without stimulation.
97813	ACUPUNCT W/STIMUL 15 MIN	Acupuncture with stimulation.
98940	CHIROPRACT MANJ 1–2 REGIONS	Chiropractic manipulation in 1–2 regions.
98941	CHIROPRACT MANJ 3–4 REGIONS	Chiropractic manipulation in 3–4 regions.
98943	CHIROPRACT MANJ XTRSPINL 1/>	Chiropractic manipulation not of the spine.
98966	Hc pro phone call 5–10 min	Telephone assessment and management service, 5–10 minutes of medical discussion.
98967	Hc pro phone call 11–20 min	Telephone assessment and management service, 11–20 minutes of medical discussion.
98968	Hc pro phone call 21–30 min	Telephone assessment and management service, 21–30 minutes of medical discussion.
98970	Qualified non physician health care professional online digital assessment and management est. patient 5–10 minutes.	Qualified non physician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes.
98971	Qualified non physician health care professional online digital assessment and management est. patient 11–20 minutes.	Qualified non physician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes.
98972	Qualified non physician health care professional online digital assessment and management for est. patients 21+ minutes.	Qualified non physician health care professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes.
99051	MED SERV EVE/WKEND/HOLIDAY	Medical service during off-hours.
99173	VISUAL ACUITY SCREEN	Eye test.
99201	OFFICE/OUTPATIENT VISIT NEW	New patient office or other outpatient visit, typically 10 minutes.
99202	OFFICE/OUTPATIENT VISIT NEW	New patient office or other outpatient visit, typically 20 minutes.
99203	OFFICE/OUTPATIENT VISIT NEW	New patient office or other outpatient visit, typically 30 min.
99204	OFFICE/OUTPATIENT VISIT NEW	New patient office of other outpatient visit, typically 45 min.
99205	OFFICE/OUTPATIENT VISIT NEW	New patient office of other outpatient visit, typically 60 min.
99211	OFFICE/OUTPATIENT VISIT EST	Outpatient visit of established patient not requiring a physician.
99212	OFFICE/OUTPATIENT VISIT EST	Outpatient visit of established patient requiring a physician.
99213	OFFICE/OUTPATIENT VISIT EST	Established patient office or other outpatient visit, typically 15 minutes.
99214	OFFICE/OUTPATIENT VISIT EST	Established patient office or other outpatient visit, typically 25 minutes.
99215	OFFICE/OUTPATIENT VISIT EST	Established patient office or other outpatient, visit typically 40 minutes.
99243	OFFICE CONSULTATION	Patient office consultation, typically 40 min.

TABLE 1—500 ITEMS AND SERVICES LIST—Continued

Code	Description	Plain language description
99244	OFFICE CONSULTATION	Patient office consultation, typically 60 min.
99283	Emergency dept visit	Emergency department visit, moderately severe problem.
99284	Emergency dept visit	Emergency department visit, problem of high severity.
99285	Emergency dept visit	Emergency department visit, problem with significant threat to life or function.
99381	INIT PM E/M NEW PAT INFANT	Initial visit for an infant.
99382	INIT PM E/M NEW PAT 1–4 YRS	Initial visit for new patients 1–4 years old.
99383	PREV VISIT NEW AGE 5–11	New preventative visit in new patients 5–11 years old.
99384	PREV VISIT NEW AGE 12–17	New preventative visit in new patients 12–17 years old.
99385	PREV VISIT NEW AGE 18–39	Initial new patient preventive medicine evaluation (18–39 years).
99386	PREV VISIT NEW AGE 40–64	Initial new patient preventive medicine evaluation (40–64 years).
99387	INIT PM E/M NEW PAT 65+ YRS	Initial visit for new patients 65 and older years old.
99391	PER PM REEVAL EST PAT INFANT	Periodic primary re-evaluation for an established infant patient.
99392	PREV VISIT EST AGE 1–4	Initial visit for new patients 1–4 years old.
99393	PREV VISIT EST AGE 5–11	New preventative visit in new patients 5–11 years old.
99394	PREV VISIT EST AGE 12–17	New preventative visit in new patients 12–17 years old.
99395	PREV VISIT EST AGE 18–39	Established patient periodic preventive medicine examination age 18–39 years.
99396	PREV VISIT EST AGE 40–64	Established patient periodic preventive medicine examination age 40–64 years.
99397	PER PM REEVAL EST PAT 65+ YR	Periodic primary re-evaluation for an established patient 65 and older.
99421	ONLINE DIGITAL EVALUATION AND MANAGEMENT SERVICE; 5–10 MINUTES.	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes.
99422	Online digital evaluation and management service; 11–20 minutes.	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes.
99441	Phone e/m phys/qhp 5–10 min	Physician telephone patient service, 5–10 minutes of medical discussion.
99442	Phone e/m phys/qhp 11–20 min	Physician telephone patient service, 11–20 minutes of medical discussion.
99443	Phone e/m phys/qhp 21–30 min	Physician telephone patient service, 21–30 minutes of medical discussion.

As outlined above, below are the five codes that appear on the commenter list of recommended items and services that are not being required for the initial list of 500 items and services.

Commenter codes not used	Reason for removal
10022	Code Retired.
11100	Code Retired.
11101	Code Retired.
77059	Code Retired.
A288	Code Retired.

The Departments understand that plans and issuers may use different billing codes (for example, MS–DRGs vs. APR DRGs). Therefore, in the first year of the implementation of the self-service tool, when plans and issuers are required to provide cost estimates for the 500 items and services identified by the Departments, plans and issuers are permitted to make appropriate code substitutions as necessary to allow them to disclose cost-sharing information for the 500 items and services through the self-service tool. If necessary, the Departments will issue future guidance regarding standards for code substitutions.

a. First Content Element: Estimated Cost-Sharing Liability

The first content element that plans and issuers are required to disclose under the final rules is an estimate of the cost-sharing liability for the furnishing of a covered item or service by a particular provider or providers. The calculation of the cost-sharing liability estimate is required to be computed based on the other relevant cost-sharing information that plans and issuers are required to disclose, as described later in this section of this preamble.

The proposed rules defined ''cost-sharing liability'' as the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the plan or coverage. The disclosure must include all applicable forms of cost sharing, including deductibles, coinsurance requirements, and copayments. The term cost-sharing liability does not include premiums, any applicable balance billing amounts charged by out-of-network providers, or the cost of non-covered items or services. For QHPs offered through Exchanges, an estimate of cost-sharing liability for a requested covered item or service provided must reflect any cost-sharing reductions the individual would receive under the coverage.

Many commenters supported the disclosure of cost-sharing liability for a particular item or service. One stated that providing cost-sharing amounts to consumers in advance of receiving a service would likely make it easier for providers to collect consumers' cost-sharing amounts. However, some commenters were concerned that information provided in advance of care would not provide an accurate estimate of actual participant, beneficiary, or enrollee liability, which would lead to consumer confusion and frustration. A few commenters requested that the tool include additional information, such as all providers expected to be involved in providing an item or service, and the price of items and services historically provided along with that particular item or service by the provider. Some commenters urged the Departments to ensure appropriate educational information is provided to patients to help them better understand and navigate the information being displayed. Others recommended a federally funded and coordinated outreach and education campaign to encourage the use of price transparency tools and help patients understand the complexities of health care prices. One commenter urged the Departments to clarify that, to the extent that the actual services provided are consistent with those provided under the estimate, plans would not be permitted to hold an enrollee responsible for more than what was provided under the estimate.

The Departments underscore that the estimates required by the final rules are

not required to reflect the actual or final cost of a particular item or service. Unforeseen factors during the course of treatment (which may involve additional services or providers) can result in higher actual cost-sharing liability following receipt of care than the estimate provided in advance. Nonetheless, the Departments are finalizing the requirement that cost-sharing liability estimates be built upon accurate information, including the relevant cost-sharing information described in 26 CFR 54.9815–2715A2(b)(1)(ii)–(iv), 29 CFR 2590.715–2715A2(b)(1)(ii)–(iv), and 45 CFR 147.211(b)(1)(ii)–(iv). However, this requirement does not mean that the estimates must reflect the amount ultimately charged to a participant, beneficiary, or enrollee. Instead, the estimate should reflect the amount a participant, beneficiary, or enrollee would be expected to pay for the covered item or service for which cost-sharing information is sought. Thus, the final rules do not require the cost-sharing liability estimate to include costs for unanticipated items or services the individual could incur due to the severity of his or her illness or injury, provider treatment decisions, or other unforeseen events. Attendant notice requirements in 26 CFR 54.9815–2715A2(b)(1)(vii), 29 CFR 2590.715–2715A2(b)(1)(vii), and 45 CFR 147.211(b)(1)(vii) also require inclusion of a statement that actual charges for the participant's, beneficiary's, or enrollee's covered items and services may be different from those described in a cost-sharing liability estimate, depending on the actual items and services received at the point of care.

Additionally, while the Departments acknowledge the value of not allowing group health plans and health insurance issuers to impose higher cost sharing than estimated, to the extent that the actual services provided were consistent with those provided under the estimate, the Departments are of the view that it would not be prudent to hold plans and issuers liable to the exact estimate that is provided through the tool, as cost-sharing obligations may ultimately vary from the estimates provided in advance. Additionally, the Departments are concerned that such a requirement could incentivize plans and issuers to provide high estimates, rather than the most accurate estimates.

Commenters recommended the final rules provide plans and issuers with the flexibility to apply a reasonable methodology for estimating reliable out-of-pocket costs for a specific network provider, and recommended that this methodology could include, but should not be limited to, using current year negotiated rates, historical negotiated rates, historical claims, or a combination of these data points. One commenter urged the Departments to remove the proposed requirement that cost-sharing liability information be calculated based on negotiated rates, stating that this is not the methodology used by most existing cost-estimate tools.

The Departments understand that plans and issuers with existing cost-estimate tools may use advanced analytics in calculating cost-sharing liability estimates. However, the Departments are of the view that the most accurate estimates of cost-sharing liability should be provided using the actual rates and fees upon which liability is determined. It is the Departments' understanding that, while provider reimbursement may be based on negotiated rates, plans and issuers do not always calculate a consumer's liability using the negotiated rate as defined in paragraph (a) of the proposed rules, such as in capitation arrangements where the provider is reimbursed retrospectively. Rather, some plans and issuers may determine a participant's, beneficiary's, or enrollee's cost-sharing liability on a contractually agreed upon underlying fee schedule between the provider and the plan or issuer.

Therefore, the final rules require that cost-sharing liability for a particular item or service be calculated based on in-network rates, out-of-network allowed amounts, and individual-specific accumulators, such as deductibles and out-of-pocket limits. However, the Departments clarify that plans and issuers may incorporate additional metrics and analytics beyond this minimum standard: For example, by using complex historical analytics to predict total costs of items and services available through a bundled payment arrangement. The Departments will assess how additional useful information can be provided to consumers in this area going forward.

Under the proposed rules, plans and issuers would be required to provide participants, beneficiaries, and enrollees with cost-sharing information for either a discrete item or service or for items or services for a treatment or procedure for which the plan uses a bundled payment arrangement, according to how the plan or issuer structures payment for the item or service. Several commenters pointed out that providing cost-sharing liability estimates for bundled payment arrangements might introduce confusion as consumers may not realize that billing and payment rates are different when items and services are rendered individually versus as part of a bundled item or service. Commenters stated that ultimately, patients would very likely receive inaccurate or misleading estimates in a significant proportion of self-service estimate requests. Similarly, several commenters sought clarification regarding how plans and issuers that incorporate innovative and cost-saving methods like reference-based pricing, value-based insurance design, and direct primary care as part of their services and plan designs would comply with the requirements of the proposed rules.

The Departments recognize the variability in pricing structures and plan designs for many plans and issuers. The Departments understand that developers have demonstrated that formulas for unique pricing models are already being incorporated into existing estimator tools. The Departments further understand that while providing cost estimates in advance for a plan or issuer that incorporates reference-based reimbursement may be complex, it is still feasible to estimate such costs. For example, plans or issuers could develop a method for analyzing past claims of specific providers to look for patterns in their payment rates from which to derive an accurate predictive estimate in advance. In response to the Hospital Price Transparency final rule, one hospital claims to have developed a tool that provides cost estimates with 95 percent to 99 percent accuracy.[110] While some factors associated with the course of care are incorporated after services are rendered, others, like gender or location, are known in advance. Therefore, the Departments expect plans and issuers to provide a reasonable estimate using information the plan or issuer knows about the participant, beneficiary, or enrollee or the average participant, beneficiary, or enrollee.

The Departments again acknowledge that how a provider is reimbursed does not necessarily indicate how a participant, beneficiary, or enrollee will be billed. Specifically, as commenters explained, the bundled payment arrangement as defined in the proposed rules may not reflect the cost-sharing liability for which the consumer is liable. For instance, if a provider is reimbursed in a bundled payment arrangement for a surgical procedure that includes the surgery and pre- and post-surgery office visits, but the

[110] Meyer, H. ''Hospitals roll out online price estimators as CMS presses for transparency.'' Modern Healthcare. June 23, 2018. Available at *https://www.modernhealthcare.com/article/20180623/NEWS/180629994/hospitals-roll-out-online-price-estimators-as-cms-presses-for-transparency*.

enrollee is billed a copayment for each office visit and coinsurance for the surgical procedure, the enrollee should be able to obtain the separate copayment liabilities for each of the office visits and the surgical procedures, not one bundled charge. However, under this example, if the individual is only responsible for one copayment that includes all office visits and the surgical procedures, the plan or issuer could provide the cost-sharing liability estimate for that bundled payment arrangement.

Therefore, the final rules clarify that plans and issuers should provide one overall cost-sharing liability estimate for a bundled payment arrangement if that is the only cost sharing for which the participant, beneficiary, or enrollee would be liable. However, if a plan or issuer reimburses a provider under a bundled payment arrangement for all covered items and services provided for a specific treatment or procedure, but cost sharing is imposed separately for each unique item and service included in the bundled payment, plans and issuers should disclose the cost-sharing liability for those distinct items and services to the participant, beneficiary, or enrollee. The Departments also recognize that providing one estimate that includes all items and services that are typically provided within an episode of care may be consumer-friendly in some situations, even where the items and services are not subject to a bundled payment arrangement. Therefore, the final rules clarify that while plans and issuers are not required to provide bundled estimates where the provider is not reimbursed through a bundled payment arrangement, nothing prohibits plans or issuers from providing bundled estimates in situations where such estimates could be relevant to participants, beneficiaries, or enrollees, as long as the plan or issuer also discloses information about the relevant items or services individually, as required by the final rules.

Plans and issuers should take a similar approach for plan designs that incorporate alternative payment structures such as direct primary care or other bundled or capitated payment arrangements. The Departments understand that there are many unique plan designs and may issue additional guidance to address specific questions from plans, issuers, and enforcement entities regarding the requirements of the final rules.

The Departments appreciate comments requesting education and outreach to help ensure that participants, beneficiaries, and enrollees know that these consumer tools exist and can understand the information displayed. The Departments recognize that more than 94 percent of plans and issuers recently surveyed already have some variation of an internet self-service tool,[111] yet another study noted that only 12 percent of participants, beneficiaries, or enrollees currently use the tools available to them,[112] which might suggest that there is an opportunity for improved awareness and understanding of these tools. However, the Departments are also of the view that plans and issuers have their own incentives to provide quality customer service and know what types of outreach and messaging would be most helpful to their participants, beneficiaries, and enrollees. Therefore, the Departments have decided not to institute specific outreach and education requirements, but rather strongly encourage plans and issuers to develop educational and outreach materials to promote awareness that self-service tools exist, where to find them on the plan's or issuer's website, how to use the tool, what, if any, further innovations above the baseline standards that differentiates their tool from competitors, and what additional information may be available. In addition, the Departments are of the view that employers may want to conduct outreach and education to encourage their employees to shop for lower-priced services that may slow increases in employer-sponsored coverage premiums.

One commenter stated that the final rules should provide the flexibility for health plans to display cost-sharing information either as dollars or using some proxy variable that either conveys costs relative to other providers or the cost-effectiveness of the providers for a given items or service relative to their peers. Another commenter recommended that cost estimates include both an average price and a reasonable range of the possible prices that the treatment could cost. Other commenters recommended the Departments allow cost estimates to be provided as a range.

The Departments are of the view that cost-sharing averages and ranges would not provide personalized and specific cost-sharing information and therefore the final rules adopt, as proposed, the provision that estimated cost-sharing liability be reflected as a dollar amount. However, the Departments understand that providing an estimated range could help consumers understand how their costs may vary depending on the complexity of a procedure. In addition to providing a cost-sharing estimate that is specific to the participant, beneficiary, or enrollee, plans and issuers may also choose to provide low and high ranges of what the consumer may expect to pay to reflect other needed services, complications, and other factors.

Several commenters expressed concerns about the ability of plans and issuers to provide these cost-sharing estimates, noting that few, if any, currently provide this level of disclosure to participants, beneficiaries, or enrollees before the incurrence of a claim. Commenters stated that most major issuers have treatment cost estimators available, but these tools are rudimentary and are not necessarily available for all plan designs. Commenters also stated that few regional issuers currently make any cost-estimation data available and the vast majority of data provided via online tools currently relies on estimated costs drawn from publicly available sources rather than personal information and circumstances.

Another commenter stated that most self-insured group health plans do not have easy access to all the data necessary to provide beneficiaries with what they described as upfront adjudication of the beneficiary's claim, like an EOB. One commenter expressed concern, stating that plans could be subject to significant penalties for failure to comply and highlighted that self-insured plans typically do not establish their own networks, but rather contract with an issuer, TPA or other entity for the use of their network. Another commenter stated that issuers, preferred provider networks, and TPAs continue to maintain network pricing information as confidential and proprietary, even with respect to their own plan clients. Some commenters stated that while the preamble to the proposed rules suggests that plans could renegotiate their contracts in order to gain access to this proprietary information, this ignores the realities of the market. These commenters opined that, in the absence of clearer guidance applicable to issuers and TPAs, plans and issuers will be burdened with trying to force disclosure of this information.

The Departments are of the view that the ability to access cost-sharing liability information in advance of

[111] Sharma A., Manning, R., and Mozenter, Z. ''Estimating the Burden of the Proposed Transparency in Coverage Rule.'' Bates White Economic Consulting. January 27, 2020. Available at: *https://www.bateswhite.com/newsroom-insight-Transparency-in-Coverage-Rule.html*.

[112] *See* Mehrotra, A., Chernew, M., and Sinaiko, A. ''Promises and Reality of Price Transparency.'' April 5, 2018. 14 N. Eng. J. Med. 378. Available at: *https://www.nejm.org/doi/full/10.1056/NEJMhpr1715229*.

seeking care should not be limited by the participant's, beneficiary's, or enrollee's plan or issuer type. The Departments are aware of several issuers that provide advance cost estimates that are based on an individual's specific information, such as out-of-pocket amount accumulators. The intent of the final rules is to make this information available to a larger number of participants, beneficiaries, and enrollees, empowering them to shop for care that best meets their needs.

Additionally, while the Departments recognize that some self-insured group health plans (or TPAs acting on their behalf) may not currently have access to the information that would be required to calculate a participant's or beneficiary's cost liability, the Departments do not foresee any barriers that would prohibit the plan or TPA from obtaining this information. As discussed in the preamble to the proposed rules, plans may have to amend existing contracts with issuers, TPAs, or providers. Consistent with the discussion of legal authority elsewhere in this preamble, even if a contract between a self-insured plan and a TPA contains a provision prohibiting the public disclosure of its terms, it is the Departments' understanding that such contracts typically include exceptions where a particular disclosure is required by Federal law, and Federal law would control over contractual terms in any case.

In response to whether other types of information are necessary to provide an estimate of cost-sharing liability prior to an individual's receipt of items or services from a provider(s), one commenter suggested—in order to enhance the usability and accuracy of these data—that CMS and payers utilize the open-source episode grouper maintained by the not-for-profit Patient-Centered Episode System (PACES) Center, to create a single industry standard for defining clinical episodes of care using current medical record and payment systems and based on consensus across multiple stakeholders including providers, payers, purchasers, and consumers.

While the Departments generally support standardization across the complex health care ecosystem, there is no current required standardization of items and services provided for certain common episodes of care. Because of the lack of this particular standard, requiring plans and issuers to use PACES or similar services to determine costs will not accurately reflect what different plans and issuers actually reimburse for different episodes of care.

The Departments acknowledge that section 2713 of the PHS Act requires non-grandfathered group health plans and issuers offering non-grandfathered coverage in the individual or group markets to provide coverage without the imposition of any cost-sharing requirements for select preventive items and services. However, if the same items or services are furnished for non-preventive purposes, the participant, beneficiary, or enrollee may be subject to the cost-sharing terms of his or her plan. The Departments are of the view that if an item or service will be furnished at no cost to the participant, beneficiary, or enrollee, the participant, beneficiary, or enrollee should know this information. One commenter expressed a desire that price transparency not serve as a disincentive for individuals seeking preventive and maintenance therapy services. The Departments are of the view that clearly indicating when items and services have a $0 cost-sharing liability may have the opposite effect—it may actually encourage consumers to seek preventive care. The Departments understand that determining whether an item or service is preventive or not for an individual may be complex, and, indeed, may be impossible prior to service. Therefore, to the extent an item or service is a recommended preventive service under section 2713 of the PHS Act, and the plan or issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the non-preventive cost-sharing liability in the internet-based self-service tool, along with a statement that the item or service may not be subject to cost sharing if it is billed as a preventive service. For example, if an individual requests cost-sharing information for an in-network colonoscopy, the plan should display the applicable cost-sharing information for a diagnostic colonoscopy and a statement that the service may not be subject to cost sharing if it is billed as a preventive service from an in-network provider. As an alternative, a plan or issuer may allow an individual to request cost-sharing information for the specific preventive or non-preventive item or service by including the appropriate terms such as ''preventive,'' ''non-preventive,'' or ''diagnostic'' as a means to request the most accurate cost-sharing information.

b. Second Content Element: Accumulated Amounts

The second content element is a participant's, beneficiary's, or enrollee's accumulated amounts. The proposed rules defined ''accumulated amounts'' as the amount of financial responsibility that a participant, beneficiary, or enrollee has incurred at the time the request for cost-sharing information is made, with respect to a deductible and/or an out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these accumulated amounts would include the financial responsibility a participant, beneficiary, or enrollee has incurred toward meeting his or her individual deductible and/or out-of-pocket limit, as well as the amount of financial responsibility that the individuals enrolled under the plan or coverage have incurred toward meeting the other than self-only coverage deductible and/or out-of-pocket limit, as applicable. The Departments interpret section 2707(b) of the PHS Act as requiring non-grandfathered group health plans to comply with the maximum out-of-pocket limit promulgated under section 1302(c)(1) of PPACA, including the HHS clarification that the self-only maximum out-of-pocket limit applies to each individual, regardless of whether the individual is enrolled in self-only coverage or in other than self-only coverage. Accordingly, the self-only maximum out-of-pocket limit applies to an individual who is enrolled in family coverage or other coverage that is not self-only coverage under a group health plan.[113] For this purpose, the Departments proposed that accumulated amounts would include any expense that counts toward the deductible or out-of-pocket limit (such as copayments and coinsurance), but would exclude expenses that would not count toward a deductible or out-of-pocket limit (such as premium payments, out-of-pocket expenses for out-of-network services, or amounts for items or services not covered under a plan or coverage).

Furthermore, to the extent a plan or issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the accumulated amounts would also include the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant, beneficiary, or enrollee has used).

[113] 80 FR 10750, 10824–10825 (Feb. 27, 2015); *see also* FAQs About Affordable Care Act Implementation (Part XXVII), Q1. Available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA/-FAQs-Part-XXVII/-MOOP/-2706/-FINAL.pdf* and *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvii.pdf.*

As discussed in the proposed rules, the Departments understand that independent of cumulative treatment limitations, cost-sharing liability may vary by individual based on a determination of medical necessity and that it may not be reasonable for a plan or issuer to account for this variance as part of the accumulated amounts. Therefore, under the final rules, plans and issuers are required to provide cost-sharing information with respect to an accumulated amount for a cumulative treatment limitation that reflects the status of the individual's progress toward meeting the limitation, and this information does not include any individual determination of medical necessity that may affect coverage for the item or service. For example, if the terms of an individual's plan or coverage limit coverage of physical therapy to 10 visits per plan or policy year, subject to a medical necessity determination, and at the time the request for cost-sharing information is made the individual has had claims paid for three physical therapy visits, the plan or coverage would make cost-sharing information disclosures based on the fact that the individual could be covered for seven more physical therapy visits in that plan or policy year, regardless of whether or not a determination of medical necessity for future visits has been made at that time.

Several commenters supported the inclusion of the accumulated amounts as one of the content elements. One commenter agreed with the proposed requirement that the accumulated amounts include the financial responsibility incurred toward both an individual deductible and/or out-of-pocket limit and toward the other than self-only coverage deductible and/or out-of-pocket limit. One commenter recommended that plans be required to disclose to prospective enrollees whether an enrollee's accumulated amounts are reduced through a plan's accumulator adjustment program because, the commenter noted, having this information prior to enrollment in a plan is crucial because of the impact such programs have on participant, beneficiary, and enrollee access, adherence, and outcomes.

The Departments agree that an essential part of providing accurate cost-sharing estimates is disclosing individuals' progress toward their accumulated amounts. However, the intent of the self-service tool is to provide current participants, beneficiaries, and enrollees with information about their plan or issuer, and, therefore, the Departments are not finalizing any provisions related to disclosures to potential enrollees. The final rules adopt this provision as proposed.

One commenter recommended the Departments confirm amounts made available in account-based arrangements that can or must be used toward cost-sharing expenses under a separate plan need not be reflected in the accumulated amounts or cost-sharing estimate under the tool. The commenter stated that there is an array of these types of arrangements of varying types and structures and to incorporate them into the cost-sharing estimate could be administratively challenging and would impose a significant burden.

The Departments clarify that the estimates do not include amounts made available through separate account-based arrangements. In addition, the Departments encourage, but are not requiring, plans and issuers to issue a disclaimer regarding such arrangements, as necessary.

Certain commenters stated that the proposed requirement to display accumulated amounts toward a cumulative treatment limitation on a particular item or service would be difficult to implement and requested elimination or delay of this requirement. Commenters expressed that in some cases, this information may be tracked by third-party vendors and not integrated into claims systems; for example, plans and issuers often contract with third parties that provide medical benefits management for certain services (physical therapy, for example). Commenters stated that building the connectivity necessary to exchange information on accumulated amounts in real time would take significant time. Other commenters recommended this requirement be optional.

The Departments acknowledge that disclosure of accumulated amounts may present challenges for plans and issuers. However, an accurate estimate of cost-sharing liability cannot be achieved without taking into account a participant's, beneficiary's, or enrollee's accumulated amounts, including cumulative treatment limitations. Nonetheless, to give plans and issuers additional time to prepare, the disclosure requirements related to cost-sharing liability estimates in the final rules are not applicable until plan years (or in the individual market, policy years) beginning on or after January 1, 2023, providing two years for implementation, which should give plans and issuers sufficient time to ensure that they are able to comply.

One commenter urged the Departments to include a requirement for plans to provide the cost for the beneficiary to purchase a non-covered prescription drug and to indicate whether and, if so, to what extent, that cost will be applied against the deductible. The commenter stated that knowing to what extent a non-covered drug expense will count towards meeting a deductible and the annual limitation on cost sharing, if at all, especially with regard to specialty drugs, is critical because there are significant coverage gaps.

While the Departments appreciate the suggestions related to non-covered prescription drugs, this rulemaking is focused on covered items and services. The Departments are not inclined to increase the burden imposed by the final rules by adding requirements to disclose information regarding non-covered services, given that plans and issuers may not have access to the costs of drugs they do not cover and include in their formulary. The Departments will take this suggestion into consideration for future rulemaking.

c. Third Content Element: In-Network Rates

Negotiated Rates

In the proposed rules, the Departments proposed to require group health plans and health insurance issuers to disclose the negotiated rate, reflected as a dollar amount, for an in-network provider or providers for a requested covered item or service, to the extent necessary to determine the participant's, beneficiary's, or enrollee's cost-sharing liability. Many commenters did not support the disclosure of negotiated rates, stating that publishing negotiated rates would not meet the Departments' purported goal of helping consumers understand costs and would possibly make purchasing more confusing and difficult for consumers. Additionally, some commenters expressed concerns that publication of negotiated rates would force plans and issuers to violate non-disclosure contracts with providers. Conversely, many other commenters did support the disclosure of negotiated rates and offered support for their disclosure to participants, beneficiaries, and enrollees. These commenters stated that consumers should be engaged and educated about health care spending, and as discussed in more detail below, several commenters supported the disclosure of negotiated rates even when it is not relevant to a consumer's cost-sharing liability.

The Departments maintain that the disclosure of the negotiated rates is a key element of overall price transparency. Participants, beneficiaries,

and enrollees are often responsible for a percentage of the negotiated rate through coinsurance or the entire negotiated rate if they have not yet met their deductible. Consistent with discussions elsewhere in this preamble, the Departments are of the view that such contracts typically include exceptions where a particular disclosure is required by Federal law.

In the preamble to the proposed rules, the Departments acknowledged that some provider contracts express negotiated rates as a formula (for example, 150 percent of the Medicare rate), but disclosure of formulas is not likely to be helpful or understandable for many participants, beneficiaries, and enrollees viewing this information. For this reason, the final rules require plans and issuers to disclose the negotiated rates and underlying fee schedules that result from using such a formula, as a dollar amount.

A few commenters recommended disclosing negotiated rate ranges or benchmarks to help consumers compare prices among providers. One commenter stated it would be useful if plans disclosed their range of in-network rates (or their average or median rate) for each service. This commenter stated that, for certain services such as complex surgeries, for which fees may be bundled and may vary widely depending on the severity of a participant's, beneficiary's or enrollee's condition, providing the range of in-network fees may be particularly appropriate. This type of disclosure could alert participants, beneficiaries, and enrollees to consider, and prompt them to consult providers about, the full range of potential expenses for their care. Another commenter recommended that, regardless of the participant's, beneficiary's, or enrollee's out-of-pocket liability, the participant, beneficiary, or enrollee should always be provided the full in-network amount, as well as a comparison of that amount to a benchmark such as the Fair Price or median in-network price. This commenter stated that the in-network price for a service can vary by as much as 200 to 1,000 percent, depending on the provider selected. In order to achieve the goals of transparency, consumers need to know the full price of a service prior to care so they are able to effectively compare providers' prices.

In the Departments' view, disclosure of formulas or ranges are not likely to be helpful or understandable for many participants, beneficiaries, and enrollees viewing this information. The purpose of the internet-based self-service tool is to provide personalized costs based on the participant's, beneficiary's, or enrollee's specific plan or coverage, and ranges and formulas do not achieve this goal. For this reason, the final rules retain the proposed requirement to disclose the rate that results from using such a formula, which is required to be expressed as a dollar amount.

Underlying Fee Schedule Rate

Given the unique nature of certain plan designs, in the proposed rules, the Departments requested comment on whether there were certain reimbursement or payment models that should be exempt from all or certain aspects of the proposed rules. A few commenters urged the Departments to clarify how capitation arrangements and value-based reimbursement designs, including bundled payment arrangements and reference-based pricing, would be regulated under the proposed rules. Commenters stated that provider payment amounts are not knowable under these types of arrangements until after care is provided and that they cannot be attributed to a particular item or service provided to a particular participant, beneficiary, or enrollee. Other commenters stated that participants, beneficiaries, and enrollees should have access to cost-sharing liability data for items and services that might be rendered in the course of their care, but that the Departments' proposed approach downplayed the complexity of payer-provider contracts in a way that could inadvertently lead to participants, beneficiaries, and enrollees receiving misleading estimates of their cost-sharing liability. The commenter stated that only the consumer's cost sharing and the fee-for-service component of reimbursement should be required to be disclosed under these requirements. Another commenter stated that the vast majority of bundled payment arrangements use a retrospective settlement, in which the payer and provider determine a final settlement after all care in the relevant episode has been delivered, suggesting that a negotiated rate under these arrangements could not be provided in advance.

The Departments are of the view that, for transparency in coverage to be truly effective, consumers should have access to all pricing information related to their care so they can make meaningful decisions about their health care spending. Further, the Departments do not agree that the disclosure of negotiated rates will be misleading to participants, beneficiaries, or enrollees. Negotiated rates are already an element of an EOB that participants, beneficiaries, and enrollees are accustomed to receiving after receiving health care items or services. As stated elsewhere in this preamble, providing this information in advance equips a more cost-conscious participant, beneficiary, and enrollee with the necessary information to make a more informed decision about their health care. Furthermore, the Departments are of the view that it is in the best interest of plans and issuers to indicate, when disclosing these rates, what each rate is and how it is applicable to the participant's, beneficiary's, or enrollee's plan or coverage.

To more fully understand the complexity of payer-provider contracts and, in an effort to clarify how the proposed rules would apply to capitated, bundled, and other alternative reimbursement designs, the Departments considered these public comments and conducted additional research to understand different contracting models and the inputs that would be necessary for determining a participant's, beneficiary's, or enrollee's cost-sharing liability under these models.

Under some capitation arrangements, payers reimburse a provider a set amount per participant, beneficiary, or enrollee for a pre-defined amount of time, regardless of whether the participant, beneficiary, or enrollee uses the provider's services. Capitation payments are generally guided by actuarial principles and may be determined by different factors, such as a participant's, beneficiary's, or enrollee's age and gender. For instance, under some capitated models, plans and issuers pay a provider or a collective panel of providers a per-member-per-month (PMPM) capitation amount, which is the negotiated rate. It is the Departments' understanding that under certain capitated and bundled payment arrangements, providers' payments may be reconciled retrospectively to account for utilization, value adjustments, or other weighting factors that can affect the final payment to a provider. The Departments understand that capitation arrangements also may include at least one underlying fee schedule rate upon which a participant's, beneficiary's, or enrollee's cost-sharing liability is determined.

As the Departments acknowledged earlier in this preamble, negotiated rates, as defined in the final rules, do not always affect a participant's, beneficiary's, or enrollee's cost-sharing liability. To account for alternative reimbursement arrangements such as capitated and bundled payment arrangements, the Departments are renaming the third content element as ''in-network rates,'' comprised of the

following elements, as applicable to the plan's or issuer's payment model: negotiated rate and underlying fee schedule rate, reflected as dollar amounts. Plans and issuers must disclose the underlying fee schedule rate used to determine participant, beneficiary, or enrollee cost-sharing liability only where that rate is different from the negotiated rate. As discussed earlier in this preamble, the final rules require that the cost-sharing liability estimate for a requested covered item or service be calculated using the current underlying fee schedule rate if the plan or issuer uses such a fee schedule. The Departments are of the view that disclosing underlying fee schedule rates will provide the most relevant data on which cost sharing is based, if cost sharing is not based on the negotiated rate, as originally proposed.

Disclosing the Negotiated Rate and Underlying Fee Schedule Rate

In the proposed rules, the Departments acknowledged that if the negotiated rate does not impact an individual's cost-sharing liability under a plan or coverage for a covered item or service (for example, if the copayment for the item or service is a flat dollar amount or zero dollars and the individual has met a deductible, or a deductible does not apply to that particular item or service), disclosure of the negotiated rate may be unnecessary to calculate cost-sharing liability for that item or service. Therefore, the Departments proposed that disclosure of a negotiated rate would not be required if it is not relevant for calculating an individual's cost-sharing liability for a particular item or service. The Departments sought comment on whether there are any reasons disclosure of negotiated rates should nonetheless be required under these circumstances.

Many commenters agreed that negotiated rates should only be disclosed to the extent they are used for determining cost-sharing liability. Commenters further expressed that only information meaningful to consumers' cost-sharing liability should be required to be disclosed. One commenter stated that this interpretation should be extended to payments tied to value, such as ''shared savings,'' bonuses, and other performance-based reimbursements.

Conversely, as stated earlier, many commenters supported the disclosure of negotiated rates in all circumstances. One commenter stated that disclosing the amount of the negotiated rate is extremely valuable regardless of whether the disclosure of this information impacts a participant's cost-sharing liability, because it will illuminate the costs of these particular items and services—reflecting the benefit consumers receive from their enrollment in the plan or coverage, as well as helping them to be conscious of the costs incurred by the plan overall. This commenter pointed out that if the plan or issuer has different negotiated in-network rates with different providers furnishing the same item or service, participants, beneficiaries, and enrollees will have the opportunity to compare the different rates among the different providers.

Another commenter suggested a number of benefits that could come from the disclosure of negotiated rates through the cost-sharing tool, even in cases in which that information is not relevant to the specific cost-sharing inquiry. The commenter pointed out that even if the participant's, beneficiary's, or enrollee's cost is not affected, the plan's or issuer's cost could be significantly affected and that allowing participants, beneficiaries, and enrollees awareness and visibility of negotiated rates could provide consumers with a greater understanding of health care costs and enable participants, beneficiaries, and enrollees to seek out lower cost providers. The commenter further stated that although participants, beneficiaries, and enrollees will use the tool to look up estimated cost-sharing for specific items and services, often they will also expect to seek services from the same provider repeatedly (for example, for ongoing treatment and follow-up care).

The Departments agree with those commenters who favored requiring disclosure of negotiated rates even when the negotiated rate is not relevant to determining cost sharing, because it may promote awareness and understanding of health care prices and promotes transparency in coverage. Accordingly, the phrase ''to the extent relevant to the participant's or beneficiary's cost-sharing liability'' that appeared in paragraph (b)(1) of the proposed regulations has been removed from the final rules. The final rules modify the third content element to require that the negotiated rate always be disclosed with cost-sharing liability estimates, even if it is not used to determine cost sharing, and that the underlying fee schedule rate also be disclosed, to the extent that it is different from the negotiated rate, as applicable to the plan's payment model.

With regard to plans and issuers using an alternative reimbursement model, such as a capitated or bundled payment arrangement that does not have negotiated rates or an underlying fee schedule, one commenter stated that issuers do not always have access to the negotiated rates or internal payment methodologies utilized by capitated medical groups or other providers and would not be able to reliably provide cost transparency based on a negotiated rate at the service level. In contrast, another commenter stated there is no justification for excluding plans that reimburse their providers based on capitation from the internet-based self-service tool requirements as this would result in an incomplete data set, and these plans already assign values to services to administer benefits with deductibles and coinsurance, as well as for risk adjustment and internal reporting purposes. Another commenter stated that the Departments should include Accountable Care Organizations (ACOs) and other capitated arrangements within the ambit of the final rules and should require transparency and full disclosure of financial incentive arrangements that underlie capitated arrangements under a specific plan or contract, not just a consumer's anticipated liability. This commenter stated that any exemptions may actually be incentives for plans and issuers to move toward opaque pricing models.

The Departments acknowledge that it is possible that some plans and issuers using alternative reimbursement models may not have negotiated rates or underlying fee schedule rates to disclose in the internet-based self-service tool. However, the numbers of plans and issuers without negotiated rates or underlying fee schedule rates is limited and the Departments are of the view that an exemption for such arrangements is not necessary. Additionally, the Departments are of the view that providing an exemption for such arrangements will result in incomplete data sets. As stated in the final rules, the in-network rate must be disclosed, as applicable to the plan's or issuer's payment model. If the plan or issuer does not have negotiated rates or underlying fee schedule rates, the third content element does not apply.

Prescription Drugs

The final rules adopt the requirement that group health plans and health insurance issuers disclose to participants, beneficiaries, or enrollees an estimate of cost-sharing liability for each item or service, including prescription drugs. As discussed in the preamble to the proposed rules, this would allow participants, beneficiaries, and enrollees to request cost-sharing information for a specific billing code

(as described later in this preamble) associated with a prescription drug or by descriptive terms (such as the name of the prescription drug), which would permit participants, beneficiaries, and enrollees to learn the estimated cost of a prescription drug obtained directly through a provider, such as a pharmacy or mail order service. In addition to allowing participants, beneficiaries, and enrollees to obtain cost-sharing information by using a billing code or descriptive term, the proposed rules would also have permitted participants, beneficiaries, and enrollees to learn the cost of a set of items or services that include a prescription drug or drugs that is subject to a bundled payment arrangement for a treatment or procedure. In the proposed rules, the Departments acknowledged that outside of a bundled payment arrangement, plans and issuers often base cost-sharing liability for prescription drugs on the undiscounted list price, such as the AWP or WAC, which frequently differs from the price the plan or issuer has negotiated for the prescription drug.[114] In these instances, providing the participant, beneficiary, or enrollee with a rate that has been negotiated between the issuer or plan and its PBM could be misleading, as this rate would reflect rebates and other discounts, and could be lower than what the individual would pay—particularly if the participant, beneficiary, or enrollee has not met his or her deductible.

The Departments sought comment as to whether a rate other than the negotiated rate, such as the undiscounted price, should be required to be disclosed for prescription drugs, and whether and how to account for any and all rebates, discounts, and dispensing fees to ensure participants, beneficiaries, and enrollees have access to meaningful cost-sharing liability estimates for prescription drugs.

Several commenters supported disclosure of rebates, discounts, and other price concessions for drugs. One commenter referred to drug price concessions as one of the ''most confounding black boxes of health care'' and stated that data suggests these concessions are actually increasing out-of-pocket costs for participants, beneficiaries, and enrollees. This commenter urged the Departments to require plans and issuers to disclose the list price, the negotiated rate, a single dollar value reflecting the total amount of price concessions, and the price used to calculate the participant's, beneficiary's, and enrollee's coinsurance along with, if different from the negotiated rate, an explanation as to why the price is different from the negotiated rate. Another commenter opined that participants, beneficiaries, and enrollees have the right to know a drug's undiscounted price, discounted or negotiated price, and the total sum of all price concessions for that drug, including fees, rebates, and discounts. This commenter stated that providing a beneficiary with these three data points strikes the appropriate balance between improving transparency without misleading or overwhelming the participant, beneficiary, or enrollee.

Many commenters suggested that plans and issuers be required to disclose when the participant's, beneficiary's, or enrollee's cost-sharing requirement exceeds the price paid by the plan or issuer. One commenter stated that in cases where plans pass through some or all rebates and other price concessions to participants, beneficiaries, and enrollees, the prices disclosed to participants, beneficiaries, and enrollees should be the price net of those rebates and concessions. The commenter emphasized the importance of plans and issuers also disclosing to participants, beneficiaries, and enrollees when manufacturer rebates and discounts are not passed through to them at the point-of-sale or factored into cost-sharing. One commenter noted that negotiated prices for prescriptions or cash price alternatives may sometimes appear less expensive, but that such alternative rates (for example, cash price options) may increase overall costs if such rates offset the ability to reach a plan's deductible or out-of-pocket maximum thresholds. Therefore, this commenter requested that the Departments provide clarity as to whether plans and issuers would be responsible for notifying participants, beneficiaries, and enrollees of such considerations and/or making such calculations. Similarly, two commenters urged the Departments to require disclosure of the negotiated rate for drugs in all situations, even where the beneficiary owes a fixed-amount copayment, and cited reports of cases when, for inexpensive generics, the beneficiary's fixed-amount copay actually exceeded the negotiated rate.

Three commenters recommended that the Departments provide plans the flexibility to display the most meaningful price to an enrollee for drugs. One commenter stated that if the participant, beneficiary, or enrollee's cost sharing is based upon a specified benchmark, the plan should be allowed to specify the benchmark used in the tool's documentation. This commenter suggested that requiring plans to conform to a single standard is not possible, and in effect may be unhelpful to consumers, given the multitude of contracts (and different contract terms) that each plan's PBM may have with pharmacies. Another commenter stated providing this flexibility will allow for issuer innovation in developing cost-estimator functionality that provides real-time, accurate, and useful prescription drug estimates to participants, beneficiaries, or enrollees.

One commenter recommended the Departments consider using ''net price'' rather than the ''negotiated rate'' for estimating cost-sharing liability for prescription drugs. The commenter explained that direct and indirect remuneration (DIR) fees under Medicare Part D and similar PBM practices in the private market were originally designed to capture rebates and other mechanisms not included at the point-of-sale. However, the commenter stated that DIR fees and other retroactive fees utilized by PBMs are now being used beyond their original purpose to retroactively adjust pharmacies' payment months after the sale, sometimes below the price paid by the pharmacy.

Some commenters stated that the Departments should not require display of negotiated drug prices, rebates, or other discounts or fees. Two commenters expressed that, rather than increasing transparency or providing actionable or meaningful information to participants, beneficiaries, or enrollees, estimated rebate information would simply confound and frustrate participants, beneficiaries, or enrollees, given its lack of direct relevance to the amount the participant, beneficiary, or enrollee is required to pay for the drug at a pharmacy. Another commenter stated that disclosing highly confidential dispensing fees would benefit only those parties being paid dispensing fees, by giving them a window into the dispensing fees paid to their competitors, and advised that the Departments should avoid requiring any disclosure of drug prices, rebates, discounts, or fees that would undermine plans' and issuers' ability to negotiate lower drug costs.

The Departments also solicited comment as to whether there are scenarios in which including drug pricing information in cost estimates would be problematic. One commenter recommended that the final rules require disclosure of an estimate of the cost-sharing liability associated with a drug only when there is an out-of-pocket cost to the participant, beneficiary, or enrollee that is directly

[114] ''Follow the Dollar.'' PhRMA. November 30, 2017. Available at: *https://www.phrma.org/report/follow-the-dollar-report.*

attributable to the drug. Another recommended that when the price of a drug is not the basis of the enrollee's cost-sharing liability, plans should be given the option to publish the benchmark price or omit a price altogether, displaying only the enrollee's cost-sharing liability.

The Departments also sought comment on whether the relationships between plans or issuers and PBMs allow plans and issuers to disclose rate information for drugs, or if contracts between plans and issuers and PBMs would need to be amended to allow plans and issuers to provide a sufficient level of transparency. If those contracts would need to be amended, the Departments sought comment on the time that would be needed to make those changes. While some commenters stated that the rates negotiated between PBMs and pharmacies are considered confidential, other commenters stated that existing contracts would not prevent PBMs or issuers from disclosing the required information. One commenter stated that it is common that contracts be modified in response to changes in a statute or regulation, and that Federal public policy imperatives override existing contractual provisions. This commenter stated the public interest in complete disclosure to reduce costs for consumers unquestionably outweighs any confidentiality provisions in current contracts that might otherwise protect disclosure of relevant information to the Federal Government.

The Departments agree that participants, beneficiaries, and enrollees, as well as health care payers such as employers, should have access to meaningful pricing information related to drug pricing in order to meaningfully evaluate plan and issuer offerings and gain transparency into potential out-of-pocket costs.

The Departments also acknowledge that contract terms may need to be amended based on the final rules. The Departments agree that disclosure of rebates, discounts, and other price concessions would further the goals of price transparency, but also acknowledge other commenters' concerns that disclosing all these elements might cause consumer confusion. The Departments also acknowledge that there could be value in using ''net price'' rather than ''negotiated rate'' and in disclosing when a participant's, beneficiary's, or enrollee's cost-sharing liability exceeds the price paid by the plan or issuer. As described by commenters, there are numerous pricing inputs throughout the drug supply chain that affect the final price for the consumer—making complete transparency on drug pricing more complex than that of other items and services. The Departments aim to strike a balance between illuminating some of the factors that drive drug costs and not overwhelming consumers with information that is not directly relevant to their cost-sharing liability. To that end, the final rules require plans and issuers to disclose in element (i), an individual's out-of-pocket cost liability for prescription drugs, and in element (iii), the negotiated rate of the drug. As discussed elsewhere in this preamble, the Departments recognize that the negotiated rate might be different for branded and generic drugs. For instance, the negotiated rate might be the WAC for branded drugs and the Maximum Allowed Cost (MAC) for generic drugs. The Departments also acknowledge that this price might be established differently for different plans and issuers. The Departments anticipate this disclosure generally will not necessitate the disclosure of information on discounts, rebates, or price concessions for a drug.

The Departments recognize there may be circumstances in which a drug carries no cost-sharing liability for a participant, beneficiary, or enrollee. If there is no cost sharing associated with a prescription drug, under the final rules, the tool should reflect a cost-sharing value of $0 for clarity, but the negotiated rate must be displayed.

The proposed rules sought comment on the possibility of requiring access to the APIs used by pharmacies in accessing drug prices. One commenter stated that drug prices frequently differ from period to period over the course of the year, as well as across pharmacy locations even within the same national pharmacy chain. The commenter recommended that the Departments consider requiring PBMs to provide payers, group plans, and third parties with access to the same price APIs accessed by pharmacies, stating that, with access to an open API, the plan or third party could request the estimated price for the same prescription at multiple retail pharmacies and receive real-time retail pricing based upon the participant's, beneficiary's, or enrollee's plan. The Departments recognize the value in requiring cost-sharing information be made available through an API and will use the comments received to inform future rulemaking.

Commenters requested that the Departments confirm that issuers may provide a link to prescription drug cost tools offered through PBMs or vendors to satisfy the requirement to provide pricing information for prescription drugs. One commenter also urged the Departments to prohibit the internet-based, self-service tool from being used by prescribers' e-prescribing and electronic medical record systems or by plans to steer patients to pharmacies other than a patient's pharmacy of choice, such as those owned wholly or partially by health plans or PBMs.

The Departments agree that plans and issuers who provide participants', beneficiaries', or enrollees' cost-sharing liability estimates and negotiated rates through a standalone tool provided by a PBM or third-party vendor satisfy the requirements under the final rules. The Departments also clarify that if the PBM or other third-party vendor fails to provide full or timely information, then the plan or issuer, not the PBM or third-party vendor, violates these transparency disclosure requirements. Regarding a prohibition on steering patients to certain pharmacies by plans or prescribers, the Departments are not finalizing any prohibitions at this time and will monitor the implementation of these disclosure requirements.

d. Fourth Content Element: Out-of-Network Allowed Amount

The fourth content element is the out-of-network allowed amount for the requested covered item or service. In the proposed rules, the Departments proposed to define ''out-of-network allowed amount'' to mean the maximum amount a group health plan or health insurance issuer would pay for a covered item or service furnished by an out-of-network provider. Under the proposed rules, plans and issuers would be required to disclose an estimate of cost-sharing liability for a participant, beneficiary, or enrollee. Therefore, the Departments proposed that, when disclosing an estimate of cost-sharing liability for a covered item or service from an out-of-network provider, a plan or issuer would disclose the out-of-network allowed amount and any cost-sharing liability the participant, beneficiary, or enrollee would be responsible for paying. For example, if a plan has established an out-of-network allowed amount of $100 for an item or service from a particular out-of-network provider and the participant, beneficiary, or enrollee is responsible for paying 30 percent of the out-of-network allowed amount ($30), the plan would disclose both the allowed amount ($100) and the individual's cost-sharing liability ($30), indicating that the individual is responsible for 30 percent of the out-of-network allowed amount. Under the proposed rules, this element would only be relevant when a participant, beneficiary, or enrollee

requests cost-sharing information for a covered item or service furnished by an out-of-network provider.

In the proposed rules, the Departments explained that the definition of cost-sharing liability does not include amounts charged by out-of-network providers that exceed the out-of-network allowed amount, which participants, beneficiaries, or enrollees must pay (sometimes referred to as balance bills). Therefore, it may be difficult for participants, beneficiaries, or enrollees to determine their likely out-of-pocket costs for covered items and services furnished by an out-of-network provider. The Departments also explained that the statutory language of section 1311(e)(3)(A)(vii) of PPACA and section 2715A of the PHS Act indicates that Congress intended that participants, beneficiaries, enrollees, and other members of the public have access to accurate and timely information regarding cost sharing and payments with respect to any out-of-network coverage. In the Departments' view, requiring plans and issuers to disclose out-of-network allowed amounts and a participant's, beneficiary's, or enrollee's cost-sharing obligation for covered items and services is necessary and appropriate to fulfill this statutory mandate, and would give individuals information necessary to estimate their out-of-pocket costs, assuming they request additional information from an out-of-network provider about how much the provider would charge for a particular item or service.

One commenter encouraged the Departments to eliminate the proposed ''maximum amount'' standard and to instead incorporate usual, customary, and reasonable (UCR) amounts as the required plan disclosure for out-of-network cost estimates under any final rulemaking. The commenter stated that the ''maximum amount'' a plan may be willing to pay a given provider for a service is not necessarily predetermined. This commenter stated that while some out-of-network providers and plans may participate in super-regional or national ''discount'' arrangements through third parties, in many cases payments to out-of-network providers are individually negotiated. Further, while a plan might generally start with payment that is consistent with UCR calculations (with every intention of paying no more than this amount), other circumstances may result in negotiated increases to that reimbursement. As such, prospectively reporting an accurate ''maximum amount'' is impossible in some cases. Additionally, this commenter stated that because many out-of-network reimbursements, and in particular high-cost claims, are individually negotiated, initial disclosure of a plan's true maximum reimbursement, insofar as this can be calculated or even estimated in advance, would materially reduce a plan's bargaining power by notifying non-contracted providers in advance of the amount they are likely to secure from a plan if they assert all available leverage in a negotiation. To the extent participant, beneficiary, or enrollee cost-sharing liability is ultimately derived from out-of-network payment amounts, this requirement is likely to increase out-of-pocket costs for consumers when seeking care from out-of-network providers.

Conversely, one commenter stated that while larger, for-profit, national health plans can afford to utilize the UCR, smaller, regional health plans are at a market disadvantage if they are compelled to base allowed amounts on the UCR, rather than negotiating on a case-by-case basis in a constrained market. As a result, some health plans will struggle to determine and provide information about maximum out-of-network allowed amounts—a range of possible ''allowed amounts'' may be the most information some health plans have available.

The Departments agree with commenters that the UCR may be a more accurate estimate of the amount a plan or issuer will pay an out-of-network provider for covered items or services, if the plan relies on UCR to determine out-of-network rates. However, the Departments acknowledge that basing allowed amounts on the UCR may disadvantage smaller plans. The Departments also acknowledge that a plan or issuer may be able to provide a participant, enrollee, or beneficiary with a more accurate estimate of an out-of-network allowed amount by using calculations based on historical claims data, because the plan or issuer does not have a pre-determined negotiated rate with out-of-network providers. The Departments acknowledge the concern that plans may lose bargaining power by disclosing out-of-network allowed amount to consumers; however, the Departments are of the view that the out-of-network allowed amount is a critical element of price transparency and its disclosure is essential to enabling consumers to estimate their out-of-network costs in advance. To this end, the Departments are modifying this provision to require plans and issuers to disclose the out-of-network allowed amount or any other calculation that provides a more accurate estimate of the amount a plan will pay for the requested covered item or service, such as a UCR. Allowing plans and issuers to provide an amount other than the out-of-network allowed amount could better serve consumers with a more accurate estimate of what a plan or issuer may reimburse an out-of-network provider. The Departments clarify that if a plan or issuer chooses to use another metric that provides a reasonably accurate estimate of what a plan or issuer will pay for a covered item or service from an out-of-network provider, the plan or issuer must still provide a participant, beneficiary, or enrollee with information regarding any cost sharing the participant, beneficiary, or enrollee would be responsible for paying.

Some commenters recommended the Departments not require plans and issuers to provide allowed amount and cost-sharing information for covered services furnished by an out-of-network provider. One commenter stated it is not possible for issuers to include allowed amounts for out-of-network providers because, without a provider contract, issuers do not have the necessary information, including provider names, National Provider Identifier (NPI), address, specialty, or other demographic information to include these providers in a price transparency tool. One commenter stated that providing real-time disclosures of allowed amounts could be challenging to the extent that plans and issuers determine the allowed amount for certain out-of-network items and services based on a percentage of billed charges, as billed charges are unknown by the plan or issuer prior to a claim for health care services.

The Departments acknowledge the challenges plans and issuers may face disclosing this element, but the Departments are of the view that information regarding out-of-network coverage is essential to the goal of price transparency. With regard to plans and issuers lacking the necessary information for providers with whom they do not contract, the Departments are of the view that plans and issuers should know what they are willing to pay for certain items and services, irrespective of provider. The final rules provide flexibility for plans and issuers to provide an estimate of what the plan will pay by allowing plans and issuers to disclose either the out-of-network allowed amount or another amount that would provide a reasonably accurate estimate of what a plan would reimburse an out-of-network provider for a covered item or service. Given that some plans and issuers determine the allowed amount for certain out-of-network items and services based on a percentage of billed charges, the final rules provide that a percentage can be

disclosed instead of a dollar amount, if plans and issuers reimburse out-of-network providers a percentage of the billed charges for a covered item or service.

One commenter sought clarification that the tool is meant to provide cost-sharing information for out-of-network providers and not just the allowed amounts.

As discussed earlier in this preamble under the first content element, under the final rules, the plan or issuer is required to disclose both the out-of-network allowed amount, as described earlier in this preamble, and any cost-sharing liability, based on that allowed amount, that the participant, beneficiary, or enrollee would be responsible for paying.

One commenter stated that the Departments should not require Health Maintenance Organizations' (HMOs') out-of-pocket calculators to provide out-of-network data. The commenter noted that the proposed rules limited the tool to covered services, and HMOs generally do not cover benefits provided by out-of-network and, therefore, should not be required to estimate out-of-network costs.

The Departments understand that some plans and issuers may not provide any reimbursement to an out-of-network provider for an otherwise covered item or service. Nonetheless, it is the Departments' understanding that some HMOs reimburse an out-of-network provider for covered items and services in certain circumstances and, therefore, the Departments expect HMOs to provide cost-sharing information with regard to out-of-network coverage. The Departments recognize that in many cases, an HMO's maximum allowed amount for an out-of-network service will be $0. However, the Departments are of the view that it is important for a participant, enrollee, or beneficiary to understand what the plan or issuer will or will not pay for out-of-network costs. Therefore, if the plan or issuer, including an HMO, does not provide any reimbursement for an item or service provided by an out of network provider, the Departments expect the plan or issuer to disclose $0 as the allowed amount.

e. Fifth Content Element: Items and Services Content List

The fifth content element is a list of those covered items and services for which cost-sharing information is being disclosed for items or services subject to a bundled payment arrangement. The Departments proposed that this requirement would apply only when a participant, beneficiary, or enrollee requests cost-sharing information for an item or service that is subject to a bundled payment arrangement that includes multiple items or services. The Departments proposed that, in cases in which an individual requests a cost-sharing liability estimate for a covered item or service that is subject to a bundled payment arrangement, plans and issuers would be required to disclose a list of each covered item and service included in the bundled payment arrangement and the individual's cost-sharing liability for those covered items and services as a bundle, but not a cost-sharing liability estimate separately associated with each covered item or service included in the bundle.

While some commenters supported the inclusion of cost-sharing information for bundled payment arrangements, others did not support requiring the disclosure of bundled payment arrangements and the items and services included in the arrangement. These commenters stated disclosure of this information would likely be unhelpful to the participant, beneficiary, or enrollee and might cause confusion. One commenter encouraged the Departments to clarify that disclosure for diagnostic imaging procedures in particular should be presented to consumers in a method that is inclusive of the combined professional and technical rates, or the globally billed rate.

The Departments are of the view that understanding which items and services are included in a bundled payment arrangement will provide helpful information for participants, beneficiaries, and enrollees, so that they understand what items and services are accounted for in calculating their cost-sharing liability. The Departments are of the view that this list is unlikely to cause confusion. Instead, it will reduce confusion by clearly identifying what individual items and services would be covered under their estimated cost-sharing liability. If the plan or issuer reimburses a procedure, such as imaging, at a global rate that includes both professional and technical charges, then that global rate is a rate for a bundled payment arrangement for which the applicable content elements must be disclosed, just as for all other items and services. The final rules adopt the provision that plans and issuers provide a list of items or services for items and services subject to bundled payment arrangements for which a cost-sharing liability estimate is being disclosed, with non-substantive edits for improved readability.

f. Sixth Content Element: Notice of Prerequisites to Coverage

The sixth content element is a notification, whenever applicable, informing the individual that a specific covered item or service for which the individual requests cost-sharing information may be subject to a prerequisite for coverage. The proposed rules defined the term prerequisite to mean certain requirements relating to medical management techniques for covered items and services that must be satisfied before a plan or issuer will cover the item or service. Specifically, the proposed rules provided that prerequisites include such techniques as concurrent review, prior authorization, and step-therapy or fail-first protocols. In the proposed rules, the Departments intended for the definition of prerequisite to capture medical management techniques that apply to an item or service that require action by the participant, beneficiary, or enrollee before the group health plan or health insurance issuer will cover the item or service. Accordingly, the proposed definition of prerequisite did not include medical necessity determinations generally, or other forms of medical management techniques that do not require action by the participant, beneficiary, or enrollee. While the prerequisites enumerated in the proposed rules were provided as an illustrative list, the Departments solicited comment on whether there are any additional medical management techniques that should be explicitly included as prerequisites in the final rules.

Several commenters supported the inclusion of this element. One commenter stated that helping patients understand any coverage prerequisites prior to care, such as prior authorization, may help to eliminate some of the confusion and unnecessary administrative burden following care. Another stated that requiring a plan to disclose prerequisites in an easily understandable format may help patients complete required protocols and thus would improve adherence.

A few commenters recommended additional disclosures or offered suggestions to strengthen these requirements. One commenter encouraged the Departments to include clinical coverage policies for services that are more specific than general medical necessity criteria. For example, some plans and issuers utilize coverage policies that require specific diagnoses or documented symptoms before an item or service may be covered. The commenter explained that while these

policies may not technically require an action by the beneficiary, they are important in determining whether the specific item or service is covered. Another commenter recommended that plans and issuers clearly disclose every utilization control that stands between the participant, beneficiary, or enrollee and a prescription, suggesting that this type of disclosure would help patients meet utilization control standards. Another commenter urged the Departments to strengthen this requirement by requiring plans and issuers to provide a description of the actual required prerequisites. The commenter stated that the proposed regulation requires only notification of the existence of a prerequisite, but not any detail about what the prerequisite is and how it can be satisfied. Two commenters encouraged the Departments to standardize this type of notification language to ensure that all consumers receive a consistent message regarding the provision of health care services.

One commenter requested that the Departments provide that the prerequisites listed in proposed rules (that is, concurrent review, prior authorization, step-therapy, and fail-first protocols) are an exclusive list. Another commenter stated that prerequisite notification should be limited to simple notifications that prerequisites apply to a service, and communication of specific prerequisites should not be required until a Fast Healthcare Interoperability Resources (FHIR) standard for transmission of this information is established and operationalized.

As discussed in the proposed rules, the Departments intended for the definition of prerequisite to capture medical management techniques that apply to an item or service that require action by the participant, beneficiary, or enrollee before the plan or issuer will cover the item or service. The Departments consider plan or policy provisions that require a diagnosis or documented symptoms before a service or item would be covered to be medical necessity determination requirements that do not require action on behalf of the participant, beneficiary, or enrollee. Therefore, the Departments did not include such terms in the proposed prerequisite requirement. The Departments are finalizing regulation text to reflect that concurrent review, prior authorization, and step-therapy or fail-first protocols are the exhaustive list of prerequisites about which plans and issuers would need to provide notice. Furthermore, while the Departments acknowledge that providing a complete description of prerequisites might be helpful to consumers, the Departments are not of the view that requiring plans or issuers to provide such descriptions is necessary. The Departments determined that requiring a complete description of the prerequisite would create unnecessary complexity and impose significant burdens on plans and issuers regarding information that is already available in plan documents. Additionally, while the Departments recognize the importance of FHIR in the push towards greater interoperability, it is not necessary to delay finalizing these rules until the FHIR standards are finalized as the final rules do not require any APIs to be built nor exposed for public consumption. The final rules adopt this content element requirement, with the modifications discussed in this section.

g. Seventh Content Element: Disclosure Notice

The seventh and final content element proposed is a notice that communicates certain information in plain language, including several specific disclosures. First, the Departments proposed that this notice would include a statement that out-of-network providers may bill participants, beneficiaries, or enrollees for the difference between providers' billed charges and the sum of the amount collected from the group health plan or health insurance issuer and the amount collected from the participant, beneficiary, or enrollee in the form of cost-sharing (the difference often referred to as balance billing) and that these estimates do not account for those potential additional amounts. In the proposed rules, the Departments acknowledged that there are numerous state laws that address balance-billing practices such that the notice described in the proposed content element regarding balance bills may be misleading or inaccurate for beneficiaries, participants, or enrollees enrolled in a plan or coverage in certain states. The Departments requested comment on whether any modifications to this content element would be appropriate to allow plans and issuers to accurately advise participants, beneficiaries, or enrollees of their potential exposure to or protection from any balance bills.

Second, the Departments proposed that the notice be required to convey that actual charges for the participant's, beneficiary's, or enrollee's covered items and services may be different from those described in a cost-sharing liability estimate, depending on the actual items and services received at the point of care.

Third, the Departments proposed that the notice be required to include a statement that the estimated cost-sharing liability for a covered item or service is not a guarantee that coverage will be provided for those items and services.

Finally, the Departments proposed that plans and issuers be permitted to include any additional information, including other disclaimers that the plan or issuer determines appropriate, so long as the additional information does not conflict with the information they are required to provide. For example, plans and issuers would have been permitted to include additional language so long as the language could not reasonably be read to disclaim the plan's or issuer's responsibility for providing a participant, beneficiary, or enrollee with accurate cost-sharing information, or plans and issuers could choose to provide a disclaimer that informs consumers who are seeking estimates of cost-sharing liability for out-of-network allowed amounts that they may have to obtain a price estimate from the out-of-network provider in order to fully understand their out-of-pocket cost liability. Plans and issuers would also have been permitted to provide a disclaimer indicating how long the price estimate will be valid, based on the last date of the contract term for the negotiated rate or rates (if multiple providers with different contract terms are involved). The Departments are of the view that this type of disclaimer could provide participants, beneficiaries, and enrollees with a better understanding of how their cost estimate may change over time. The Departments sought comment on whether a specific disclaimer indicating the expiration of the cost estimate should be required. Furthermore, the Departments explained in the proposed rules that plans and issuers may also include disclaimer information regarding prescription drug cost estimates and whether rebates, discounts, and dispensing fees may impact the actual cost to the participant, beneficiary, or enrollee.

The Departments developed model language that plans and issuers could use, but would not be required to use, to satisfy the disclosure notice requirements described above. This model language was proposed contemporaneously with, but separate from, the proposed rules.[115] The

[115] "Transparency in Coverage. Model Notice." United States Department of Labor. Available at: *https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/affordable-care-act/for-*

Continued

Departments sought comment on the proposed model language and any additional information that stakeholders believed should be included in the model notice or any information that should be omitted from the model notice.

The proposed rules clarified that this disclosure notice would be in addition to the information that QHP issuers are currently required to publish on their websites pursuant to 45 CFR 156.220(a)(7) regarding cost-sharing and payments with respect to out-of-network coverage. In addition, some portions of this disclosure may overlap with network adequacy disclosure standards under 45 CFR 156.230(e). That section requires QHP issuers to count the cost-sharing paid by an enrollee for an out-of-network essential health benefit (EHB) provided by an out-of-network ancillary provider in an in-network setting toward the enrollee's out-of-pocket limit or provide a notice to the enrollee that additional costs may be incurred for an EHB, including balance billing charges, if applicable.

The Departments requested comment on the proposed notice disclaimers and whether any additional disclaimers would be necessary or beneficial to participants, beneficiaries, and enrollees in learning about their potential cost-sharing liability for covered items and services. For example, the Departments inquired whether the Departments should require a notice that explains that the cost-sharing information provided may not account for claims a participant, beneficiary, or enrollee has submitted that the plan or issuer has not yet processed. The Departments also considered whether to require plans and issuers to provide a participant, beneficiary, or enrollee information regarding non-covered items or services for which the individual requests cost-sharing information. For example, there could be a requirement that a plan or issuer provide a statement, as applicable, indicating that the item or service for which the participants, beneficiaries, and enrollees has requested cost-sharing information is not a covered benefit under the terms of the plan or coverage, and expenses charged for that item or service will not be reimbursed by the plan or coverage.

Several commenters agreed with the proposed disclosure notice requirements. Specifically, many commenters supported the disclosure that estimates may not reflect the amount ultimately charged to the participant, beneficiary, or enrollee. One commenter recommended the disclosure include examples of circumstances under which a participant's, beneficiary's, or enrollee's actual cost-sharing liability may differ from the estimate provided by their plan or issuer (for example, comorbidities or unanticipated complications). The commenter stated that a more comprehensive explanation of how participant, beneficiary, or enrollee characteristics might affect charges for covered items and services would help them better understand their potential exposure to higher cost-sharing amounts. One commenter suggested that the notice include stronger wording to educate the plan participant about the strong likelihood of a surprise amount due that differs greatly from the estimate. One commenter recommended that the notice include information that DIR Fees charged to pharmacies inflate participants', beneficiaries', and enrollees' cost sharing and that plans and issuers may claw back that inflated cost sharing from the pharmacy.

One commenter recommended that plans and issuers be required to disclose additional information to help participants, beneficiaries, and enrollees understand the appropriate point of contact for questions and complaints. This commenter recommended that the final rules require issuers to provide participants, beneficiaries, and enrollees with contact information for their state departments of insurance when covered by insurance that is primarily state-regulated. For group health plans that are not fully insured, the commenter recommended that the plan provide contact information for the appropriate Federal regulator.

One commenter requested flexibility with disclaimer language regarding a notice provided in paper form to reflect that the estimate may not be reflective of services received or claims processing, or to direct the participant, beneficiary, or enrollee to call their plan or issuer or use the internet for more up-to-date information. Similarly, one commenter recommended that a timestamp be required for notices provided in paper form to account for potential price changes. Several commenters supported requiring plans and issuers to add to the notice a date on which the estimate will expire, while other commenters did not.

One commenter expressed concern regarding the statement in the preamble to the proposed rules that the required disclosure notice regarding balance-billing information ''may be misleading or inaccurate for beneficiaries, participants, or enrollees enrolled in a plan or coverage in certain states,'' given the multi-state nature of most employer-sponsored plans. Another commenter stated that state regulators should be able to direct issuers to include information in the disclosure that accurately describes the state's balance billing laws, and that any notice provided to consumers in advance of receiving services should have information as to whether the participant, beneficiary, or enrollee is likely to be protected from liability under state or Federal balance billing laws. The commenter further stated that some states already have state laws related to disclosure of costs to consumers and the final rules should be clear that this requirement does not preempt these state requirements. Two commenters urged the Departments to make clear that participants, beneficiaries, and enrollees are not protected from out-of-network provider and facility balance billing, except where balance billing would be barred by state law.

The final rules are not intended to preempt state laws regarding balance billing. In the final rules, the Departments have modified this requirement to clarify that the balance billing statement is only required if balance billing is permitted under state law. Plans and issuers have flexibility to use the model notice language or create their own notices with greater specificity regarding their state's laws.

One commenter expressed concern that allowing plans to include a statement that the estimated cost-sharing liability is not a guarantee of coverage negates the intent of the proposed rules, given that consumers who receive a notice from their health plan regarding estimated out-of-pocket costs would naturally assume coverage of those services.

The Departments acknowledge this concern; however, there are many reasons estimated cost-sharing information may not be accurate when items and services are ultimately furnished. For example, it is possible for coverage to end (for example, due to non-payment of premiums) between the time an estimate is provided and an item or service is furnished. Additionally, an estimate may show the cost for an item or service as a treatment for a certain condition, but the item or service may not be covered for the condition that is ultimately diagnosed at the point of care. Therefore, the final rules adopt the provision as proposed.

Several commenters recommended that the Departments issue guidelines as to what is considered ''plain language.'' The commenters recommended that the Departments provide examples of

employers-and-advisers/transparency-in-coverage-draft-model-disclosure.pdf.

typical disclosure language compared to its ''plain language'' equivalent. They further recommended that these examples be tested through various focus groups to ensure consumer comprehension.

The final rules define ''plain language'' to mean language written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee.[116] Determining whether this standard has been satisfied requires taking into account such factors as the level of comprehension and education of typical participants, beneficiaries, or enrollees in the plan or coverage and the complexity of the terms of the plan. Accounting for these factors would require limiting the use of technical jargon and long, complex sentences, so that the information provided will not have the effect of misleading, misinforming, or failing to inform participants, beneficiaries, or enrollees. The Departments are of the view that the final rules and this preamble provide sufficient detail regarding the meaning of plain language.

Some commenters recommended that plans and issuers should disclose whether they count copayment assistance and other third-party payments in the calculation of the beneficiary's deductible and out-of-pocket maximum. The commenter noted that as more plans implement copay accumulators that do not count these payments, issuers should be required to disclose these policies to their beneficiaries.

The Departments are of the view that knowing whether these payments apply to accumulators is germane to price transparency and should be required in the final rules. To that end, the final rules adopt a fifth notice content requirement (codified at 26 CFR 54.9815–2715A2(b)(1)(vii)(D), 29 CFR 2590.715–2715A2(b)(1)(vii)(D), and 45 CFR 147.211(b)(1)(vii)(D)) that plans and issuers must provide a statement disclosing whether copayment assistance and other third-party payments are included in the calculation of the participant's, beneficiary's, or enrollee's deductible and out-of-pocket maximum.

As discussed under the first content element, some items or services may not be subject to cost sharing if they are furnished as preventive items or services, while the same item or service could be subject to cost sharing if it is furnished for non-preventive purposes or provided by an out-of-network provider. Therefore, the final rules adopt an additional notice requirement (codified at 26 CFR 54.9815–2715A2(b)(1)(vii)(E), 29 CFR 2590.715–2715A2(b)(1)(vii)(E), and 45 CFR 147.211(b)(1)(vii)(E)) stating that, for an item or service that is a recommended preventive service under section 2713 of the PHS Act where the plan or issuer cannot determine whether the request is for a preventive or non-preventive item or service, the plan or issuer must provide a statement that the item or service may not be subject to cost-sharing if it is billed as a preventive service.

One commenter recommended information be included to help participants, beneficiaries, and enrollees understand the appropriate point of contact for questions and complaints. This commenter recommended issuers provide consumers with contact information for the appropriate regulator—either the State Department of Insurance or the appropriate Federal office.

The Departments appreciate this recommendation, but are declining to finalize this additional requirement because the Departments are of the view that plans and issuers already have avenues in place to address participants', beneficiaries', and enrollees' complaints.

Several commenters recommended that additional notice disclaimers be provided. One commenter suggested that the final rules require a statement that cost-sharing liability estimates may differ from actual costs, depending on changes after claims are processed. Another commenter recommended that the Departments develop model disclaimers stating that quoted amounts for drugs may be time-limited and subject to manufacturer pricing practices. Another commenter recommended the addition of consumer disclaimers indicating that ''services subject to the cost estimate may be provided and billed by providers associated with multiple payer contracts which will result in multiple EOBs.'' Another commenter recommended the Departments permit plans to require participants, beneficiaries, and enrollees to review and acknowledge a disclaimer prior to viewing or searching for any pricing information, which would help ensure that consumers understand that what they are receiving may not be an accurate estimate of their total out-of-pocket costs. Another commenter recommended that the presentation of the out-of-network information make clear that the issuer is unable to provide an estimate for the full cost of the service. The commenter suggested that this disclosure should be presented on the same screen as the maximum allowed amount and the participant, beneficiary, or enrollee's cost liability because it may be unclear that the maximum allowed amount is not the total cost of care. Another commenter requested that the Departments add a requirement that plans or issuers provide participants, beneficiaries, or enrollees with meaningful and simple explanations regarding emergency care, including informing them of the prudent layperson standard.[117] Another commenter that recommended plans and issuers be required to provide explanatory information about the operation of their plans, including glossaries of relevant terms and explanations of insurance plan features and health care services, including in-network and out-of-network costs, limited plan designs, deductibles, telehealth, and additional features in consumer-friendly language.

The Departments decline to adopt these commenters' suggestions for additional notice disclaimers. The Departments are of the view that adopting these additional requirements would add to the burden imposed on plans and issuers without creating corresponding benefits for participants, beneficiaries, or enrollees that would outweigh the burden, and would be unhelpfully prescriptive regarding the information plans and issuers are required to convey to these individuals. Existing plan and issuer resources for this information, such as the uniform glossary required under the Summary of Benefits and Coverage (SBC) final regulation[118] provide consumer-friendly language definitions of insurance terms. Additionally, in response to comment, the Departments are providing flexibility to plans and issuers to design their internet-based tools and disclosures so that they meet the needs of their participants, beneficiaries, and enrollees. However, the Departments encourage plans and issuers to provide additional information at their discretion, if appropriate. The final rules adopt these provisions as proposed, with one correction of a typographical error (''bill'' rather than ''billed'') in 26 CFR 54.9815–2715A2(b)(1)(vii)(A), 29 CFR 2590.715–2715A2(b)(1)(vii)(A), and 45 CFR 147.211(b)(1)(vii)(A) and a clarification that this statement element is only required if balance billing is permitted under state law, with paragraph (b)(1)(vii)(D) redesignated as paragraph (b)(1)(vii)(F), and with new paragraphs (b)(1)(vii)(D) and (E) added,

[116] 29 CFR 2520.102–2(a).

[117] 42 CFR 438.114.

[118] 80 FR 34292 (Jun. 16, 2015).

as described earlier in this section of this preamble.

2. Required Methods for Disclosing Information to Participants, Beneficiaries, or Enrollees

Section 1311(e)(3)(C) of PPACA requires that cost-sharing information be made available through an internet website and other means for individuals without access to the internet. Therefore, in the proposed rules, the Departments proposed to require that group health plans and health insurance issuers disclose to participants, beneficiaries, or enrollees the cost-sharing information described earlier in this preamble in two ways: (1) Through a self-service tool that meets certain standards and is available on an internet website, and (2) in paper form.

a. First Delivery Method: Internet-Based Self-Service Tool

Under the proposed rules, plans and issuers would be required to make available a self-service tool on an internet website for their participants, beneficiaries, or enrollees to use, without a subscription or other fee, to search for cost-sharing information for covered items and services. The tool would be required to allow users to search for cost-sharing information for a covered item or service provided by a specific in-network provider, or by all in-network providers. The tool also would be required to allow users to search for the out-of-network allowed amount for a covered item or service provided by out-of-network providers. The tool would be required to provide users real-time responses that are based on cost-sharing information that is accurate at the time of the request.

Many commenters supported the Departments' proposal to require plans and issuers to make available personalized out-of-pocket cost information for all covered health care items and services through an internet-based self-service tool and urged the Departments to finalize this section of the regulation as proposed. Some commenters recommended the Departments identify a core set of functional requirements that must be included in all price transparency tools. Commenters suggested that these functional requirements should ensure all people enrolled in commercial products have access to the same baseline functionality, while providing enough flexibility for issuers to develop, and iterate on, innovative existing internet-based self-service tools. Examples of functional requirements include providing tailored information to participants, beneficiaries, or enrollees on their benefit summary (plan coverage, copayments, deductibles); being able to browse by service category (for example, medical specialty, procedures, drugs, imaging, labs) or diagnosis; or being able to select from an A–Z list of popular searches or episodes of care. One commenter recommended the following functional requirements: (1) Provide individuals with their personal health plan details, a digital ID card, deductible and copay information, the ability to download and view claims, and information on provider network status and quality performance; (2) display cost and quality information in clear, user-friendly language to facilitate and inform health care decisions; (3) allow consumers to compare facilities and clinicians based on curated cost estimates, common quality measures, value metrics, and patient ratings; (4) offer personalized out-of-pocket cost estimates for episodes of care, services, and prescriptions, calculated using their specific health plan design before they receive care; (5) comply with all state and Federal health care data privacy and security laws, including the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules and the Health Information Trust (HITRUST) Common Security Framework.

The Departments agree that the self-service tool requirements should ensure all people enrolled in group health plans and health insurance coverage have access to the same baseline functionality, while providing enough flexibility for plans and issuers to develop and iterate on innovative internet-based self-service tools. It is the Departments' intent that the required elements be broad enough to avoid being overly prescriptive for plans and issuers. The Departments agree that certain additional content elements could be beneficial to participants, beneficiaries, and enrollees, including general benefit summary information and quality metrics. However, the primary initial goal of the self-service tool is to provide personalized out-of-pocket cost estimates for episodes of care, services, and prescriptions, and to provide transparency around the pricing elements that determine out-of-pocket costs. Therefore, the Departments are not inclined to require additional elements unrelated to this primary goal at this time. The Departments note that the intent of the final rules is to provide a minimum standard for the disclosure of pricing information to lay a foundation for transparency in coverage and the Departments may consider additional disclosure requirements to build upon the final rules in the future. To that end, the Departments are finalizing the required content elements for the self-service tool as described earlier in this preamble to the final rules. The final rules include a change regarding the search function related to out-of-network allowed amounts. Specifically, that element is modified to include the other metrics that a plan or issuer is permitted to use in place of out-of-network allowed amounts, as discussed earlier in this preamble in connection with the fourth content element that must be disclosed to participants, beneficiaries, and enrollees. Additionally, the Departments encourage plans and issuers to add additional elements to their tools according to the needs of the populations they serve.

In order for plans and issuers to provide accurate cost-sharing information, the Departments noted that the participant, beneficiary, or enrollee will have to input certain data elements into the tool. Therefore, under the proposed rules, plans and issuers would be required to make available a tool that allows users to search for cost-sharing information: (1) By billing code (for example, Current Procedural Terminology (CPT) Code 87804) or, (2) by a descriptive term (for example, ''rapid flu test''), at the option of the user. The tool also would be required to allow users to input the name of a specific in-network provider in conjunction with a billing code or descriptive term, to produce cost-sharing information, and a cost-sharing liability estimate for a covered item or service provided by that in-network provider. Regarding a request for cost-sharing information for all in-network providers, under the proposed rules, if a plan or issuer utilizes a multi-tiered network, the tool would be required to produce the relevant cost-sharing information for the covered item or service for individual providers within each tier. In the proposed rules, the Departments explained that to the extent that cost-sharing information for a covered item or service under a plan or coverage varies based on factors other than the provider, the tool would also be required to allow users to input sufficient information for the plan or issuer to disclose meaningful cost-sharing information. For example, if the cost-sharing liability estimate for a prescription drug depends on the quantity and dosage of the drug, the tool would be required to allow the user to input a quantity and dosage for the drug for which he or she is seeking cost-

sharing information. Similarly, to the extent that the cost-sharing liability estimate varies based on the facility at which an in-network provider furnishes a service (for example, at an outpatient facility versus in a hospital setting), the tool would be required to either permit a user to select a facility, or display in the results cost-sharing liability information for every in-network facility at which the in-network provider furnishes the specified item or service.

It remains the Departments' understanding that a plan or issuer may require certain information, in addition to the identification of a covered item or service, before it can provide an out-of-network allowed amount for a covered item or service, and that plans and issuers may have different ways of establishing an allowed amount for covered items or services from an out-of-network provider (such as by zip code or state). Therefore, under the final rules, plans and issuers are required to allow users to search for the out-of-network allowed amount or other metric as discussed in the fourth content element, for a covered item or service provided by out-of-network providers, by inputting a billing code or descriptive term and the information that is necessary for the plan or issuer to produce the out-of-network allowed amount (such as the zip code for the location of the out-of-network provider).

To the extent a user's search returns multiple results, the tool would be required to have functionalities that would allow users to refine and reorder results (also referred to as sort and filter functionalities) by geographic proximity of providers and the amount of estimated cost-sharing liability. The Departments solicited comment on whether the tool should be required to have additional refining and reordering functionality, including whether it would be helpful or feasible to refine and reorder by provider subspecialty (such as providers who specialize in pediatric psychiatry), or by the quality rating of the provider, if the plan or issuer has available data on provider quality.

Some commenters stated that it is unrealistic to expect consumers to know and understand CPT/Diagnosis Related Group (DRG)/International Classification of Disease-10 (ICD–10) codes and supported the inclusion of descriptive terms. One commenter stated that search capability by standard medical terms will be crucial, and that, to be successful, this type of search system will need to be broad and user-friendly, accommodating an extensive range of consumer inputs and terms. Another commenter recommended the tool also contain a layperson-friendly descriptor of the service to improve understanding. Other commenters lauded the requirement that issuers must use plain language when disclosing price information, which would ensure that patients can understand their expected costs without expert knowledge of insurance language and practices. Some commenters recommended that the Departments follow industry standards and use the CMS-approved National Correct Coding Initiative (CCI) for consumer searches, as well as for any information relating to standards for services that fall into bundled payment arrangements.

One commenter expressed concern that the conversion of thousands of CPT codes into plain English by thousands of health plans, carriers, and TPAs is inefficient, and will result in inconsistencies across the country. For example, there are multiple CPT codes for procedures in a hospital that differ in price depending upon severity, which is often unknown when a procedure is first recommended.

The Departments agree that it is essential for tools to support descriptive terms because consumers may not be familiar with specific procedure codes. The Departments acknowledge the challenge of converting CPT code descriptions to plain language but are of the view that the benefit to consumers outweighs the burden to plans and issuers. The Departments also acknowledge the potential value in requiring the use of CCI standards but are of the view that their use should be voluntary, not required, in order to avoid placing additional burdens on plans and issuers in the absence of clear benefits to consumers. As noted earlier in this preamble, the intent of the final rules is to provide foundational requirements and to allow plans and issuers maximum flexibility to build upon existing tools while providing consumers with reliable cost estimates. The Departments also highlight that the phased implementation of the final rules affords plans and issuers additional time to address administrative challenges. Accordingly, the final rules adopt this provision as proposed.

One commenter sought clarification that the tool is not required to support searches with multiple parameters at the same time (for example, by provider name and medical code at once). Another commenter suggested that the Departments allow that, as one permissible method, the tool may provide for geographic proximity based on a zip code entered by the participant, beneficiary, or enrollee to enable the consumer to choose whether to search based on the proximity to home or work or some other location.

The self-service tool must allow users to search for cost-sharing information for a covered item or service by inputting the name of a specific in-network provider in conjunction with a billing code or descriptive term, as well as other relevant factors like location of service, facility name, or dosage. For covered items and services provided by out-of-network providers, the tool should provide the out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a plan or issuer will pay by allowing consumers to input a billing code, descriptive code, or other relevant factor, such as location. In addition, the final rules adopt the requirement that the tool must allow the user to refine and reorder search results based on geographic proximity of in-network providers. The final rules require refining and reordering search results only for in-network providers, as the Departments are of the view that doing so for out-of-network providers would be too burdensome at this stage. The Departments expect that in order for beneficiaries, participants, and enrollees to search for out-of-network providers, they would have to input, at minimum, the billing code or name of an item or service and the geographical location of the provider. In addition, in order to align with revisions to the fourth content element allowing flexibility to provide another rate instead of the out-of-network allowed amount, the final rules have been revised to reflect that participants, beneficiaries, and enrollees can search for the out-of-network allowed amount, the percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a plan or issuer will pay for a covered item or service provided by out-of-network providers. This ''other rate'' is also included in paragraph (b)(2)(i)(B)(*2*) of the final regulations for consistency.

Regarding refining and reordering features, one commenter suggested that the tools include an ability to display only in-network providers and an ability to filter or sort by provider quality if a quality metric is made available. Three commenters requested that requirements not limit plans to developing provider and service filters that only account for price and geographic proximity: they suggested that the tools should also have functionality filters based on sub-specialty and a measure of value. Another commenter requested that any

additional functionality relating to refining and reordering search results be optional for plans and issuers at this time.

One commenter stated that, to enhance the accuracy of the tool and better account for fluctuations in cost-sharing amounts, the Departments should require that it be configured to allow users to self-select health characteristics (for example, chronic conditions, body mass index) in order to further personalize its outputs for consumers. The commenter recommended that payers be given flexibility to dictate the specific health characteristics to be included in their tools based on their participant, beneficiary, and enrollee populations, the types of products that they offer, and other elements that might cause cost-sharing estimates to fluctuate.

The Departments agree that plans and issuers should have flexibility to design tools that can maximize consumer utility and acknowledge that the suggested additions to search functionality could be beneficial to consumers. However, the Departments decline to require the adoption of these suggestions to preserve plans and issuers' discretion regarding the most effective way to provide search results and to avoid being overly burdensome or prescriptive.

The Departments intend that plans and issuers create user-friendly internet-based self-service tools, but the proposed rules did not include a definition for ''user-friendly'' because there are a variety of ways a tool can be designed to be user-friendly. The Departments wish to preserve plan and issuer flexibility to create tools that are best for their participants, beneficiaries, or enrollees, including by soliciting user feedback and consumer testing in the development of their tools. However, it is the Departments' view that a user-friendly tool would mean a tool that allows intended users to search for the cost-sharing information outlined in the final regulations efficiently and effectively, without unnecessary steps or effort. The Departments are of the view that plans and issuers can look to Federal plain language guidelines, ERISA requirements for a Summary Plan Description's method of presentation at 29 CFR 2520.102–2(a), and general industry standards for guidance when designing and developing their internet-based self-service tools.[119]

The Departments also received comments on whether the self-service tool should be made available through an internet website, through a mobile application, or both. The proposed rules provided that the self-service tool be made available on an internet website to be consistent with section 1311(e)(3)(C) of PPACA, which provides that ''at a minimum,'' cost-sharing information be made available through an ''internet website.'' However, the Departments sought feedback on whether this term should be interpreted to include other comparable methods of accessing internet-based content. The statute was enacted in 2010, when the primary mode of accessing internet-based content was through a personal computer. Since that time, ownership of mobile devices with internet access and use of internet-based mobile applications has become much more common. The Departments acknowledged that there may be technical differences between a website and other methods of viewing internet-based content, such as mobile applications. However, as stated in the proposed rules, the Departments also understand that technology evolves over time, and it is the Departments' view that Congress did not intend to limit the ability to access information via alternative methods of viewing internet-based content that may be available now or in the future.

The Departments acknowledged that mobile applications may provide benefits beyond those of traditional websites. Due to the portability of mobile devices, a self-service tool that is made available through a mobile application might provide participants, beneficiaries, enrollees, and their health care providers greater opportunities to use the tool together at the point of care to evaluate treatment options based on price. The Departments further acknowledged that mobile applications, as a general matter, may offer greater privacy and security protections than an internet website, accessed either from a mobile device or a computer.[120] Accordingly, the Departments sought comment on whether the final rules should permit the proposed disclosure requirements to be satisfied with a self-service tool that is made available through a website or comparable means of accessing the internet, such as a mobile application, or whether multiple means, such as websites and mobile applications, should be required. The Departments also sought comment on the relative resources required for building an internet website versus an internet-based mobile application.

Some commenters recommended that the Departments finalize the proposed rules with the self-service tool requirement satisfied by being made available through a website or comparable means of accessing the internet. Others believed that plans and issuers should be free to determine whether to offer a mobile app, an internet website, or both. One commenter stated the resources necessary for building and supporting a mobile application are significantly greater than building a website and did not support a proposal to require multiple applications, while other commenters supported a mobile application to enable patients to make cost-effective decisions in the doctor's office. Another commenter recommended both a mobile application and an internet-based platform with fully responsive internet-based design. Two commenters recommended that the requirements not preclude a plan, issuer, or TPA from developing other means of electronic delivery beyond internet disclosure.

The Departments have considered these comments and are of the view that requiring an internet website, as opposed to a comparable means of accessing the internet, such as a mobile application or both, ensures access to a broader set of consumers while limiting the burden on plans and issuers to produce both an internet site and a mobile application. Internet websites can be accessed on mobile devices and people without access to the internet or mobile devices can access tools through resources where internet access may be available, such as a local library. Conversely, if the tool were available only through a mobile device, people without a capable mobile device would not have access to the tool. The final rules, therefore, adopt the requirement that the self-service tool be provided via internet website; however, the Departments encourage plans and issuers to also provide a mobile application version in addition to an internet website.

[119] ''Federal plain language guidelines.'' United States General Services Administration. Available at: *https://www.plainlanguage.gov/guidelines/*.

[120] Kassner, M. ''Apps vs. mobile websites: Which option offers users more privacy?'' Tech Republic. September 30, 2016. Available at *https://www.techrepublic.com/article/apps-vs-mobile-websites-which-option-offers-users-more-privacy/*; *see also* Colburn, K. ''Is using a banking app safer for managing your account online?'' AZcentral. September 17, 2018. Available at *https://www.azcentral.com/story/money/business/tech/2018/09/17/online-banking-app-safety-security-smartphone-tech-tips/1212736002/*; *see also* Ogata, M., et al. ''Vetting the Security of Mobile Applications.'' National Institute of Standards and Technology, United States Department of Commerce. April 2019. Available at: *https://doi.org/10.6028/NIST.SP.800–163r1*.

b. Second Delivery Method: Paper Form

Paragraph (e)(3)(C) of section 1311 of PPACA specifies that at a minimum, cost-sharing information be made available to an individual through an internet website and such other means for individuals without access to the internet. Therefore, the proposed rules included a proposal that group health plans and health insurance issuers would have to furnish, at the request of the participant, beneficiary, or enrollee, without a fee, all of the information required to be disclosed under paragraph (b)(1) of the proposed regulations, as outlined earlier in this preamble, in paper form. Further, the proposed rules included a proposal that a plan or issuer would be required to provide the information in accordance with the requirements under paragraph (b)(2)(i) of the proposed regulations and as described earlier in this preamble. That is, the plan or issuer would be required to allow an individual to request cost-sharing information for a discrete covered item or service by billing code or descriptive term, according to the participant's, beneficiary's, or enrollee's request. Further, the plan or issuer would be required to provide cost-sharing information for a covered item or service in connection with an in-network provider or providers, or an out-of-network allowed amount for a covered item or service provided by an out-of-network provider, according to the participant's, beneficiary's, or enrollee's request, permitting the individual to specify the information necessary for the plan or issuer to provide meaningful cost-sharing liability information (such as dosage for a prescription drug or zip code for an out-of-network allowed amount). To the extent the information the individual requests returns more than one result, the individual would also be permitted to request that the plan or issuer refine and reorder the information disclosed by geographic proximity and the amount of the cost-sharing liability estimates.

The Departments proposed that this information would be required to be mailed to a participant, beneficiary, or enrollee via the U.S. Postal Service or other delivery system no later than 2 business days after a participant's, beneficiary's, or enrollee's request is received.

Two commenters supported the Departments' proposal to allow individuals the ability to access their information through electronic means or via paper form, given that many Americans lack access to high-speed internet services. Some commenters opposed the requirement to deliver the cost-sharing information to participants in paper form due to administrative burden, while others recommend limiting the requirements. Several recommended the timeframe to respond be expanded, including a range of 5 days to 10 days. One commenter requested that the compliance time for producing paper copies of personalized information be consistent with current Federal requirements for furnishing paper copies of the SBC, Summary Plan Description, or Consolidated Omnibus Budget Reconciliation Act (COBRA) notices. Other commenters expressed concern about volume, given that a participant, beneficiary, or enrollee could request cost estimates for all in-network providers of a given service, which could be tens of thousands of providers, resulting in thousands of pages of results. Some recommended a reasonable limit to the volume of information that would be provided in response to any single request for a covered item or service—for, example, no more than 20 or 25 providers per request.

Several commenters recommended that the Departments reconsider mandating paper responses ''without a fee.'' While these commenters did not support charging participants, beneficiaries, or enrollees for access to cost-sharing information in general, they asserted that it is unreasonable to expect health plans to provide what could easily be boxes worth of information in response to multiple requests per enrollee.

Nothing in the proposed rules would have prohibited a plan or issuer from providing participants, beneficiaries, or enrollees with the option to request disclosure of the information required under paragraph (b)(1) of the proposed regulations through other methods (such as, over the phone, through face-to-face encounters, by facsimile, or by email). The Departments requested comment on these proposed disclosure methods, including whether additional methods of providing information should be required, rather than permitted. The Departments were particularly interested in feedback on whether plans and issuers should be required to provide the information over the phone, or by email, at the request of a participant, beneficiary, or enrollee.

Several commenters requested alternatives to the paper disclosure, particularly a phone option. One commenter recommended the final rules require that plans or issuers set up a designated toll-free number that participants, beneficiaries, or enrollees can call to receive pricing information, in addition to offering that as an option on their main consumer information phone line. Two commenters urged the Departments to consider making the second form of disclosure one of the plan or issuer's choice (that is, paper or phone service). Conversely, one commenter stated that the volume and complexity of information that a given request could produce would preclude providing this information over the phone or in-person. Another commenter recommended the alternative format to include telephone, in-person, or fax. One commenter recommended emailing digital versions of the paper requests to a participant's, beneficiary's, or enrollee's inbox at the participant's, beneficiary's, or enrollee's request, and another requested that if results were emailed, the same information should not also need to be provided via paper form.

The Departments acknowledge commenters' concerns that the volume of paper requests could be unwieldy. To that end, the final rules adopt the requirement that cost-sharing information be provided in paper form, but a plan or issuer may limit any results for a paper request to 20 providers per request, as suggested by some commenters. The Departments are of the view that the commenters' suggestion of limiting paper request to 20 providers per request is a reasonable approach to balancing the burdens on plans and issuers with the benefits of providing consumers with enough information to be able to compare cost and provider options. The final rules provide an additional flexibility that, to the extent participants, beneficiaries, or enrollees request disclosure by another means (for example, by phone or email), plans and issuers may provide the disclosure through the means requested by the participant, beneficiary, or enrollee, provided the participant, beneficiary, or enrollee agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method. The Departments further acknowledge that requiring plans and issuers to set up a designated toll-free number for pricing information could be beneficial to participants, beneficiaries, and enrollees, but are not requiring this step given the Departments' view that its burden outweighs its benefit in light of the other available disclosure methods, including the flexibility to provide this information via the preferred disclosure method of the participant, beneficiary, or enrollee.

3. Special Rule To Prevent Unnecessary Duplication

a. Insured Group Health Plans

The proposed rules included a special rule to streamline the provision of the required disclosures and to avoid unnecessary duplication of the disclosures with respect to group health insurance coverage. The Departments are finalizing this special rule, which provides that, to the extent coverage under a plan consists of fully-insured group health insurance coverage, the plan satisfies the requirements of the final rules if the plan requires the issuer offering the coverage to provide the information pursuant to a written agreement between the plan and issuer. For example, if a plan and an issuer enter into a written agreement under which the issuer agrees to provide the information required under the final rules, and the issuer fails to provide full or timely information, then the issuer, but not the plan, has violated the transparency disclosure requirements.[121]

Many commenters requested that the Departments extend the special rule to self-insured group health plans that are administered by an administrative service organization or other TPA. These commenters stated that self-insured plan sponsors that contract in good faith with their TPAs to comply with the reporting requirements should be held harmless with respect to compliance obligations and liability under this regulation because in many instances a provider network is merely rented from a TPA, necessary information may not be held by the plan itself, and because liability could be contractually assigned to the TPA.

Section 2715A of the PHS Act provides the authority for the Departments to require this information from plans and issuers, but not TPAs. Therefore, it is ultimately the responsibility of the plan or issuer to provide the information required by the final rules. Nonetheless, the Departments note that nothing in the final rules prevents a self-insured plan from contracting with another party to provide the required disclosure, including, to the extent permitted under other Federal or state law, entering into an agreement for the other party to indemnify the plan in the event the other party fails to make the full or timely disclosure required by the final rules. However, the plan must monitor the other party to ensure that the entity is providing the required disclosure. Moreover, the Departments are of the view that the special rules providing certain safe harbors for actions taken in good faith as further described later in this preamble provide adequate protections for self-insured plans. The final rules also include the addition of the phrase ''insured group health plans'' to clarify that this special rule applies to insured group plans.

b. Other Contractual Arrangements

The Departments also received requests for clarification about the responsibility of employer plan sponsors that offer benefits under a level-funded arrangement. In general, under a level-funded arrangement, a plan sponsor self-insures expected claims and purchases stop-loss insurance for claims that exceed a specified threshold. Group health plans that are offered through a level-funded arrangement are subject to the final rules. Just like self-insured plans that are not level-funded, nothing in the final rules prevents a level-funded plan from contracting with another party to provide the required disclosures, but the level-funded plan remains liable for compliance with the final rules, and must monitor the other party to ensure that the entity is providing the required disclosure.

In several of the comments that addressed the special rule to prevent unnecessary duplication, commenters requested that the Departments permit plans and issuers to fulfill pricing disclosure requirements for prescription drugs through a third-party tool, such as a PBM tool. The Departments agree that this approach is permissible under the final rules. The Departments recognize that self-insured plans may rely on written agreements with other parties, such as PBMs, to obtain the necessary data to comply with the disclosure requirements. A plan or health insurance issuer may satisfy the requirements for prescription drug items and services under paragraph (b) by entering into a written agreement under which another party (such as a PBM or other third-party) provides the information required by paragraph (b) related to prescription drugs in compliance with this section. Nonetheless, if a plan or issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with the final rules, the plan or issuer may be held responsible for violating the transparency disclosure requirements of the final rules for the same reasons explained above in connection with self-insured plans entering into agreements with TPAs.

c. Application to Account-Based Arrangements

Another commenter sought clarification about the responsibility of employer plan sponsors that offer the following types of coverage to employees: (1) Individual coverage health reimbursement arrangements (HRAs); (2) qualified small employer HRAs (QSEHRAs); and (3) flexible spending arrangements (FSAs) that are not fully integrated with group major medical coverage, stating that these types of plans were not explicitly addressed in the exemptions and the anti-duplication provisions outlined in the proposed rules.

The final rules do not apply to account-based group health plans, such as HRAs, including individual coverage HRAs, or health FSAs. QSEHRAs are not group health plans and are, thus, not subject to the requirements of section 2715A of the PHS Act.[122] Therefore, these types of arrangements are not required to comply with the final rules.

4. Privacy, Security, and Accessibility

The requirements for group health plans and health insurance issuers to provide cost-sharing liability estimates and related cost-sharing information will operate in tandem with existing state and Federal laws governing the privacy, security, and accessibility of the information that will be disclosed under these disclosure requirements. For example, the Departments are aware that the content to be disclosed by plans and issuers may be subject to the privacy, security, and breach notification rules under HIPAA or similar state laws. Nothing in the final rules is intended to alter or otherwise affect plans', issuers', and other entities' data privacy and security responsibilities under the HIPAA rules or other applicable state or Federal laws.

The Departments also expect that plans and issuers will follow applicable state and Federal laws regarding persons who may or must be allowed to access and receive the information that is required to be disclosed under the final rules. The final rules refer to such persons as ''authorized representatives'' and do not establish any new class of persons or entities who are authorized

[121] Under section 4980D(d)(1) of the Code, the excise tax for group health plans failing to satisfy the final rules is not imposed on a small employer (generally fewer than 50 employees) which provides health insurance coverage solely through a contract with an issuer on any failure which is solely because of the health insurance coverage offered by the issuer.

[122] Section 9831(d)(1) of the Code; section 733(a)(1) of ERISA; and section 2791(a)(1) of the PHS Act.

to access the information specified by the final rules.

One commenter expressed concerns about potential privacy violations related to implementation and compliance with the proposed measure. This commenter stated that all entities need to be made aware of their existing privacy and data-security responsibilities and that states and Federal regulators need to be diligent about compliance and enforcement. This commenter further stated it is important to note that employers, TPAs, and carriers may incur increased costs related to complying with the proposed rules regarding potential data breaches, increased liability, and cyber-coverage costs that could impact plan premiums.

The Departments agree that it is important that entities subject to the final rules be aware of their privacy and data-security responsibilities. Accordingly, the Departments are finalizing, as proposed, a provision that reminds plans and issuers of their duty to comply with requirements under other applicable state or Federal laws, including requirements governing the accessibility, privacy, or security of information, or those governing the ability of properly authorized representatives to access participant, beneficiary, or enrollee information held by plans and issuers.

The Departments further appreciate the concern that employers, TPAs, and issuers may incur cybersecurity costs related to providing an online tool that provides some access to participant, beneficiary, and enrollee protected health information (PHI). However, given the Departments' understanding that as many as 94.4 percent of surveyed plans and issuers already maintain and operate an internet-based self-service tool,[123] the Departments anticipate any additional costs associated with cybersecurity will not be substantial.[124] The Departments have otherwise evaluated the burden of operating an internet-based self-service tool in section VI, later in this preamble.

One commenter expressed concern that certain requests for cost-sharing information could include items and services that may reveal particularly sensitive health information (for example, information related to substance abuse, mental health, or HIV). This commenter recommended the Departments provide carve-outs so that plans and issuers are not required to disclose such information through unsecured methods of communication (for example, email or phone). Alternatively, they recommended that the Departments provide more clarity or examples of when plans and issuers are not required to disclose certain information to comply with HIPAA and other Federal and state privacy laws.

The Departments remind stakeholders that current privacy and security requirements applicable under HIPAA rules and other applicable Federal requirements continue to apply under these rules. As noted earlier in this section of the preamble, the final rules are not intended to alter or otherwise affect plans', issuers', or other entities' responsibilities under HIPAA or other applicable Federal privacy laws. Furthermore, to the extent that state laws are more stringent regarding the disclosure of information subject to the final rules, plans and issuers are required to comply with the relevant state laws. The Departments acknowledge that there have been several recent security breaches affecting plans, issuers, and third-party vendors that may have compromised the PII and PHI of participants, beneficiaries, and enrollees. As acknowledged elsewhere in this preamble, privacy and security are important to the Departments and, while outside the scope of this rule, these are issues the Departments will continue to monitor. In light of existing risks and new risks that may arise as a result of increased innovation in the health care space, the Departments encourage plans and issuers to continue to educate their participants, beneficiaries, and enrollees about these risks and about ways to minimize or prevent unintended usage or sharing of their health data and encourage consumers to pay close attention to any new internet-based tools or applications they may choose to use.

C. Requirements for Public Disclosure of In-Network Rates, Historical Allowed Amount Data, and Prescription Drug Pricing Information for Covered Items and Services From In- and Out-of-Network Providers

As explained earlier in this preamble and in the proposed rules, the Departments proposed to exercise specific authority under section 1311(e)(3)(A)(vii) and (ix) of PPACA (as applied to group health plans and health insurance issuers in the individual and group markets through section 2715A of the PHS Act), which requires plans and issuers to publicly disclose information on cost-sharing and payments with respect to any out-of-network coverage and any other information the Secretary of HHS determines to be appropriate to enhance transparency in health coverage. Consistent with this authority, the Departments proposed for plans and issuers to make public negotiated rates with in-network providers and data outlining the different amounts a plan or issuer has paid for covered items or services, including prescription drugs, furnished by out-of-network providers. The Departments proposed to require plans and issuers to make this information available in machine-readable files that would include information regarding negotiated rates with in-network providers, allowed amounts for all covered items or services furnished by particular out-of-network providers, and other relevant information in accordance with specific method and format requirements. The Departments proposed to require plans and issuers to update this information on a monthly basis to ensure it remains accurate. The Departments are finalizing these policies and requirements with modifications to clarify the proposed requirements and underlying policies, and to respond to commenter suggestions and concerns.

The preamble to the proposed rules outlined several reasons why the public disclosure of negotiated rates and historical out-of-network allowed amounts is both appropriate and necessary for transparency in coverage. First, the Departments asserted that the public availability of negotiated rates and historical out-of-network allowed amounts would empower the nation's 26.1 million uninsured consumers to make more informed health care decisions.[125] Uninsured consumers generally must pay a provider's full charges for health care items and services. Though negotiated rates will not apply to the uninsured, it will offer a baseline when negotiating with providers. Pricing information is critical to their ability to evaluate their service options and control their health care spending. Uninsured consumers could also use publicly available pricing information to find which providers offer the lowest price, depending on the consumer's personal needs and priorities. The Departments noted in the preamble to the proposed rules that provider lists of standard charges often do not reflect the true cost of particular

[124] Sharma A., Manning, R., and Mozenter, Z. ''Estimating the Burden of the Proposed Transparency in Coverage Rule.'' Bates White Economic Consulting. January 27, 2020. Available at: *https://www.bateswhite.com/newsroom-insight-Transparency-in-Coverage-Rule.html.*

[125] Income, Poverty and Health Insurance Coverage in the United States: 2019.'' United States Census Bureau. September 15, 2020. Available at: *https://www.census.gov/newsroom/press-releases/2020/income-poverty.html.*

items and services.[126] Again, although a provider's negotiated rates with plans and issuers do not necessarily reflect the prices providers charge to uninsured patients, uninsured consumers could use this information to gain an understanding of the payment amounts a particular provider accepts for a service. Uninsured patients or participants, beneficiaries, or enrollees seeking care from an out-of-network provider also may use this data to negotiate a price prior to receiving an item or service or negotiate down a bill after receiving a service.[127]

Second, the Departments stated in the proposed rules that information regarding negotiated rates and historical out-of-network allowed amounts is critical for any consumer, insured, or uninsured, who wishes to evaluate available options for group or individual market coverage. Specifically, negotiated rate information for different plans or coverage and their in-network providers is key to consumers' ability to effectively shop for coverage that best meets their needs at prices they can afford, whether the consumer wishes to purchase new coverage or change existing coverage. Publicly-available negotiated rate data will assist all consumers in choosing the coverage that best meets their needs in terms of deductible requirements, coinsurance requirements, and out-of-pocket limits—all factors frequently determined by plan's or issuer's in-network rates, including negotiated rates, or out-of-network allowed amounts. This information, added to plan premium information and benefit design (for example coinsurance percentages), will give consumers an understanding of how affordable a particular coverage option will be.

In the preamble to the proposed rules, the Departments noted that publicly available historical allowed amount data for covered items and services provided by out-of-network providers would enable consumers who require specialized services to find the best coverage for their circumstances. For instance, plans and issuers often place limitations on benefits for specialized services, which causes many specialists to reject insurance; this can make it difficult, if not impossible, for consumers in need of certain services to find in-network providers in their area who are accepting new patients or who have sufficient availability or expertise to meet their needs. The Departments understand, for example, that many speech therapists and pathologists do not accept insurance because of the limitations plans and issuers place on coverage for their services, such as annual visit limits on speech therapy services. Accordingly, consumers who have a need for such specialized services may base their coverage choices primarily, if not solely, on a plan's or issuer's out-of-network benefits. Historical data outlining different amounts paid to out-of-network providers will enable consumers who rely on out-of-network providers to ascertain potential out-of-network benefits among different plans and issuers.

Third, the Departments stated in the preamble to the proposed rules that public disclosure of pricing information is necessary to enable consumers to use and understand price transparency data in a manner that will increase competition, potentially reduce disparities in health care prices, and potentially lower health care costs. One of the recognized impediments to increased competition for health care items and services is the widespread lack of knowledge many consumers have regarding health care pricing. In the preamble to the proposed rules, the Departments noted that many consumers do not fully comprehend the basics of health coverage, much less the more complex facets of the health care system that can affect an individual's out-of-pocket cost for items and services, including: Its specialized billing codes and payment processes; the various specialized terms used in plan and coverage contracts and related documents (such as copayment and coinsurance); and the various billing and payment structures plans and issuers use to compensate providers and assign cost-sharing liability to individuals (for example, bundled payment arrangements).[128] Pricing information is necessary to spur innovation that will help educate consumers on how to get the most value out of their plan or coverage. Making the required pricing information public could facilitate and incentivize the design, development, and offering of internet-based self-service tools and support services that are necessary to address the general inability of consumers to use or otherwise understand the available health care pricing information.

In developing the proposed rules, the Departments considered that, due to the complexity of the health care system and the data that drives plan and issuer payments for health care items and services, such raw data is likely to be difficult for the average consumer to understand and effectively use. As a result, the Departments determined that proposing to make public negotiated rates with in-network providers and historical payment data outlining out-of-network allowed amounts would be appropriate because it would encourage innovation that could ultimately help consumers understand and effectively use price transparency information.

The Departments stated that the proposed requirement to make pricing information publicly available could allow health care software application developers and other innovators to compile, consolidate, and present this information to consumers in a manner that allows consumers to consider price as a factor when making meaningful comparisons between different coverage options and providers.[129] For instance, third-party developers could develop mobile applications that operate as look-up tools and permit comparison of prices for specific services across plans. The tools could also allow consumers to access their medical records or other information about their health care utilization and create estimates based upon patient-specific information. Ultimately, the Departments are of the view that improved access and usability of this information has the potential to increase health insurance literacy, consumerism, and competition, resulting in more reasonable costs for health care items and services.

Fourth, in the proposed rules the Departments noted that, along with

[126] Arora, V., Moriates, C., and Shah, N. ''The Challenge of Understanding Health Care Costs and Charges.'' 17 AMA J. Ethics 1046 (2015). Available at: *https://journalofethics.ama-assn.org/article/challenge-understanding-health-care-costs-and-charges/2015-11*.

[127] ''How to Research Health Care Prices.'' Wall Street Journal. Dec. 4, 2009. Available at: *https://guides.wsj.com/health/health-costs/how-to-research-health-care-prices/* (''Researching health-care pricing online can also help after you've already had a medical procedure, if you want to dispute a bill, negotiate it down, or figure out if you've been overcharged.'').

[128] Satter, M. ''Survey: Most workers don't understand health insurance.'' BenefitsPRO. September 30, 2016. Available at: *https://www.benefitspro.com/2016/09/30/survey-most-workers-dont-understand-health-insuran/?slreturn=20190803010341* (a UnitedHealthcare Consumer Sentiment Survey found that even though 32 percent of respondents were using websites and mobile apps to comparison shop for health care, only 7 percent had a full understanding of all four basic insurance concepts: Plan premium, deductible, coinsurance, and out-of-pocket maximum; although 60 percent of respondents were able to successfully define plan premium and deductible, respondents were not as successful in defining out-of-pocket maximum (36 percent) and coinsurance (32 percent)).

[129] The Departments recognize that implementation of the API discussed in section III, Request for Information, could go even further toward the goal of empowering application developers and other innovators to support price transparency in the health care market.

consumers, sponsors of self-insured and fully-insured group health plans are also disadvantaged by the lack of price transparency.[130] Absent action taken such as through the final rules, health care cost trends are expected to continue to outpace inflation, with employer-sponsored large group plans' annual per employee costs expected to increase between 5.5 to 9.0 percent over the next decade.[131] Without information related to what other plans or issuers are actually paying for particular items and services, employer plans currently lack the pricing information necessary to shop or effectively negotiate for the best coverage for their participants and beneficiaries. In the proposed rules, the Departments stated that public availability of pricing information is appropriate to empower plans to make meaningful comparisons between offers from issuers and evaluate the prices offered by providers who wish to be included in their pool of in-network providers. The Departments noted that the pricing information would also assist employer plans that contract with TPAs or issuers to provide a network of physicians. That information would provide valuable data an employer plan could use to assess the reasonableness of network access prices offered by TPAs and issuers by evaluating the specific price providers in a TPA's or issuer's network are accepting for their services.

Armed with transparency data, employers could also use their leverage to negotiate for lower prices for their participants and beneficiaries and, potentially, if enough employers take action, it could help lower health care prices.[132] For instance, employers could employ network and benefit design tools to move participants and beneficiaries toward lower-priced providers and shift from less favorable provider contracting models (such as a discounted-charge contact, which can be vulnerable to list-price inflation) to more favorable, alternative value-based contracting models (such as reference-based pricing and bundled payment arrangements).[133] As stated elsewhere in this preamble, based on 2019 Census data, there are 183 million Americans enrolled in employer-sponsored health coverage through a household member's employer at some point during the year.[134] Based on estimates of the United States population in 2019, this would mean that more than 56 percent of the nation's insured population has employer-sponsored coverage. Therefore, the ability of employer plans to effectively negotiate pricing for coverage and services could be a boon to competition in the health care market.

Fifth, the Departments stated in the proposed rules that public disclosure of price transparency information is also appropriate because it could assist health care regulators in carrying out their duties to oversee issuers in their states, as well as in designing and maintaining sustainable health care programs. Regulators may be able to independently access, aggregate, and analyze the data to support oversight of plans and issuers. For example, because the machine-readable files must be updated regularly, regulators could use the pricing information to identify trends in rates of items and services over time or identify potentially collusive practices or substantial price variations within a geographic area that may be in need of additional monitoring or future regulatory action. It may also become possible for regulators to use the pricing information related to items and services to assist in better understanding and monitoring premium rate fluctuations and increases in their respective markets; further allowing them to assess whether the trend rates issuers use in their rate filings are reasonable in order to assess whether proposed rates should be approved. Because the in-network applicable rate data will be reasonably current, regulators may be able to address potential concerns more quickly than at present.

Local, state, and Federal agencies responsible for implementing health care programs that rely on issuers to provide access to care would be privy to actual pricing information that could inform their price negotiations with issuers. Insights gained from research using the pricing information could support regulators in their oversight of plans and issuers and could also help identify new ideas for market reforms to enhance the performance and efficiency of health insurance markets.

The public availability of health care pricing information offers researchers the ability to better understand the impact of specific plan, issuer, and provider characteristics on negotiated rates and out-of-network payments, evaluate and supplement existing models and predictions, and formulate new policies and regulatory improvements to improve competition and lower health care spending. Researchers have already utilized localized and state-wide data to review trends in issuer market share, issuer location, and covered services and their corollary effects on consumer pricing and experience in the market.[135] They have also examined these similar effects on consumers by provider market shares, structures, and offered similar data. Expanding the availability of this data could allow for the expansion and validation of these and other models and hypotheses. With larger and more complete datasets, researchers could refine their policy and regulatory suggestions regarding payment and delivery models, including those that are most likely to mitigate upwards pricing pressure from issuer, provider, consumer, and geographic factors. The release of this data could also supplement ongoing efforts to help control health care costs.

The Departments acknowledge that these stakeholders, notably researchers, may have access to some pricing data through existing sources, such as the Health Care Cost Institute (HCCI) and databases established through state health care price transparency efforts. However, it is the Departments' understanding that these health care pricing datasets are often costly to purchase, only contain older, historical data, and generally only include de-identified plan data for a limited number of plans and issuers who voluntarily participate in the data collection.[136]

[130] Whaley, C., et al. ''Nationwide Evaluation of Health Care Prices Paid by Private Health Plans: Findings from Round 3 of an Employer-Led Transparency Initiative.'' RAND Corporation. 2020. Available at: *https://www.rand.org/pubs/research_reports/RR4394.html*.

[131] Congressional Budget Office, ''The Budget and Economic Outlook: 2019 to 2029.'' Congress of the United States Congressional Budget Office. January 2019. Available at: *https://www.cbo.gov/system/files/2019-03/54918-Outlook-3.pdf*; *see also* ''Medical cost trend: Behind the numbers 2020.'' PwC Health Research Institute. June 2019. Available at: *https://heatinformatics.com/sites/default/files/images-videosFileContent/pwc-hri-behind-the-numbers-2020.pdf*.

[132] Whaley, C., et al. ''Nationwide Evaluation of Health Care Prices Paid by Private Health Plans: Findings from Round 3 of an Employer-Led Transparency Initiative.'' RAND Corporation. 2020. Available at: *https://www.rand.org/pubs/research_reports/RR4394.html*.

[133] *Id.*

[134] ''Income, Poverty and Health Insurance Coverage in the United States: 2019.'' United States Census Bureau. September 15, 2020. Available at: *https://www.census.gov/newsroom/press-releases/2020/income-poverty.html*.

[135] *See* Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' The Review of Economics and Statistics. Volume. 101. No. 4. September 30, 2019. Available at: *https://www.mitpressjournals.org/doi/full/10.1162/rest_a_00765*; *see also* Wu, S. et al ''Price Transparency For MRIs Increased Use Of Less Costly Providers And Triggered Provider Competition.'' Health Affairs. August 2014. Available at: *https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.0168*.

[136] For example, HCCI is expected to release their ''2.0'' dataset in December 2020. The ''2.0'' dataset

Continued

By contrast, the pricing information required through the final rules would generally be current data for all plans and issuers and will be available to the public free of charge. This data, where it is related to in-network coverage, can also be tied back to specific plans and issuers and the geographic regions in which they provide plans or coverage. With access to the pricing data required through the final rules, researchers may be able to design new studies that develop novel insights into the health insurance markets. Stakeholders, including employers, may be able to gain insights, inform oversight efforts, negotiate improved terms for items and services, or make improvements to insurance products, such as plans and issuers moving toward value-based plan designs or broadening or narrowing networks based on customer shopping habits. The pricing information could also support market innovation and improvements by plans and issuers. For example, researchers and industry experts could use pricing information to establish baseline data to assist in identifying, designing, and testing new or existing health care delivery and coverage models.

While all of these stakeholders stand to benefit from access to the pricing information required through the final rules, the Departments continue to be of the view that the ultimate beneficiaries of access to pricing information are consumers. Indeed, public access to health care pricing information could lead to more targeted oversight, better regulations, market reforms to ensure healthy competition, improved benefit designs, and more consumer-friendly price negotiations.

The Departments expressed the view that effective downward pressure on health care pricing cannot be fully achieved without public disclosure of pricing information. Standard economic theory holds that markets work best when there is price competition.[137] When consumers shop for services and items based on price, providers and suppliers typically compete to lower prices and improve quality.[138] Based on this understanding of standard economic principles and past experience, the Departments are persuaded that innovators and other entities in the health care market will be incentivized to innovate in the price transparency and health care consumerism space once access to pricing information that allows for meaningful evaluation of different options for delivering health care items or services, coverage options, and provider options becomes available.

1. Information Required To Be Disclosed to the Public

The Departments are finalizing requirements, under 26 CFR 54.9815–2715A3(b), 29 CFR 2590.715–2715A3(b), and 45 CFR 147.212(b), for plans and issuers to make public applicable rates, including negotiated rates, with in-network providers; data outlining the different billed charges and allowed amounts a plan or issuer has paid for covered items or services, including prescription drugs, furnished by out-of-network providers; and negotiated rates and historical net prices for prescription drugs furnished by in-network providers.[139] The Departments are of the view that public availability of in-network applicable rates, including negotiated rates, billed charges and historical out-of-network allowed amounts, and in-network negotiated rates and historical net prices for prescription drugs is appropriate and necessary to provide comprehensive effective transparency in coverage, which may, in turn, empower consumers to make informed decisions about their health care, spur competition in health care markets, and slow or potentially reverse the rising cost of health care items and services.

The vast majority of the commenters agreed with the Departments' objectives of price transparency under the proposed rule. Many commenters offered general support (in whole or in part) of the proposed requirements for public disclosure of in-network negotiated rates and out-of-network allowed amounts. One commenter supported the public disclosure of out-of-network allowed amounts but expressed concerns about disclosure of in-network negotiated rates.

Disclosure of Pricing Information Generally

Some commenters who offered support stated that the requirements will help create more efficient and value-based health care systems by, for example, encouraging plans and issuers to adopt innovative benefit designs that push patients toward lower-cost care. Another commenter who offered support stated that requiring plans and issuers to share publicly the negotiated rates for in-network providers and allowed amounts for out-of-network providers has the potential to increase competition among issuers. One commenter stated that public disclosure of negotiated rates is needed to address the provider consolidation that is driving up health care costs and leading to more favorable reimbursements to large hospitals with bargaining power. Another commenter recommended the Departments reject arguments against transparency that payment data should be protected as proprietary, and adopt a presumption in favor of transparency.

The Departments received comments from state and local government regulators who were supportive of the rules generally and provided suggestions for improving the proposals. Regulators recognized that greater transparency holds promise in improving pricing of health care items and services in ways that improve consumer comprehension and policymakers' ability to manage the health care system. One local government commenter supported the goal of price transparency, but voiced concern that the proposed rules might unintentionally drive up the cost of health care. Individual consumers who submitted comments offered general support and emphasized the importance of obtaining pricing information in advance of receiving health care for their personal health care decision-making. Some individual commenters noted that consumers seek the price of a product or service in every other sector prior to making a spending decision and should be able to do so when purchasing health care. Other individual commenters stated their support for policies that will help consumers choose whether to seek care

includes over one billion commercial claims and 60 million covered lives per year from Aetna, Humana, Kaiser Permanente, and the Blue Cross Blue Shield (BCBS) companies from 2012 through 2018. The data is nearly three years old and will cost $45,000 annually on a per-project basis and does not include other ''standard add-ons,'' such as data mergers. Institutional membership prices will be customized for each organization. Taken from ''Power Up Your Analytics on the Privately Insured.'' Health Care Cost Institute. Available at: *https://healthcostinstitute.org/images/pdfs/Health_Care_Cost_Institute_-_Power_Up_Your_Analytics.pdf*. In addition to the HCCI dataset, BCBS companies also sell their data through their analytics and consulting platform, Blue Health Intelligence, with 20.3 billion claims from 203 unique member organizations. The access price is not listed on their website. More information is available at: *https://www.bluehealthintelligence.com/*.

[137] ''FTC Fact Sheet: How Competition Works.'' United States, Federal Trade Commission. Available at: *https://www.consumer.ftc.gov/sites/default/files/games/off-site/youarehere/pages/pdf/FTC-Competition_How-Comp-Works.pdf*.

[138] Kessler, D., and McClellan, M. ''Is Hospital Competition Socially Wasteful?'' 115 Q. J. of Econ. 577. May 2, 2000. Available at: *https://www.nber.org/papers/w7266*.

[139] As discussed in section II.B of this preamble, the Departments are also finalizing requirements under 26 CFR 54.9815–2715A2(b)(1)(iii)–(iv), 29 CFR 2590.715–2715A2(b)(1)(iii)–(iv), and 45 CFR 147.211(b)(1)(iii)–(iv) that plans and issuers include negotiated rates and out-of-network allowed amounts within the internet-based self-service tool.

from an in-network or out-of-network provider.

Many other commenters, comprised largely of health insurance issuers and health care providers, offered support for the objective of price transparency, but did not support the requirements for public disclosure of in-network provider rates and out-of-network allowed amounts, expressing particular concerns about the in-network provider rate disclosure requirements

Commenters stated that, as proposed, the disclosure of payer-specific negotiated rates could distort the markets, creating an unbalanced focus on costs at the expense of other factors influencing market dynamics, such as quality, efficiency, and effectiveness. Some commenters stated that negotiated rates reflect factors other than price such as experience, previous volumes/market power, anticipated growth, strategic initiatives, and select concessions.

The Departments do not agree that publication of negotiated rates for items and services will have negative distortive effects on health care markets. Rather, the Departments are of the view that the final rules will help to counteract the recognized price distortions that result from the unavailability of pricing information to health care consumers.[140] As discussed elsewhere in this preamble, the current unavailability of pricing information for health care items and services prohibits the health care markets from achieving a meaningful level of competition based on price because it ensures that health care consumers typically are not able to include price in their health care purchasing decisions. The Departments are of the view that making pricing information available could begin to ameliorate price distortions in health care by encouraging consumer decision-making that takes cost into account.

Another commenter stated that the release of negotiated rates would inappropriately result in the steering of consumers to particular providers based on contractual prices. The commenter stated that informed decision-making is not solely based on price, but is multi-factorial, involving looking at a provider's clinical expertise, ability to coordinate care, quality, effectiveness of utilization management, and guidance from a referring physician. The Departments agree that informed decision-making is not solely based upon price. The final rules are only one part of the solution to address issues contributing to the lack of competition in the health care market and resulting increases in health care costs. While the Departments address the problem of price transparency through this rulemaking, other government and industry stakeholders are working to address other issues highlighted by commenters, such as the availability of reliable quality data.

The Departments, in shaping the proposed and final rules, considered that there is quality data available to individual consumers and other consumers of health care like employers and government programs. Various government and industry stakeholders sponsor programs that aim to provide reliable health care quality information to health care purchasers. For instance, HHS engages in continual efforts to develop quality measures that are meaningful and accurately reflect hospital quality. CMS's Hospital Inpatient Quality Reporting Program collects quality data from certain hospitals with the goal of driving quality improvement through measurement and transparency.[141] CMS publicly displays this quality data to help consumers make more informed decisions about their health care.[142] HHS's Agency for Healthcare Research and Quality (AHRQ) publishes comparative information on health plans that include reports sponsored by Federal and state agencies, private organizations, and purchasing coalitions.[143] The Departments appreciate comments received through the RFI in the proposed rule and are also evaluating future actions to help ensure quality information is more readily available.

The Departments are also of the view that it is worth noting that private sector entities have been working to provide useful quality information to consumers.[144] For example, the National Quality Forum (NQF) is a private standard-setting organization focused on the evaluation and endorsement of standardized performance measurements that makes available on its website all NQF work products, reports, and quality measures.[145] As another example, the Joint Commission is a not-for-profit organization that develops and applies standards that focus on patient safety and quality of care.[146] Finally, the National Committee for Quality Assurance (NCQA) measures and accredits health plans as well as the quality of medical providers and practices. For example, more than 191 million people are enrolled in health plans that report quality results using NCQA's Healthcare Effectiveness Data and Information Set (HEDIS),[147] which includes more than 90 measures across six ''domains of care,'' including effectiveness of care, access/availability of care, and experience of care.[148]

Once pricing data is available through the final rules, existing quality data can be considered with pricing data to produce a more complete and accurate picture of total value. The same third-party developers who will have access to the information published pursuant to these final rules could develop platforms capable of presenting available quality data alongside pricing information. The Departments, therefore, anticipate that making health care prices transparent may spur consumers to seek and consider available quality and price information to determine whether a particular item or service is worth a higher or lower price. There is evidence from retail sector studies showing that consumers want high-quality, low-priced goods and will seek the lower price among

[140] Under ideal market conditions, consumers have sufficient information to make good choices. When consumers do not have information on price, standard market forces cannot operate, and prices for health care are distorted resulting in price discrimination (charging consumers different prices for the same product) and other problems that currently plague the health care markets. *See generally* Mwachofi, Ari, and Assaf F. Al-Assaf. ''Health care market deviations from the ideal market.'' Sultan Qaboos University Medical Journal vol. 11, 3 (2011): 328–37. Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3210041/*.

[141] *See* CMS Hospital inpatient Quality Reporting Program web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU*, last accessed Sep. 21, 2020.

[142] CMS Hospital Compare website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU*, last accessed Sept. 21, 2020.

[143] AHRQ Comparative Reports on Health Plans, *https://www.ahrq.gov/talkingquality/resources/comparative-reports/health-plans.html*, last accessed Sept. 21, 2020.

[144] *See, for example,* Ranard, B.L., Werner, R.M., Antanavicius, T., Schwartz, H.A., Smith, R.J., Meisel, Z.F., Asch, D.A., Ungar, L.H., & Merchant, R.M. (2016). ''Yelp Reviews Of Hospital Care Can Supplement And Inform Traditional Surveys Of The Patient Experience Of Care. Health Affairs'' (Project Hope), 35(4), 697–705. Available at: *https://doi.org/10.1377/hlthaff.2015.1030* (''Online consumer-review platforms such as Yelp can supplement information provided by more traditional patient experience surveys and contribute to our understanding and assessment of hospital quality.'').

[145] *See* the National Quality Forum website, *http://www.qualityforum.org/how_we_do_it.aspx*, last accessed Oct. 8, 2020.

[146] *See* The Joint Commission website, *https://www.jointcommission.org/about-us/facts-about-the-joint-commission/joint-commission-faqs/*, *last accessed Oct. 8, 2020.*

[147] *See* NCQA website, *https://www.ncqa.org/hedis/*, last accessed Oct. 8, 2020.

[148] *Id.*

products of the same quality.[149] Given the high cost of health care, the Departments are of the view that the same trend toward seeking lower prices will more likely than not hold true in the health care market when prices become transparent.[150]

The Departments received many comments stating that publishing negotiated rates is unlikely to meet the Departments' goal of helping consumers understand their health coverage and reasonably predict their out-of-pocket costs. Many of these commenters stated that negotiated rates information would not provide consumers with meaningful, actionable pricing information, and could possibly make purchasing decisions more confusing and difficult for consumers. One commenter noted that the public disclosure of negotiated rate information could distract from relevant participant, beneficiary, or enrollee-specific cost-sharing information such as accumulated amounts. One commenter stated that confusing and unhelpful pricing information would erode consumer trust and present long-term challenges for the health care system.

The Departments disagree that public knowledge of the price of health care items and services will increase individual consumers' confusion regarding health coverage or distract them from other information relevant to their out-of-pocket costs, such as the status of their accumulated amounts and note that commenters who raised this point cited no empirical or anecdotal evidence supporting these concerns. On the contrary, as explained throughout this preamble, the Departments are of the view that standard economic theory, experience from several states, and evidence from other markets demonstrate that increased transparency leads to better-informed purchasing decisions, generally lower prices, and quality improvements. Moreover, the Departments expect that third-party developers will compete to make pricing information available to the public in formats that are user-friendly, so disclosure of detailed pricing information is unlikely to lead to significant consumer confusion.

As noted earlier in this preamble, the Departments expect the public disclosure of pricing information related to health care items and services to help both uninsured and insured individuals in their health care and health coverage purchasing decisions. Furthermore, research suggests that having access to pricing information can increase consumers overall satisfaction and provide opportunities for education and engagement on health care pricing.[151] For instance, when the Children's Hospital of Philadelphia incorporated a Patient Cost Estimate Department, they found that cost estimates resulted in ''fewer billing-related complaints, decreased revenue losses, and increased overall patient satisfaction.'' [152] A targeted study in the American Surgeon journal found five out of six medical centers that adopted price transparency reported increases in patient satisfaction and patient engagement after price transparency.[153]

One commenter stated that public disclosure of pricing information through the machine-readable files is unlikely to benefit uninsured consumers, in particular, as it will be difficult for them to make the necessary comparisons or negotiate with providers as providers are not incentivized to negotiate with uninsured consumers. Another commenter stated that the machine-readable files would not be very helpful for current beneficiaries, participants, or enrollees, but acknowledged they could benefit uninsured individuals and enrollees considering alternative coverage.

By contrast, other commenters, including many individual commenters, stated that access to negotiated rate information would empower both insured and uninsured consumers by helping to correct the lack of consumer choice and information and help support efforts by other market actors. In particular, one commenter stated that consumers would likely use the pricing information, especially if their cost-sharing liability is in the form of coinsurance that is tied to the negotiated rates. One commenter stated that release of information on negotiated rates would help consumers by spurring innovation by third-party application developers to create tools to help consumers and payers, especially self-insured group health plans. Finally, one commenter did not support the requirements for public disclosure of in-network provider rates but did acknowledge that public disclosure of de-identified aggregated data for both in-network and out-of-network providers could empower consumer decision-making.

The Departments agree that transparency would help provide more consumer information and support consumer choice for both insured and uninsured consumers. The Departments continue to be of the view that market actors, including IT developers, researchers, industry experts, and plans and issuers would be incentivized to innovate in the price transparency and health care consumerism space once access to the pricing information required to be disclosed through the final rules becomes available. In the proposed rule, the Departments emphasized that individual consumers need easy to use tools and resources to help them better understand their current health care coverage, health coverage they consider purchasing, and their out-of-pocket exposure under those plans. Health care stakeholders and other industry participants, including web and mobile application developers, are already attempting to meet this need, despite the incomplete pricing information available to them. Given actionable data that can improve such tools and resources, industry actors will likely be incentivized to design innovations to deliver the help and information consumers need to make informed health care decisions based, at least in part, on the important factor of price. The final rules will support current and future efforts to help guide consumers to the lowest cost items and services that meet their specific needs and qualifications. To spur this innovation, the pricing information must allow for meaningful evaluation of different options for delivering health care items or services, coverage options, and provider options. One of the main avenues through which

[149] Shirai, M. ''Impact of 'High Quality, Low Price' Appeal on Consumer Evaluations.'' Journal of Promotion Management. December 2015. Available at *https://www.tandfonline.com/doi/full/10.1080/10496491.2015.1088922*.

[150] Recent research evaluating the impact of New Hampshire's price transparency efforts shows that providing insured patients with information about prices can have an impact on the out-of-pocket costs consumers pay for medical imaging procedures, not only by helping users of New Hampshire's website choose lower cost options, but also by leading to lower prices that benefited all patients, including consumers in New Hampshire that did not use the website. *See* Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' The Review of Economics and Statistics. Volume. 101. No. 4. Available at: *https://www.mitpressjournals.org/doi/full/10.1162/rest_a_00765*; *see also* Brown, Z.Y. ''An Empirical Model of Price Transparency and Markups in Health Care.'' August 2019. Available at: *http://www-personal.umich.edu/~zachb/zbrown_empirical_model_price_transparency.pdf*.

[151] Revere, F.L., et al. ''A consumer-based evaluation of Healthcare Price and Quality Transparency.'' Journal of Health Care Finance. Summer 2016. Available at: *http://www.healthfinancejournal.com/index.php/johcf/article/download/72/74*.

[152] Otero, H., et al. ''The Cost-Estimation Department: A Step Toward Cost Transparency in Radiation.'' Journal of the American College of Radiology. Vol 16. Issue 2. February 2019. Available at: *https://doi.org/10.1016/j.jacr.2018.07.033*.

[153] Mehta, A., et al. ''The Impact of Price Transparency for Surgical Services.'' The American Surgeon. April 2018. Available at: *https://pubmed.ncbi.nlm.nih.gov/29712614/*.

the Departments assumed this innovation would materialize is through IT developers who could be incentivized to design and make available internet-based tools and mobile applications that could guide consumers in accessing available price information; as well as researchers who would have the ability to analyze health care pricing at local and national levels and provide the public with their findings. Industry experts and plans and issuers would also have the ability to use pricing information to develop innovative plan benefit designs that could result increased competition and cost savings. Based on comments received from interested IT developers and other innovators, the Departments continue to believe many innovators are interested in utilizing this pricing information, once available, to spur innovation in the health care space, as intended. The Departments expect internet-based tools and mobile applications will increase the likelihood that both insured and uninsured consumers will be able to use the information to make informed health care purchasing decisions. And, as stated by a commenter, the information required to be made public through the proposed rules would help reduce wasteful spending because it would support efforts by employers, state regulators, and other purchases of health care to evaluate prices and identify unwarranted spending variation. Therefore, the Departments did not intend or expect that behavioral changes emanating from public disclosure of this information will be limited to consumers but will benefit a variety of stakeholders.

The goals the Departments seek to achieve through these requirements for public disclosure are not mutually exclusive. The Departments expressed a desire to bring about an outcome where innovators, including researchers, would enter or expand in the health care purchasing space to develop tools, applications, and public information that would support consumer decision-making. Thus, the Departments disagree with commenters who argued that public disclosure of negotiated rates would not support consumer decision-making.

The Departments disagree with commenters who suggested that pricing information presented through the public disclosures would be confusing and misleading to consumers and could erode consumer trust and present long-term challenges for the health care system. Based on the review of the over 25,000 comments received on the proposed rules, the vast majority of which were submitted by individuals, consumer trust in the health care system is already quite low, due in substantial part to the opacity of health care pricing.[154] In one study of a nationally representative sample, researchers found that participants often believed that providers and issuers set prices that do not reflect either the quality or the cost of goods and services, contributing to the study's conclusion that most Americans do not perceive the price and quality of health care to be associated. Study participants described prices as both too high and irrational, noting that prices varied within their regions for unknown reasons.[155] The Departments' transparency efforts are meant to increase transparency of health care pricing information. The Departments do not agree that this information would further frustrate consumers compared to the status quo, even if it is difficult to navigate for the average consumer without the use of internet-based tools or applications.

One commenter stated that disclosure of negotiated rates could harm the ability of health issuers to reward high performing providers with higher reimbursements. Additionally, some commenters noted that focus on price could particularly harm small health plans and TPAs who may have been able to negotiate discounted rates by offering health plans in a limited service area.

The Departments understand that requiring release of this pricing information may impact commercial arrangements and result in certain one-time and ongoing administrative costs, which could disproportionately affect small group plans, TPAs, and issuers offering coverage in the small group market. However, the Departments view making this information available to consumers and the public as beneficial to the public's long-term interests in facilitating a consumer-oriented, information-driven, and more competitive market. In addition, as discussed below, the Departments are establishing several special rules for streamlining the provision of public disclosures required through the final rules. These special rules will help mitigate the concerns of small group plans and issuers by allowing them to leverage a contractual relationship through an issuer or clearinghouse to satisfy the public disclosure requirements of the final rules.

Several commenters submitted feedback on how disclosures in the proposed rules could affect contractual arrangements. One commenter expressed the view that the requirement to release negotiated rates threatens contracts negotiated between two private entities. Several commenters submitted comments related to gag clauses or non-disclosure agreements contained in provider contracts as well as other contract terms that are often included in contracts between providers and payers (such as anti-steering and anti-tiering provisions) that may limit the ability of third parties to use the data. Gag clauses, which also may be referred to as non-disclosure agreements, are terms that are often included in provider-payer contracts, which prohibit one or both parties from making public the negotiated rates therein.[156] Anti-steering and anti-tiering provisions are terms that may be included in provider-payer contracts (usually between issuers and hospital systems), which prohibit the plan or issuer from directing participants, beneficiaries, or enrollees toward higher-quality or lower-cost providers, and require that all providers associated with the contracting provider (for example, for a hospital system this could include hospitals, other affiliated facilities, and physicians) to be placed in the most favorable tier of providers.[157]

One commenter stated that if the Departments do not fully address the implications of non-disclosure agreements in provider and payer contracts, legal complications could arise from payers attempting to meet the requirements to disclose negotiated rates and violating these agreements in the process. Another commenter strongly supported revisions to the proposed rules to address the barriers associated with gag clauses. To address this issue, another commenter recommended the Departments provide that the final rules supersede any provider contract gag clause to the extent the final rules conflict with current or future contractual language.

The Departments understand that this requirement may require alterations to some existing contracts. For example, payers and providers may need to remove contract terms that conflict with the requirement to disclose negotiated

[154] *See, for example,* Phillips, K.A., Schleifer, D., and Hagelskamp, C. ''Most Americans Do Not Believe That There Is An Association Between Health Care Prices And Quality Of Care.'' Health Affairs. 2016. Available at *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2015.1334.*

[155] *Id.*

[156] ''Provider Contracts.'' The Source on Healthcare & Price Competition, UC Hastings College of Law. Available at: *https://sourceonhealthcare.org/provider-contracts/.*

[157] *Id.*

rates such as gag clauses or non-disclosure agreements.[158] It is not uncommon for new or modified regulatory requirements or new statutory provisions to alter private contractual arrangements such as those between a health insurance payer and health care provider. Because changes in law or statute that may need to be reflected in payer-provider contracts is not uncommon, the Departments expect that providers and payers have processes in place address to these requirements of the final rules. Often, the possibility that that new or modified regulatory requirements or new statutory provisions could alter such contracts is contemplated by the contracts themselves; for example, drafters may include contract language that indicates terms may be altered by changes in law or regulation. Such language would obviate the need for updates outsides of the regular contracting schedule.

As a general matter, the onus for ensuring a contract provision does not violate applicable law rests with the parties to the contract. Nothing in the final rules prevents providers and payers from implementing contract revisions to ensure terms are not in conflict with the requirements of the final rules. Because the Departments are of the view that prescription or prohibition of specific contract terms or language in payer-provider contracting is not necessary, the Departments leave it to plans, issuers, and providers to avoid contract terms that would prohibit or frustrate either party's compliance with the final rules.

Many commenters who did not support the requirements for public disclosure of in-network provider rates and out-of-network allowed amounts requested that the Departments withdraw the proposed rules or otherwise work with stakeholders to develop policy solutions that meet consumer needs with less burden and guard against potential unintended consequences. Some commenters suggested the Departments collect more data about the potential impacts of public disclosure of negotiated rates to ensure the policy is modified, if needed, to protect against the risk of unintended consequences, noted earlier. One commenter suggested the Departments pilot the requirement for public disclosure of negotiated rates. Another commenter recommended the Departments pilot the release of negotiated rates in a state where there are a few small carriers to gain a clearer understanding of potential consequences of the public disclosure requirements. Another commenter recommended the Departments pilot full price transparency in several markets and conduct longitudinal studies on the impacts.

Some commenters suggested the Departments refocus transparency efforts to already existing solutions or different initiatives. Some commenters recommended that the final rules require plans and issuers to send claims data to the HCCI to ensure that health care cost data reaches the public domain through researchers without disclosing confidential information or distorting the market. A few commenters suggested the Departments leverage existing data sources such as all-payer claims databases to promote transparency goals. One commenter stated the Administration should support congressional and states' efforts to pursue and expand upon transparency efforts, including through all-payer claims databases.

The Departments appreciate both private and public transparency efforts already underway. In the development of the proposed and final rules, the Departments sought feedback from industry and other stakeholders. While the Departments agree that expanding data sent to HCCI will help researchers gain a better understanding of market dynamics, the Departments are of the view that health care pricing data should be coupled with plan and issuer information. If the information were to be decoupled, as through HCCI or in an all-payer claims database, it would not provide the degree of transparency in prices needed to effectuate the objectives the Departments seek to achieve through the final rules. For example, pricing data, decoupled from plan and issuer data, would not provide actionable information to consumers that seek to evaluate health coverage options, as they would not be able to connect pricing to specific plans.

The Departments view the disclosure requirements set forth in the final rules as complementary to and supportive of state-level efforts. States act as incubators for transparency efforts. Nothing in the final rules precludes states from continuing to establish and run state-level transparency efforts. Indeed, the Departments intend for state regulators to be able to use the disclosures required to be made public through the machine-readable files to support their oversight of health insurance markets, including supporting their own state-level transparency efforts such as all-payer claims databases. However, the Departments are also aware that there are limits to the pricing information that states can obtain through state-level transparency efforts. For instance, states are not able to obtain pricing information from self-insured group health plans; the final rules will help states obtain this information.

The Departments further maintain that the final rules are significantly more likely to achieve positive results for consumers and health care markets than they are likely to result in the potential negative consequences outlined by certain commenters. The Departments are of the view that traditional market forces that affect prices in any market, including competition between providers; the threat of new market entrants that offer quality, lower cost services; and the increased bargaining power of consumers will be supported by the final rules. The Departments also are of the view that providers who choose to arbitrarily or unreasonably increase their prices based on publicly-available negotiated rate data are more likely to damage their own competitive positions and reputation than they are to cause widespread health care cost increases in their particular markets. For these reasons, the Departments remain confident that the final rules' requirements for disclosure of negotiated rate information will benefit health care consumers by giving them information necessary to effectively shop for and choose the health care coverage and providers that fit their needs and budgets. As consumers make more informed choices, based on available price data, market forces will have a chance to operate and potentially correct the current course of unsustainable increases in health care costs.

In light of the Departments' commitment to health care price transparency and the importance of addressing the distortive effects of the absence of pricing information, the Departments are not convinced there is a need to change the policies in the final rules to mitigate the risk of unintended consequences or violations of law such as price fixing and collusion among providers. As discussed elsewhere in this preamble, research, academic literature, and the experience of various state efforts have provided support for the Departments' conclusion that the public availability of in-network rate

[158] The Departments note that gag clauses that would prohibit a pharmacy from informing a participant, beneficiary, or enrollee of any differential between that individual's out-of-pocket cost under the coverage option offered by his or her plan or issuer regarding acquisition of the drug and the amount that individual would pay without using any health plan or health coverage are already prohibited. *See* Sec. 2729 of the PHS Act.

information is substantially more likely than not to lead to more informed health care choices, increased competition, and lower prices.

The Departments note that price transparency is not a novel concept, even in health care pricing. Several states, including New Hampshire and Maine, have implemented state-level price transparency efforts. While the Departments acknowledge that these state efforts differ in material ways from the disclosure requirements of the final rules, the same underlying principle of price transparency that undergirds state efforts also undergirds the final rules. These state efforts provide evidence that transparency at a more localized geographic level does not result in the extreme unintended consequences postulated by some commenters. The Departments acknowledge that other national health policy initiatives are sometimes tested through pilots; however, the Departments are of the view that such an approach is not necessary for price transparency, in part, because there is already evidence through state initiatives that price transparency is achievable.

The proposed and final rules reflect the Departments' conclusion that an expansive implementation of these requirements will be the most effective manner in which to reasonably ensure that the impact will be spread across all markets, rather than isolated to particular geographic areas, markets, or groups of consumers. The goal of the final rules is to expand access to price transparency information among the public, which will not be realized without an expansive implementation. The Departments are concerned that if pricing information for group health plans and insurance in the individual and group markets is not made available to the public or is made public in a piecemeal fashion, there will be little incentive for health care researchers, third-party application developers, or other industry actors to invest scarce resources into a tool that will only offer regional or otherwise limited pricing data. Other stakeholders, such as researchers and regulators, would also find incomplete pricing information less useful to their efforts to better understand, better oversee, and develop innovations in the health care markets. Finally, the Departments are concerned that limiting the implementation of this rule, by scope or by geographic market area, will limit the impact for the millions of consumers (both individuals and employers) who are expected to benefit from the public disclosures required through the final rules. Consumers located in a geographic market where data would not be made available under a more limited requirement would not experience any benefit from the availability of actionable pricing information in other markets. Even those consumers located in geographic markets where pricing information would be made available under a more limited requirement would likely experience more limited benefits than with a market-wide requirement to release pricing information because these consumers would likely not have access to tools developed by third-party application developers. These consumers would also be less likely to experience downstream benefits from contributions expected from other stakeholders, such as researchers and regulators.

In addition to establishing a preference for establishing market-wide rules, in the preamble to the proposed rules, the Departments explained the importance of timely action to increase transparency.[159] The Departments observed that continuously rising health care costs and increases in out-of-pocket liability, without transparent, meaningful information about health care pricing, have left consumers poorly equipped to make cost-conscious decisions when purchasing health care items and services. In addition, consumers across all markets should come to expect and receive the same access to standardized pricing information and estimates. This broader applicability also has the greatest potential to reform health care markets. The Departments recognized the need for a faster and nimbler approach to addressing the pressing issue of rising health care prices. For these reasons, the Departments are of the view that a pilot approach in a specific geographic area or an otherwise phased-in approach for the requirement to publicly disclose negotiated rates through the machine-readable files would not be sufficient to meet the requirement for transparency in coverage.

Because the Departments have determined a need for an expansive implementation of transparency in coverage requirements, and for the reasons discussed at length in response to public comments, the final rules adopt the requirement to publicly disclose negotiated rates for all group health plans and individual and group market issuers, regardless of geographic market.

[159] 84 FR 65464, 65465 (Nov. 27, 2019).

Scope of Pricing Information To Be Made Publicly Available

Several commenters explicitly supported public disclosure of negotiated rates and out-of-network allowed amounts for all items and services. However, other commenters recommended the Departments limit the items and services to only the most common items and services or a narrow set of shoppable services in order to make the machine-readable files more meaningful to consumers. Another commenter did not support the negotiated rate disclosure proposals, but acknowledged that disclosure of rates for a subset of shoppable services would be manageable, could allow issuers to account for innovative payment arrangements, and could be used to gather empirical evidence on the impact of transparency on the health care markets.

The Departments understand that requiring plans and issuers to include all items and services in the machine-readable files could produce large data sets that could be cumbersome and may be costlier to maintain than a more limited file of shoppable services. However, the Departments are of the view that release of this information for all items and services, as proposed, is crucial for advancing the key objectives of the final rules to spur innovation, increase competition, and empower consumer activities in the health insurance markets. The Departments are of the view that limiting the data in the machine-readable files would undermine efforts to achieve these objectives. In particular, the Departments are concerned that if the requirement were to be modified to apply to only a shoppable subset of items and services, then third-party application developers may not be as interested in innovating in this area.

Furthermore, the Departments are of the view that efficiencies will be gained after initial development of these files. Although the initial implementation burden for some plans and issuers may be sizeable, future releases of data could be automated, greatly reducing the burden in subsequent years.

One commenter stated the type of data being required to be disclosed is prohibited from disclosure by CMS for laboratory services under section 1834A of the SSA, which requires CMS to keep confidential payer rates reported by applicable laboratories. The commenter stated section 1834A of the SSA should also apply to disclosure of similar information by health plans.

Section 1834A of the SSA is applicable to reporting of private sector

payment rates for the limited purpose of establishing Medicare reimbursement rates for laboratory services. Section 1834A protects the confidentiality of information disclosed to HHS by a laboratory and prohibits the Secretary of HHS or a Medicare contractor from disclosing the information in a manner that identifies the particular payer or laboratory, identifies the prices charged, or identifies the payments made to any such laboratory notwithstanding any other provision of law. The confidentiality protections of the data required to be disclosed to HHS under section 1834A protects laboratories and payers from re-disclosure by HHS and Medicare contracts. These protections are not applicable to the public disclosures required under the final rules. First, the final rules require plans and issuers to publicly disclose in-network providers' negotiated rates and out-of-network providers' allowed amounts for all covered items and services. These disclosures must be made through machine-readable files posted in a public location on a plan or issuer's website. HHS or contractors of HHS will have no active role in publicizing the information required to be public through the final rules. Second, the confidentiality requirements in section 1834A are applicable ''notwithstanding any other provision of law.'' The public disclosure requirements in the final rules are being finalized through an exercise of specific authority under section 1311(e)(3)(A)(vii) and (ix) of PPACA (as applied to plans and issuers in the individual and group markets through section 2715A of the PHS Act). Even if the public disclosures were to be subject to section 1834A of the SSA, the confidentiality provision of section 1834A would not be applicable because the public disclosure requirements established under the final rules are required by an exercise of authority under a separate provision of law. For these reasons, and because laboratory services fall within the scope of all covered items and services, the final rules clarify that disclosure by plans and issuers of pricing information for laboratory services is required under the final rules.

As discussed earlier in this preamble, the Departments are modifying the proposed requirements relating to inclusion of all items and services in the internet-based self-service tool. For the internet-based self-service tool, 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211 adopt a phased-in approach under which plans and issuers are required to include only include a subset of items and services during the initial year of implementation. However, plans and issuers will still eventually be required to include all covered items and services in their internet-based self-service tools in order to meet the requirements of the final rules. The Departments are of the view that a similar phased-in approach for the machine-readable files is not necessary and would not support the achievement of the goals of the final rules.

For these reasons, the final rules adopt, as proposed, the requirement to include all covered items and services, including prescription drugs, in the public disclosures required to be made through the machine-readable files.

One commenter made the point that in order to provide meaningful transparency to consumers, as well as to address the issues of inconsistent pricing among hospitals in particular, the Departments should require public disclosure of data related to pricing in addition to the negotiated rate. The commenter stated the data elements should include the following: Number of procedures performed by the provider in the reported period, number of bed days, total billed charges in the reporting period, total amount received/paid for services in the reporting period, mean billed charged amount, mean accepted amount, median billed charged amount, mean accepted amount, median billed charged amount, median accepted payment, minimum billed charged amount, maximum billed charged amount, minimum accepted payment, and maximum accepted payment.

A goal of the final rules is to provide transparency for all covered health care items and services. To this end, the final rules' public disclosures are tailored to require only certain critical pricing information that the Departments view as most likely to achieve this goal, while minimizing the burdens for plans and issuers of producing and maintaining the information. Requiring additional data elements, such as those listed by the commenter, would introduce an increased level of complexity to the machine-readable files and increase the burden of making the public disclosures.

Additionally, the Departments are of the view that it would be unnecessarily burdensome to isolate hospital pricing information for additional disclosure when hospitals already have separate price transparency disclosure obligations. As discussed elsewhere in this preamble, the Hospital Price Transparency final rule requires hospitals to make public their standard charges for items or services they provide.[160] The Hospital Price Transparency final rule requires disclosure of five types of standard charges:

- The gross charge (the charge for an individual item or service that is reflected on a hospital's chargemaster absent any discounts);
- the discounted cash price (the charge that applies to an individual who pays cash, or cash equivalent, for a hospital item or service);
- the payer-specific negotiated charge (the charge that a hospital has negotiated with a third-party payer for an item or service);
- the de-identified minimum negotiated charge (the lowest charge that a hospital has negotiated with all third-party payers for an item or service); and
- the de-identified maximum negotiated charge (the highest charge that a hospital has negotiated with all third-party payers for an item or service).

The Departments are of the view that the public disclosure requirements for hospitals under the Hospital Price Transparency final rule, in combination with the public disclosure requirements of the final rules, will address the concern raised by one commenter regarding inconsistent pricing among hospitals. The disclosure required for hospitals under the Hospital Price Transparency final rule will help provide local and more specific pricing information through the availability of information on five types of standard charges, but the information will only be made publicly available for the items and services that hospitals provide. The final rules supplement this information by providing information related to negotiated rates or derived amounts and allowed amounts for all covered items and services. Thus, the final rules will provide a window into pricing for all items and services, while the Hospital Price Transparency final rule requires disclosure of more specific pricing information for the items and services provided by hospitals. Finally, the final rules also supplement the Hospital Price Transparency final rule because the final rules make the information for all contracted network hospitals available from one plan or issuer in a single, centralized file. Therefore, the final rules permit consumers—especially when using third-party web-based tools—to more readily compare hospital rates within and across plans and issuers.

Several commenters expressed concerns about participant, beneficiary,

[160] 84 FR 65524 (Nov. 27, 2019).

and enrollee privacy related to the proposed disclosures of negotiated rates and allowed amounts. Some commenters expressed concerns about how third-party developers or other downstream entities would use and protect participant, beneficiary, and enrollee data. They noted that even though the Departments' disclosure requirements do not include PHI, patients could be enticed to share personal data with third-party developers and other secondary entities who could potentially use the information to re-identify consumers. Some commenters stated that parties not subject to HIPAA could seek to commercialize consumers' information. One commenter suggested the Departments look to HCCI as an example of how de-identified data can advance the goals of transparency, which could mitigate concerns about proprietary information while maintaining meaningful, granular information that illuminates price variation in the health care system.

One commenter stated that the Departments should consider the proposed rules in the context of other HHS rules related to the interoperability of data and delay the implementation of all such rules until HHS develops consumer privacy and protection requirements for third-party applications developed by non-HIPAA-covered entities. Another commenter recommended that, if the rules are finalized without additional privacy protections, the Departments should conduct an educational campaign to inform consumers of the consequences of providing information to third-party application developers. A commenter also expressed national security concerns regarding the machine-readable files, noting that the health status of Americans is a valuable commodity for foreign intelligence services.

The Departments acknowledge commenters' concerns about third-party application developers and other entities gaining access to personally identifiable information (PII) and PHI through consumer use of online applications. The Departments further acknowledge comments that consumers may not always fully understand how their information, including sensitive medical information, will be used or stored by such third parties. However, the Departments also acknowledge that consumers have a right to access, use, and share their own health information, both generally and under HIPAA. The Departments are also of the view that there is ample evidence that consumers require help to understand their health coverage, their out-of-pocket costs for health care items and services, and how their health care choices affect the overall costs of their health coverage and health care items and services.[161] The final rules will allow access to data, supplementary resources, and other assistance consumers need to make informed choices by fostering innovation and offering access to tools that consumers may use to make informed health care choices.

The Departments likewise considered evidence of significant consumer reliance on the internet for all kinds of information, but especially for health information. In a study conducted by the Pew internet & American Life Project and published in July 2003, researchers found that 80 percent of internet users, or about 93 million Americans, have searched for a health-related topic online, a 62 percent increase since 2001.[162] Popular search topics included health insurance (25 percent); a particular doctor or hospital (21 percent); and alternative treatments (28 percent).[163] By 2013, the number of Americans searching for health information online had nearly doubled from 2003, to about 182 million people.[164] A 2018 study found a significant correlation between the use of online resources to obtain health information and the decisions consumers take concerning health care services.[165]

The Departments are of the view that many American consumers have some experience with dealing with the disclosure of sensitive health information on the internet[166] and that consumer reliance on the internet for health care information will only increase despite inherent privacy risks. The Departments considered that websites and internet applications that collect consumer information provide information through privacy policies and terms of service that are available to users of how their information may be used and shared. Federal laws and enforcement mechanisms are in place to help protect consumers from unfair and deceptive practices, including deceptive data collection and the sale of data collected without adequate consumer notice.[167] Given existing measures to protect consumer privacy on the internet, the Departments are of the view that common internet privacy risks should not operate to deprive consumers of the information, tools, and support they need to make informed choices related to health care coverage, providers, items, and services.

Even though the Departments are not persuaded that privacy risks common to the use of internet applications outweigh the benefits of the disclosures under these the final rules or the general need for price transparency, ensuring the privacy and security of consumer PII and PHI is a top priority for the Departments. The Departments will work with plans and issuers to provide information they can use to educate participants, beneficiaries, and enrollees about sharing their health information with third party applications. This will include information on about the roles of Federal agencies such as the Office for Civil Rights (OCR), the FTC, and ONC, which already focus on ensuring that consumer privacy rights and interests are appropriately protected. The Departments will encourage plans

[161] Arora, V., Moriates, C., and Shah, N. ''The Challenge of Understanding Health Care Costs and Charges.'' The American Medical Association Journal of Ethics. November 2015. Available at: *https://journalofethics.ama-assn.org/article/challenge-understanding-health-care-costs-and-charges/2015-11.*

[162] ''Health Searches and email Have Become More Commonplace, But There is Room for Improvement in Searches and overall internet access.'' internet Health Resources. Pew Research Center. July 16, 2003. Available at: *https://www.pewresearch.org/internet/2003/07/16/internet-health-resources/.*

[163] *Id.*

[164] Fox, S., and Duggan, M. ''Health Online 2013.'' Pew Research Center. January 15, 2013. Available at: *https://www.pewresearch.org/internet/2013/01/15/health-online-2013/.*

[165] Chen, Y. et al. ''Health Information Obtained From the internet and Changes in Medical Decision Making: Questionnaire Development and Cross-Sectional Survey.'' Journal of Medical internet Research. Volume 20. No. 2. February 2017. Available at: *https://www.jmir.org/2018/2/e47/pdf.*

[166] Zhu, P., Shen, J., and Xu, M. ''Patients' Willingness to Share Information in Online Patient Communities'' Questionnaire Study.'' Journal of Medical internet Research. Volume 22. No. 4. April 2020. Available at: *https://pubmed.ncbi.nlm.nih.gov/32234698/.*

[167] ''Privacy & Data Security Update: 2019.'' United States Federal Trade Commission. Available online at: *https://www.ftc.gov/system/files/documents/reports/privacy-data-security-update-2019/2019-privacy-data-security-report-508.pdf*; *see also* ''Privacy and Security Enforcement.'' United States Federal Trade Commission. Available at: *https://www.ftc.gov/news-events/media-resources/protecting-consumer-privacy/privacy-security-enforcement* (''the FTC can and does take law enforcement action to make sure that companies live up to [the] promises'' regarding how consumer information will be safeguarded); *see also* Complaint in *United States* v. *Facebook,* Case No. 19–cv–2184, U.S. District Court for the District of Columbia. Available at: *https://www.ftc.gov/system/files/documents/cases/182_3109_facebook_complaint_filed_7-24-19.pdf* (FTC complaint leading to a historic $5 billion fine for, among other things, deceptive practices in violation of section 5(a) of the FTC Act where the social media company failed to effectively disclose that consumer information would also be used for advertising). The referenced fine can be found at: *https://www.ftc.gov/news-events/press-releases/2019/07/ftc-imposes-5-billion-penalty-sweeping-new-privacy-restrictions*, last accessed Sep. 11, 2020 (press release announcing fine).

and issuers to share this information with their participants, beneficiaries, and enrollees who might elect to share health information with third-party applications.

In finalizing the rules, the Departments considered the large number of consumers who have decided to share personal information because they have determined that the benefits offered by an internet website or mobile application outweigh potential risks to their privacy. The Departments are of the view that consumers will be able to make similar determinations with regard to applications that make use of data to be disclosed through the machine-readable files required by the final rules.

As discussed earlier in the preamble to the final rules, the Departments also are not persuaded by the argument that the disclosures required under the final rules, or disclosures consumers may make to applications that leverage the data required, could introduce national security concerns. First, the information the Departments are requiring to be disclosed through the machine-readable files does not include PHI or PII. Additionally, as discussed in more detail later in this preamble, in an effort to ensure that the disclosures balance price transparency with the need to protect privacy, the Departments have modified the proposed rules to increase the minimum disclosure threshold from 10 to 20 unique payment amounts, where any historical payment amounts connected to less than 20 claims for payment would be omitted from the machine-readable file containing out-of-network allowed amounts and historical billed charges (the Allowed Amount File). The increase will further limit the possibility that individual participants, beneficiaries, and enrollees may be identified through historical allowed amount data. Second, the information a consumer could share with applications incorporating data required to be disclosed through the final rules is not significantly different from data consumers already actively share through similar applications. Therefore, the Departments are not convinced there are unique national security concerns flowing from the disclosures required by the final rules.

One commenter was concerned about allowing third parties to use plan and issuer information to provide cost and pricing information to consumers without those third parties being obligated to provide accurate and relevant information to consumers. The accuracy of third-party internet-based tools and applications will be important to achieving the goals of transparency in coverage. However, the cost and pricing information included in third-party internet-based tools, and tools developed by other secondary entities, would only be as accurate as the public disclosures made by plans and issuers. Therefore, the Departments are of the view that it is in the best interest of plans and issuers to ensure data accuracy through a robust quality assurance process if they have concerns about the accuracy of cost and pricing information being provided to consumers through third-party internet-based tools. Furthermore, nothing in the final rules prohibits plans and issuers from including comprehensive data dictionaries and other supplementary documentation along with the machine-readable files. Plans and issuers are also free to provide plan-specific disclaimers or clarifications regarding the information they are required to produce. Finally, the Departments expect that consumers, plans, issuers, and other health care stakeholders will monitor third-party internet-based tools for accuracy and will and report concerns to the developer, the public, and appropriate state and Federal agencies, including the Departments, for evaluation and potential action.

The Departments further expect that market forces will act to weed out applications that do not provide reliable information. Consumers who use a third-party application or other online tools for health care decision support and later conclude that the tool misled or misinformed them will, at minimum, cease use of the tool. Such consumers are also likely to rate the application poorly or leave unfavorable reviews, reducing the likelihood that other consumers who see the rating or review will rely on the tool. Over time, consumers and other stakeholders may collectively identify the most accurate and highest quality tools, while reducing use of less accurate, unreliable tools. The Departments also expect that third-party tools will inform users of limitations on the accuracy of their information and will present relevant disclaimers informing consumers that any estimates of out-of-pocket liability are not guarantees regarding consumer liability for services. Tool users also will have the opportunity to evaluate and could attempt to confirm any cost estimates provided by online tools by contacting the plan, issuer, or health care provider they ultimately choose based on information provided by the tool. Such measures will address the risk that consumers will be led to unreasonably rely on any cost estimate provided by a third-party tool to their financial detriment.

The Departments are of the view that it is in plans', issuers', and developers' best interests to provide accurate information. However, the Departments will monitor the accuracy of the information provided through third-party developers and secondary entities and will take information obtained through this monitoring into account for future regulatory action or guidance, as appropriate.

One commenter recommended that any information made available to the public should provide an explanation of why the cost of care is variable among hospitals. The commenter further suggested the explanation reference unique challenges faced by essential hospitals that care for a larger proportion of vulnerable patients.

Being mindful of the goal to provide sufficient technical flexibility in the formatting of the machine-readable files, the Departments decline to require plans and issuers to include specific supplementary information beyond reporting the data specified for the machine-readable file formats. As noted above, nothing in the final rules prevents a plan or issuer from providing supplementary materials, including footnotes, disclaimers, data dictionaries, and other explanatory language, as accompaniments with the machine-readable files. The Departments are of the view that any additional context around the machine-readable files that can be provided through supplementary materials are likely to be a benefit to consumers and others who seek to understand and use the data contained in the machine-readable files. The Departments recommend plans and issuers work closely with providers, consumers, developers, community leaders, and other stakeholders to ensure that all perspectives are taken into account when developing materials supplemental to the machine-readable files. While declining to require plans and issuers to include a specific explanation for why the cost of care could vary among hospitals, the Departments acknowledge that this information is an example of appropriate explanatory language that could accompany the machine-readable files.

The final rules adopt, with modifications, the requirements that plans and issuers publicly disclose applicable in-network rates (including negotiated rates, derived amounts, and underlying fee schedule rates), out-of-network allowed amounts for covered items and services, including prescription drugs, through machine-

readable files. The final rules also adopt the requirement that plans and issuers publicly disclose in-network historical net prices for covered prescription drugs through a machine-readable file. In recognition of the unique pricing attributes of prescription drugs, the final rules require the reporting of information on prescription drugs that would have been included in the In-network Rate File (referred to as the Negotiated Rate File in the proposed rules) in a separate machine-readable file, as described later in this preamble. The Departments continue to be of the view that the release of this information is appropriate and necessary to empower consumers to make informed decisions about their health care, spur competition in health care markets, and to slow or potentially reverse the rising cost of health care items and services.

The Departments stated the intention in the proposed rules to make available non-substantive technical implementation guidance through the collaborative GitHub platform (an online hosting platform for development and source code management that permits version control), which will facilitate further technical assistance in addressing how unique plan designs can comply with the requirements of the final rules, as needed. The Departments received comments that supported the Departments' development of specific technical standards for the files to which plans and issuers must adhere. One commenter recommended the Departments provide guidance to plan sponsors who are able to provide some, but not all, of the file data elements. Another commenter stated that the proposed rules do not make clear how to report items and services provided through capitated and bundled payment arrangements in the files; noting that this information is necessary for consumers to measure provider value. One commenter supported the Departments' statement that it would provide technical implementation guidance for the files but requested a robust public comment solicitation far in advance of the applicability date for the rules.

The Departments are of the view that providing specific technical direction in separate technical implementation guidance, rather than in the final rules, will better enable the Departments to update the file technical requirements to keep pace with and respond to technological developments. The Departments note that the technical implementation guidance is intended to facilitate a collaborative effort between the Departments and plans and issuers in order for plans and issuers to meet the public disclosure requirements of the final rules, while providing flexibility to account for unique IT systems, and issuer and plan attributes. To the extent a plan's or issuer's unique attributes (such as use of an alternative contracting model) are not addressed sufficiently through the technical implementation guidance, the Departments intend to provide targeted technical assistance to help ensure all plans and issuers are able to meet the public disclosure requirements under the final rules. Therefore, the Departments are developing technical implementation guidance for plans and issuers, which will be available on GitHub, to assist them in developing the machine-readable files.

In the proposed rules, the Departments indicated that minimum requirements for standardized data elements would be necessary to ensure users would have access to accurate and useful pricing information. Without such baseline requirements, the negotiated rate and allowed amount data for out-of-network services made available by each group health plan and health insurance issuer could vary dramatically. This would further create a disincentive to health care innovators developing tools and resources to enable consumers to accurately and meaningfully use, understand, and compare pricing information for covered items and services across providers, plans, and issuers. Accordingly, under the proposed rules, a plan or issuer would be required to publish two machine-readable files. The first file would include information regarding rates negotiated with in-network providers. The second file would include historical data showing allowed amounts for covered items and services furnished by out-of-network providers. The preamble to the proposed rules referred to these files as the Negotiated Rate File and the Allowed Amount File, respectively. For the final rules, the file referred to as the Negotiated Rate File in the proposed rules has been renamed the In-network Rate File to reflect modifications made in the final rules to ensure the file accommodates plans and issuers operating under payment models other than the fee-for-service (FFS) model. The final rules adopt the requirement to produce both the In-network Rate File and Allowed Amount File with the modifications discussed elsewhere in this preamble. As previously discussed, the final rules also adopt the requirement to produce an additional file, referred to in this preamble as the Prescription Drug File through which plans and issuers are required to publicly disclose negotiated rates and historical net prices connected to prescription drugs.

As noted, the final rules modify the In-network Rate File requirements to clarify the expectations for reporting negotiated rates (or comparable derived amounts, which are explained in detail later in this section) for plans and issuers using alternative reimbursement models. The final rules also clarify that plans and issuers must include an underlying fee schedule rate when one is used to determine cost-sharing liability, where that amount differs from the negotiated rate (or comparable derived amount) used to determine provider reimbursement.

The final rules modify the Allowed Amount File to clarify that it must also include information related to billed charges in addition to allowed amounts. The final rules also finalize additional requirements for the In-network Rate File, Allowed Amount File, and Prescription Drug File to require plans and issuers to include a Place of Service Code and a provider tax identification number (TIN) in addition to the provider NPI. These modifications are discussed in more detail later in this section of this preamble.

Specific Content Elements

In the proposed rule, the Departments indicated that the Negotiated Rate File and the Allowed Amount File would be required to include content elements discussed in this section of this preamble. In the final rules, these content elements continue to apply to the In-network Rate File and the Allowed Amount File, as well as to the Prescription Drug File, except where otherwise indicated.

a. First Content Element: Name and Identifier for Each Coverage Option

The first content element that plans and issuers will be required to include in the machine-readable files is the name and identifier for each coverage option offered by a group health plan or health insurance issuer. For the identifier, the Departments proposed that plans and issuers use their Employer Identification Number (EIN) or Health Insurance Oversight System (HIOS) IDs, as applicable. The Departments sought comment on whether EINs and HIOS IDs are the appropriate identifiers for this purpose. The Departments also sought comment on whether there are other plan or issuer identifiers that should be considered and adopted.

The Departments did not receive any comments on this content element, and the final rules adopt this provision with

modifications to ensure clarity of the expectations for reporting. As reflected in the updated regulatory text, the Departments are clarifying whether an EIN or HIOS ID is applicable for this element. Plans and issuers must include their HIOS ID at the 14-digit product level unless the plan or issuer does not have a HIOS ID at the plan or product level, in which case the plan or issuer must use the HIOS ID at the 5-digit issuer level. If a plan or issuer does not have a HIOS ID, it must use its EIN.

b. Second Content Element: Billing Codes

The second content element that plans and issuers will be required to include in the machine-readable files is any billing code consistent with the definition of billing code provided in the final rules, including:

- A CPT code,
- a Healthcare Common Procedure Coding System (HCPCS) code,
- a DRG,
- a National Drug Code (NDC) (The final rules define the NDC code as a unique 10-digit or 11-digit 3-segment number assigned by the Food and Drug Administration (FDA), which provides a universal product identifier for drugs in the United States),[168] or
- another common payer identifier used by a plan or issuer, such as a hospital revenue code, as applicable, and a plain language description for each billing code.

The Departments proposed to require that plans and issuers associate each negotiated rate or out-of-network allowed amount with a CPT, HCPCS code, DRG, NDC, or other common payer identifier, as applicable, because plans, issuers, and providers uniformly understand these codes and commonly use them for billing and paying claims (including for both individual items and services and items and services provided under a bundled payment arrangement). The Departments also proposed that plans and issuers must include plain language descriptions for each billing code. In the case of items and services that are associated with common billing codes (such as the HCPCS codes), the Departments specified that the plan or issuer could use the codes' associated short text description.

In order to ensure that the machine-readable files provide meaningful information to consumers, as well as other stakeholders, the final rules adopt this content element as proposed, with the following modifications. For clarity, the regulation text is amended to remove language that merely restated the definition for the term ''billing code'' for each machine-readable file.[169] This modification has been made purely to streamline the regulatory language, and it does not substantively alter the requirement to include a billing code, except as otherwise noted in this preamble. Additionally, along with separating prescription drugs into a separate machine-readable file, the final rules include a modification that clarifies that, in the case of prescription drugs, plans and issuers may only use the NDC as the billing code type because, as discussed later in this preamble, the accuracy of pricing information for prescription drugs requires precise and specific product information, including package size and manufacturer, which can only be achieved through the use of the NDC billing code. However, the Departments recognize that prescription drug products may be included in the In-network Rate File to the extent a plan or issuer uses an alternative payment arrangement, such as a bundled payment arrangement that includes prescription drugs. Therefore the final rules clarify that the In-network Rate file must include the required information under paragraph (b)(1)(i) of the final rules for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which would be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of the final rules.

The final rules require plans and issuers to include in the machine-readable files a billing code or other code used to identify covered items or services for purposes of claims adjudication, payment, and cost-sharing liability when making public the disclosure required under 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212. The final rules adopt the requirement that plans and issuers associate each amount required to be reported with a CPT, HCPCS, DRG, NDC, or other common payer code identifier, as applicable, because plans, issuers, and providers uniformly understand these codes and commonly use them for billing and paying claims (including for both individual items and services and for bundled payment arrangement). As provided by the definition of billing code in the final rules, the Departments intend to provide flexibility to plans and issuers to make the data available through the codes that they use for billing services. While the final rules do not require plans and issuers to use a specific billing code (for example, CPT codes) for making public the disclosures required through the final rules, definition of billing code states that it is the code used by the plan or issuer ''for purposes of billing, adjudicating, and paying claims for a covered item or service.'' Therefore, where a plan or issuer uses a CPT code to identify a covered item or service for purposes of billing, adjudicating, and paying claims for that covered item or service, then they would need to use the CPT code in order to make public the disclosure required through the final rules for that item or service.

One commenter recommended that the negotiated rates should be clearly stated in plain language that should be easy to understand rather than provided by billing codes through the machine-readable files. As an alternative, the Departments received some comments stating that the Departments should require hospitals and health insurance issuers to disclose all negotiated reimbursements by International Classification of Disease (ICD) code.

The preamble to the proposed rules identified several common billing codes, noting that the list provided was not exhaustive. Further, the Departments did not explicitly prohibit including ICD–10 codes on the file. The Departments note that nothing in the final rules would constrain plans or issuers from including ICD codes in the machine-readable files when these codes are used by the plan or issuer in a manner that meets the definition of a billing code in the final rules. In other words, where the plan or issuer uses an ICD code to identify health care items or services for the purpose of billing, adjudicating, and paying claims for a covered item or service, the plan or issuer may use the ICD code in the machine-readable files. As discussed earlier in this preamble, the Departments intend to issue technical implementation guidance; this guidance will include sample file schemas for the machine-readable files. To facilitate identification of the billing code type,

[168] In the preamble to the HIPAA regulations, HHS stated that it was adopting a uniform 11-digit format to conform with customary practice used in computer systems (65 FR 50314, 50329). (Aug. 17, 2000). The HIPAA 11-digit NDC format is standardized such that the labeler code is always 5 digits, the product code is always 4 digits, and the package code always 2 digits. To convert a 10-digit NDC to an 11-digit HIPAA standard NDC, a leading zero is added to the appropriate segment to create the 11-digit configuration as defined above. *See* 83 FR 38666 (Aug. 7, 2018).

[169] Specifically, the Departments have removed the following language from billing code requirements for the machine-readable files: ''. . . or other code used by the group health plan or health insurance issuer to identify covered items or services for purposes of claims adjudication and payment.''

there will be an indicator in the file schemas that will allow plans and issuers to specify the particular type of billing code entered for each data entry in the machine-readable files.

The Departments are aware that some covered items and services may not have a corresponding HCPCS, ICD, DRG, NDC or CPT code. The Departments clarify that plans and issuers are still required to include these covered items and services in their machine-readable files regardless of whether all corresponding data elements are available. When a covered item or service does not have a corresponding HCPCS, ICD, DRG, or CPT code associated with an item or service, a plan or issuer is permitted to choose its own indicator or other method to communicate to the public that there is no corresponding code. In the alternative, a plan or issuer is permitted to use the code to be defined by the Departments in technical implementation guidance issued along with the final rules that indicates that an item or service is not defined.

At this time, the Departments have concluded that the common data requirements adopted by the final rules, which include a requirement to include a plain language description for each billing code, provides consumers with sufficient information to meaningfully inform health care purchasing decisions.

Regarding information about prescription drug pricing, a commenter also suggested that, in lieu of NDC or HCPCS codes, a useful unit for reporting for drugs would be the RxNorm concept unique identifier (RxCUI).[170] The commenter suggested use of RxCUIs because it would minimize burden by reducing the list of entries (3,000 to 4,000 RxCUIs down from 100,000 active NDCs) and because existing prescription drug machine-readable file requirement for Medicare Part D (Part D) and QHPs use RxCUIs.

The Departments appreciate the commenter's alternative suggestion for including prescription drug information in the machine-readable files. The Departments considered requiring prescription drug pricing information through an alternative identifier. The Departments understand that an RxCUI could minimize the burden on plans and issuers by reducing the number of codes required to be included in the Prescription Drug File. RxCUI is a drug naming system that is produced by the National Library of Medicine (NLM), and RxCUIs are unique identifiers, which can represent multiple NDCs for similar drug products with the same brand name, active ingredient, strength and dose form (for example, multiple package sizes and/or manufacturers can be represented by a single RxCUI). The NDC, in contrast, is a unique 10-digit or 11-digit 3-segment number, which provides a universal product identifier for drugs in the United States. The three segments of the NDC identify: The labeler (any firm that manufactures the drug); the product (specific strength, dosage form, and formulation of a drug); and the commercial package size and types. As noted above, multiple NDCs can be encompassed by one RxCUI, which is why there are many fewer RxCUI codes than NDCs. However, the accuracy of pricing information requires precise and specific product information, including package size and manufacturer. The Departments are concerned that permitting drug pricing information disclosures to be made through RxCUIs would potentially lead to inaccurate or misleading information being provided to the consumer. If drug pricing information is provided in the machine-readable files in the form of RxCUIs, then plans and issuers may not be able to provide the manufacturer negotiated rate, especially for those RxCUIs that include NDCs from several manufacturers.

Some commenters noted that, because RxCUI is used by the Part D program and in the QHP program, the Departments should also require RxCUI in the machine-readable file for consistency across programs. While the Departments acknowledge that RxCUI is used in some contexts in both the Part D and QHP programs, namely formulary development, these programs do not exclusively use RxCUI. Indeed, both the Part D and QHP programs use NDC in addition to RxCUI, and NDCs are more generally used when information is required to be submitted to CMS for payment programs. For example, the Part D program receives the NDC on claims submitted by Part D plan sponsors through Prescription Drug Events (PDEs) and issuers in the individual and small group market include NDCs on claims data submitted to issuers' EDGE servers for HHS risk adjustment purposes. In short, other programs cited by commenters actually use NDCs for prescription drugs data submissions, particularly for payment that is similar to the pricing data required by the final rules. The Departments therefore conclude that requiring use of NDCs for the prescriptions drug pricing information included in the machine-readable files is consistent with the practices CMS follows in other programs. Therefore, as stated earlier, the Departments are requiring that the only allowable billing code for prescription drugs in the machine-readable files is the NDC. The Departments determined that the NDC should be the required billing code for the reasons stated above and because the NDC is a standard billing code required for prescription drug transactions.

c. Third Content Element: In-Network Applicable Amounts (Negotiated Rates, Amounts in Underlying Fee Schedules, and Derived Amounts); Out-of-Network Allowed Amounts; or Negotiated Rates and Historical Net Prices for Prescription Drugs

The third-content element in the machine-readable files depends on the type of file: in-network amounts for the In-network Rate File, allowed amounts and historical billed charges for the Allowed Amount File, or negotiated rates and historical net prices for the Prescription Drug File.

All Machine-Readable Files

The proposed rules specified that the specific pricing information within each file would have to be associated with a provider identifier, specifically the provider's NPI. Some commenters suggested additional data elements to support accurately identifying the provider through the machine-readable files. One commenter recommended that the Departments include the Place of Service Code in the machine-readable files. The commenter explained that this data element would clarify prices when provider entities associated with the same NPI have multiple sites of service. Place of Service Codes are CMS-maintained two-digit codes that are placed on professional claims, including Medicare, Medicaid, and private insurance, to indicate the setting in which a service was provided.[171] The Place of Service code set is required for use in the implementation guide adopted as the national standard for electronic transmission of professional health care claims under HIPAA.[172]

[170] The Departments note that the comments used the term ''Rx Common Unit Identifier'' to identify the full phrase for the RxCUI. The Departments assume that this is a misnomer and that the commenter was referring to RxNorm concept unique identifier, which is the generally accepted term for the acronym RxCUI.

[171] ''Place of Service Code Set.'' Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.*

[172] ''Place of Service Codes.'' Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/Medicare/Coding/place-of-service-codes.*

The Departments have considered this comment and agree that, in addition to NPI, including a Place of Service Code is important where a provider could be using the same NPI for multiple places of service. For instance, the same procedure from the same provider NPI received at an ambulatory surgery center (Place of Service Code 24) could have a significantly different price if received at an on-campus outpatient hospital (Place of Service Code 22). The Departments are of the view that being able to identify the place of service would be beneficial to consumers seeking to rely on the machine-readable files or third-party applications developed using the information publicly disclosed through the machine-readable files, in order to make health care purchasing decisions. The Departments are also of the view that this data element will help provide valuable insights regarding market dynamics for researchers, employers, regulators, and other files users. Because the Place of Service Code is information that must be included on a professional medical claim, the Departments do not foresee any issue with plans and issuers including this data element in the machine-readable files in addition to the NPI. For these reasons, the Departments are finalizing a requirement to include the Place of Service Code in all three machine-readable files.

In addition to the NPI and the Place of Service Code, the Departments have also become aware, through independent research, that a provider's TIN can be relevant to communication of accurate negotiated rates and allowed amounts information. It is the Departments' understanding that negotiated rates for items and services are based on the unique combination of a provider (NPI), service or item location (Place of Service code), and the TIN under which the provider is furnishing the item or service. If the TIN is not required in the file, the Departments are concerned that plans and issuers could report multiple negotiated rates for the same NPI for the same item or service without context to identify the underlying source of the difference. For example, if a provider NPI has a relationship with two different entities that have negotiated rates and bills under both of these entities, the same item or service for that provider NPI could appear in the report with two different negotiated rates. Without the TIN, consumers of the file would not be able to discern the reason for the difference in the two distinct negotiated rates. With the TIN, consumers of the file could see that the provider is billing for the same services under two separate entities. Therefore, if this unique combination of NPI, Place of Service Code, and TIN is not required, the pricing information represented in the machine-readable files might not present a complete and accurate picture of the market or provide consumers with reliable data upon which to base health care purchasing decisions. The Departments are of the view that this information is crucial to ensure that consumers are ultimately receiving location-specific pricing information upon which they can rely to help make informed health care purchasing decisions. In order for the machine-readable files to provide meaningful and actionable information, the final rules adopt a modification to all three machine-readable files, to require plans and issuers to provide the provider TIN in the file in addition to provider NPI and the Place of Service Code.

The Departments have updated the technical implementation guidance and schemas for all three machine-readable files, so that location-specific pricing information can be provided in the machine-readable files. This guidance will also provide more details on how the Place of Service Code, TIN, and NPI should be reported in order to represent the information for which public disclosure is required through the machine-readable files. The Departments are aware that this modification to the machine-readable files will increase the complexity and size of the machine-readable files and have considered this additional burden in the Information Collection Requests (ICR) section of the of the final rules. The benefits of including the Place of Service Code and TIN outweigh the costs, as the Departments are of the view that location-specific pricing information is critical to the meaningfulness of these files for the public.

Another commenter noted that using NPIs to identify providers would make it difficult for consumers to use the machine-readable files because consumers do not usually have NPI information. The commenter stated that it would also be useful for consumers using the In-network Rate Files (including the uninsured and those shopping for alternative coverage) to have access to public information that lists the providers who participate in local plan and issuer networks.

The Departments agree that including provider names in the machine-readable files in addition to NPIs would help consumers and other stakeholders review and use the machine-readable files. However, the Departments have some concerns about requiring inclusion of provider names in the files. From a technical perspective, the Departments are concerned that inclusion of provider names, which do not have a consistent character length and can be quite long, will increase the size of the machine-readable files and, therefore, increase the burden of the files for plans and issuers. Additionally, provider names may include non-alphanumeric or other non-standard character encoding types that could interfere with the coding of the machine-readable files and cause defects. The Departments are concerned that the additional quality assurance procedures that plans and issuers would need to implement in order to address these issues could add even more burden with limited benefit.

In addition, because the Departments expect the greatest benefits of these machine-readable files will be through the innovative tools developed by third parties, the Departments are of the view that the lack of availability of provider names in the machine-readable files is not a significant concern. The Departments anticipate that third-party internet-based developers and other secondary entities will be able to link the NPIs in the machine-readable files to publicly available provider information. The Departments note that there are several internet-based NPI lookup tools available online, including CMS's National Plan & Provider Enumeration System (NPPES) NPI registry.[173] Nothing in the final rules prevents a plan or issuer from linking to an NPI lookup tool or providing more information for consumers and other stakeholders on its website through supplementary materials supporting the machine-readable files.

For these reasons, the final rules do not require plans and issuers to include provider names in addition to NPI, TINs, and Place of Service Codes in the three machine-readable files.

In-Network Rate File

The Departments finalize with modifications the proposed requirement that group health plans and health insurance issuers publish as the third content element negotiated rates in a machine-readable file for all covered items and services—except that the Negotiated Rate File in the proposed rules has been re-named the In-network Rate File. With the exception of information relevant to prescription drug products that are included as part

[173] CMS's NPPES registry is available online at the following website address: *https://npiregistry.cms.hhs.gov/*.

of an alternative payment arrangement (such as a bundled payment arrangement), the In-network Rate File will exclude information relevant to prescription drugs, as that information will be provided in the third machine-readable file. Based on comments and technical expertise within the agencies, the Departments have made modifications to clarify the expectations for reporting negotiated rates (or comparable derived amounts as explained elsewhere in this section) for plans and issuers using alternative reimbursement models for health care items and services. These modifications also clarify that plans and issuers must include an underlying fee schedule rate when one is used to determine cost-sharing liability, where that amount differs from the negotiated rate (or comparable derived amount) used to determine provider reimbursement. The Departments also finalize this change to reflect other modifications to the proposed rules meant to ensure the required In-network Rate File accommodates plans and issuers operating under payment models other than a standard fee-for-service (FFS) model.

In the proposed rules, the third content element was negotiated rates under a plan or coverage regarding each covered item or service, including prescription drugs furnished by in-network providers. To the extent a plan or issuer reimburses providers for an item or service based on a formula or reference based-pricing (such as a percentage of a Medicare reimbursement rate), the proposed rules would have required the plan or issuer to provide the calculated dollar amount of the negotiated rate for each provider.

In the proposed rules, the Departments expressed the understanding that some plans and issuers do not vary negotiated rates across in-network providers. For instance, some plans and issuers have a negotiated rate that applies to every provider in a certain network tier. In such a case, the Departments proposed to require the plan or issuer to provide the negotiated rate for a covered item or service separately for every provider that participates in that tier of the network. If the plan or issuer reimburses for certain items and services (for example, maternity care and childbirth) through a bundled payment arrangement, the Departments proposed to require the plan or issuer to identify the bundle of items and services by the relevant billing code.

The Departments also proposed to require plans and issuers to include the last date of the contract term for each provider-specific negotiated rate that applies to each item or service (including rates for both individual and bundled items and services).

Several commenters suggested modifications to the requirement for public disclosure of negotiated rates, which they claimed would help mitigate the risk of unintended consequences, such as anticompetitive practices and increased health care prices. Commenters suggested that the final rules require plans and issuers to disclose the median rate or lowest negotiated rate instead of negotiated rates. Other commenters also expressed the opinion that information presented as summary or aggregated data would be more helpful for consumers. One of these comments noted that this could be achieved through plans identifying a range of in-network rates for common services.

The Departments considered modifying the requirement to require plans and issuers to report the median negotiated rate, the lowest negotiated rate, or some other aggregated negotiated rate. The Departments noted in the proposed rules that consumers, researchers, and regulators gaining access to pricing information, including information on the variation in prices, could place downward pressure on health care prices and reduce overall health care spending, which is one of the goals of the final rules. The Departments are concerned that using an aggregated or otherwise summarized rate would not sufficiently address issues of pricing variation and could undermine other goals of price transparency efforts. A median or summarized rate would not be as reliable for insured or uninsured consumers to use when making health care purchasing decisions as it is individual prices upon which these consumers must rely to make health care purchasing decisions. Under standard economic theory, it is individual prices, and consumers' responses to those prices, that drive market forces. If the public disclosures do not include specific individual prices for in-network items and services, consumers may not have actionable information upon which to rely to make specific decisions.[174] A median or summarized rate would not address the issue of price variation or dispersion, as it would mask the variation in a given geographic area.[175] Additionally, a median or summarized rate could mask the differences between plans and coverages in a manner incompatible with drawing comparisons between coverage options. Therefore, the Departments are of the view that release of alternative data points, such as aggregated negotiated rates, or other summarized forms of negotiated rates, would not sufficiently advance the price transparency efforts and could undermine the intended impacts of the In-network Rate File.

Commenters suggested the Departments limit the requirement for public disclosure of negotiated rate information in a way that protects plans and issuers from reverse engineering specific rates. For example, a commenter suggested the Departments limit the disclosure to plans and employer plan sponsors, while another commenter suggested that the final rules require plans and issuers to provide limited information to the public, such as statistical ranges, or rates distributions and require the provision of more detailed information to other stakeholders.

The Departments considered limiting these disclosures by stakeholder type such that the disclosure of the most detailed information to the widespread public would be more limited. The Departments' determined that these limitations would conflict with the statute, which requires public disclosure, and the goals of the final rules. The Departments' goal is to empower consumers through the disclosure of actionable pricing information through the In-network Rate Files, as translated into consumer-friendly tools by third-party application developers.

Some commenters expressed the view that public disclosure of rates by plans and issuers with alternative reimbursement models should be required and suggested the Departments work with stakeholders to establish requirements that are consistent with innovative payment models. One commenter stated that the Departments should not exclude from the negotiated file requirements plans with reimbursement arrangements different from FFS arrangements, such as plans with reimbursements based on a capitated amount or a value-based agreement. Some commenters noted that the release of negotiated rates places emphasis on FFS provider contracting and may hinder innovation in alternative payment contracting models, such as value-based contracting.

The Departments received some comments on how the Departments could require plans and issuers to report

[174] Stigler, G. ''The Economics of Information.'' The Journal of Political Economy. Volume 69. Issue 3. June 1961. Available at *https://home.uchicago.edu/~vlima/courses/econ200/spring01/stigler.pdf.*

[175] *Id.*

capitated and bundled payment arrangements through the In-network Rate File. One commenter noted that plans with a capitated arrangement should be able to assign a price to items and services based on an internal methodology. The commenter observed that plans with capitated payment arrangements must assign prices for purposes of submission of claims in support of the HHS risk adjustment program under 45 CFR 153.710(c). Some commenters, however, argued that implementing some aspects of the proposed rules would not be feasible, such as listing prices for quality-adjusted and risk-adjusted contracts, which can only be calculated after the fact.

By contrast, other commenters did not support a requirement for plans and issuers with alternative reimbursement arrangements to make public the disclosures required through the In-network Rate File. Commenters stated that releasing negotiated rate information for bundled or capitation arrangements would be a significant operational burden and could lead to inaccuracies and misinformed consumers. For example, several commenters noted that the entire suite of services that a consumer might need to look up for an episode of care is not known to patients or providers prior to the receipt of care. Another commenter noted that the information could be misleading to consumers because prices may not include the services provided by all providers that are involved in a patient's hospital care such as surgeons and anesthesiologists.

The Departments agree that plans and issuers that use alternative reimbursement arrangements should still be subject to requirements to disclose rates through the In-network Rate File. Nowhere in the proposed rules did the Departments indicate that only plans and issuers that reimburse on a standard FFS model would be required to make public the disclosure of negotiated rates. As evidenced by the discussion of reporting of bundled payment arrangements and plans and issuers using alternative reimbursement models such as formula-based or reference-based pricing in the proposed rules, the Departments intended the disclosures required through the final rules to apply to all plans and issuers, regardless of reimbursement model. The Departments clarify that plans and issuers that reimburse providers on a basis that is different from a standard FFS model would still be required to make public the disclosures of in-network negotiated rates, out-of-network allowed amounts and prices for prescription drugs as required by the final rules.

Later in this preamble, the Departments have summarized the general reporting expectations for several alternative reimbursement models, including bundled payment arrangements and capitation arrangements (including sole capitation arrangements and partial capitation arrangements), reference-based pricing without a defined network, reference-based pricing with a defined network, and value-based purchasing. This summary is not meant to be exhaustive, as the Departments are aware that other alternative reimbursement or contracting models exist. However, before clarifying how these payment arrangements would work under the final rules, the Departments note modifications to the requirements for the pricing information that must be publicly disclosed through the In-network Rate File.

Some commenters stated that the proposed rules did not acknowledge that negotiated rates alone provide an inaccurate or incomplete picture of health care item and service pricing. In response, the Departments conducted additional research to understand how the final rules could require the appropriate level of detail in the In-network Rate File and provide a more complete and transparent picture of prices of health care items and services. In response to comments, and as a result of this additional research, the Departments are modifying the language describing the requirement for the pricing information that must be publicly disclosed through the file. Specifically, the Departments are clarifying that the In-network Rate File should include all applicable rates, even where not referred to as negotiated rates. As described in the final rules, this could include negotiated rates, an underlying fee schedule rate or, derived amounts, as applicable. These modifications are intended to clarify disclosure requirements for plans and issuers that use alternative reimbursement arrangements and to ensure that the rates upon which consumer cost-sharing liability is determined as well as negotiated rates are publicly disclosed through the In-network Rate File. The Departments are of the view that this approach is consistent with the goals of transparency as outlined in the proposed rules because it ensures that the In-network Rate File will be both meaningful for consumers and requires transparency in price disclosures that will promote increased competition in health care markets. Without this clarification, the In-network Rate File could have potentially excluded rates that are used to determine cost-sharing liability, which is essential information upon which consumers would need to rely to make health care purchasing decisions. Further, retaining as proposed the requirement to include the negotiated rates that plans and issuers use to determine provider reimbursement is crucial to price transparency efforts, which will help foster competition and lower prices. Public disclosure of negotiated rates and derived amounts will also support research and regulatory oversight. For example, this information will help researchers evaluate alternative payment models in relation to the traditional FFS payment model, which could help spur more innovation in health care markets. State regulators will also be able to gain further insight into the various payment models, which would support general oversight of plans and issuers using different payment models, and could support market reform efforts.

One commenter noted that plans and issuers that use capitated reimbursement arrangements may assign prices to items and services as a normal course of business. Thus, they should be able to disclose those prices as part of the In-network Rate File. The Departments agree. The final rules require a plan or issuer that does not have a negotiated rate to disclose a ''derived amount,'' which is defined as the price that a plan or issuer assigns an item or service for the purpose of internal accounting, reconciliation with providers, or for the purpose of submitting data in accordance with the requirements of 45 CFR 153.710(c).

Title 45 CFR 153.710(c) sets forth a process through which capitated plans that do not generate individual enrollee claims in the normal course of business must submit data for the purpose of the HHS-operated risk adjustment program.[176] As stated in the preamble to the HHS Notice of Benefit and Payment Parameters for 2014 final rule, many capitated plans currently use some form of encounter data pricing methodology to derive claims' prices, often by imputing an amount based upon the Medicare fee-for-service equivalent price or the usual, customary, and reasonable equivalent that would have been paid for the service in the applicable state market risk pool.[177] For

[176] HHS has operated the risk adjustment program for the individual and small group markets under section 1343 of PPACA on behalf of all states and the District of Columbia since the 2017 benefit year.

[177] 78 FR 15410, 15499–15500 (Mar. 11, 2013).

the purposes of 45 CFR 153.710(c), an issuer offering a capitated plan is required to use its principal internal methodology for pricing those encounters for purposes of submitting risk adjustment data, such as the methodology in use for other State or Federal programs (for example, a methodology used for the Medicare Advantage market).[178] If an issuer, including an issuer of a capitated risk adjustment covered plan, has no such methodology, or has an incomplete methodology, it must supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific market that the plan is serving. Given these requirements under 45 CFR 153.710(c), the Departments are of the view that most issuers offering capitated plans that do not process claims on an individual basis, and therefore do not have negotiated rates, will have a derived amount.

The Departments acknowledge that 45 CFR 153.710(c)does not apply to group health plans or all health insurance issuers subject to these rules and so they may not calculate derived amounts for this purpose. The final rules do not require plans or issuers to develop a new methodology for providing derived amounts if the plan or issuer does not have an existing methodology used in the normal course of business. Therefore, the final rules require plans and issuers that do not have a negotiated rate to provide a derived amount, to the extent these amounts are already calculated in the normal course of business. Where a plan or issuer does not have a derived amount calculated in the normal course of business, they are not required to provide a derived amount.

The Departments also note that under the final rules, where a plan or issuer includes in the In-network Rate File a comparable derived amount in lieu of the negotiated rate (for example, under a capitation arrangement where a specific negotiated rate is not available for a particular item or service), they will be required to add a notation to the machine-readable files indicating that the rate is subject to an alternative payment arrangement. The Departments are also aware that some plan and issuer contracting models use a mixture of approaches and note that plans and issuers should follow the general guidelines (to be provided by the Departments in the technical implementation guidance) based on how a particular covered item or service is reimbursed where a mixture of approaches is used in the same plan or coverage.

The final rules clarify that, where plans and issuers use negotiated rates or a comparable derived amount and an underlying fee schedule rate as defined in the final rules, they are required to report both the negotiated rate or comparable derived amount and the underlying fee schedule rate used for that item or service. Therefore, the Departments are also modifying the In-network Rate File to require public disclosure of an underlying fee schedule rate, when applicable. The Departments are aware that under some reimbursement models, one set of negotiated rates is used for provider reimbursement (or comparable derived amounts are used for internal accounting purposes) and another set of rates, referred to in the final rules as an underlying fee schedule rate, is used for determining consumer cost-sharing liability. The Departments view the modification to the In-network Rate File to require public disclosure of an underlying fee schedule rate important to ensuring the public disclosures required through the rules include transparency in the prices used by all plans and issuers in making determinations of consumer cost-sharing liability. The final rules define the underlying fee schedule rates as the rate for an item or service that a plan or issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability from a particular provider or providers, when that rate is different from the negotiated rate. For instance, under certain capitation payments which reimburse a provider a PMPM rate, the PMPM rate would be the negotiated rate. However, the plan or issuer would also have assigned a price for an item or service from that provider for the purpose determining cost-sharing liability; that amount is the underlying fee schedule rate. Therefore, in this example, in the In-network Rate File, the plan or issuer would be required to report the negotiated rate, which in this case is the PMPM rate, and the underlying fee schedule rate used to determine cost-sharing liability.

In the final rules, plans and issuers are required to disclose only those rates that are applicable to their particular reimbursement arrangement model. If a plan or issuer only uses one rate for determining both provider reimbursement and consumer cost-sharing liability, then only that rate would be applicable to the plan or issuer, and therefore required to be disclosed through the In-network Rate File. Where a plan or issuer uses an alternative reimbursement arrangement and does not have a negotiated rate, as defined in the final rules, the plan or issuer would be required to publicly disclose through the In-network Rate File the derived amount, to the extent the plan or issuer generates such an amount in the normal course of business. If a plan or issuer has a negotiated rate or a derived amount but does not also use that applicable rate to make determinations of consumer cost-sharing liability, then the plan or issuer would be required to publicly disclose both the negotiated rate or derived amount and the underlying fee schedule rate used to determine consumer cost-sharing liability.

The Departments note that, while a scenario where a plan or issuer uses both negotiated rates or a comparable derived amount and an underlying fee schedule rate in their operations is more likely to occur under an alternative reimbursement model, it is possible to have both a negotiated rate and an underlying fee schedule rate in an FFS reimbursement arrangement. Such a scenario is possible where a plan that uses a traditional negotiated rate to reimburse a provider for a particular covered item or service and bases participant, beneficiary, or enrollee cost-sharing liability upon a different rate for the same item or service.

Under bundled payment arrangements, plans and issuers may reimburse a provider for multiple services and items under a single billing code. Under these arrangements, plans and issuers should provide a negotiated rate (or comparable derived amount) for that single billing code and list the items and services, including prescription drugs, that are included in that bundle. If a negotiated rate (or comparable derived amount) exists for each item and service, including prescription drugs, within the bundle, the plan or issuer should include the negotiated rate for the total bundle and also include in the In-network Rate File the respective negotiated rates (or comparable derived amount) for all covered items or services included in the bundle.

It is the Departments' understanding that, if the bundled payment arrangement exists to the exclusion of any reimbursement arrangement for the underlying services and items, payers and providers often continue to track, for purposes of informing renegotiation of the bundle, reimbursement at the level of the individual item or service using a derived amount. For the In-network Rate File, plans and issuers with this type of model are required to disclose the negotiated rate for the total

[178] *Id., see also* 78 FR 15410, 15470–71 (Mar. 11, 2013).

bundle and the derived amounts for individual items or services in the bundled payment arrangement. If a derived amount for these purposes does not exist, then plans and issuers would not be required to report a derived amount. Where a plan or issuer uses a derived amount or reasonable estimate in lieu of the negotiated rate, they will be required to add a notation to the machine-readable files indicating that the rate is subject to an alternative payment arrangement.

The Departments acknowledge that there are many different types of capitation models. As stated in the example earlier, for capitation arrangements that reimburse a provider a capitated amount, such as a PMPM, or a similar direct primary care arrangement, the plan or issuer would report the negotiated rate, which in this case is the PMPM amount, and the underlying fee schedule, as applicable. Under certain other capitation models, the provider's capitation amount may be weighted dependent upon certain characteristics of the participant, beneficiary, or enrollee, such as age, gender, or co-morbidities. Plans and issuers with this type of capitation arrangement should provide the base negotiated rate, which is the negotiated rate before adjustments have been made for certain participant, beneficiary, or enrollee characteristics. Plans and issuers using capitation arrangements should notate any entry that represents a capitated amount and list all items and services, including prescription drugs that are covered under a particular capitation amount in the In-network Rate File.

In some cases, a sole capitation arrangement exists, such as staff model HMOs under which services are provided by in-network salaried providers and there are neither negotiated rates nor an underlying fee schedule rate. In this case, plans and issuers are required to include a derived amount in the In-network Rate File. If an applicable rate (a negotiated rate, derived amount, or underlying fee schedule rate) does not exist for an item or service, then plans and issuers are not be required to report pricing information for that particular item or service.

The Departments are aware that some plans and issuers use a partial capitation model where the plan or issuer reimburses providers under a variable FFS amount in addition to a flat capitation amount. The Departments expect plans and issuers using a partial capitation model to make public the FFS negotiated rate as well as the capitation amount. Plan and issuers must also add a notation to the file indicating that a capitation arrangement (or a partially capitated arrangement) exists. For specific items and services where plans and issuers using this model do not have an FFS negotiated rate in addition to a capitation amount (that is, for items and services where they do follow a full capitation model), plans and issuers are required to follow the reporting requirements described for sole capitation arrangements.

Reference-based pricing without a defined network is an arrangement where payers reimburse providers based on a percentage (usually 120 percent to 200 percent) of the Medicare rate, but do not have contractual agreements with providers. The Departments expect there will be no In-network Rate File for this type of arrangement because the plan or issuer does not have in-network providers as defined in the final rules.

By contrast, under a reference-based pricing model with a defined network, payers have contractual agreements to reimburse providers based on a percentage of a different rate that is known or determinable by the parties (usually 120 percent to 200 percent of the Medicare rate), which is subject to change based upon adjustments that can be specific to the participant, beneficiary, or enrollee, such as age, gender, and severity of illness. To represent this type of arrangement, and other provider reimbursement models that are based upon participant, beneficiary, or enrollee-specific adjustments, the final rules clarify that plans and issuers are required to include for each item or service in the In-network Rate File, the base negotiated rate that applies before adjusting for participant, beneficiary, or enrollee -specific characteristics. The negotiated rate in the referenced-based pricing model must be represented as a dollar value that is the result of the calculation of the referenced amount and the applicable reference-based percentage. For example, a plan calculates provider reimbursement using a reference-based pricing model that sets reimbursement to Provider X at 120 percent of the Medicare rate for covered Item A. The reference-based percentage used to determine the base negotiated rate would be 120 percent. In the general course of business, the plan determines the Medicare rate for Item A using participant, beneficiary, or enrollee-specific characteristics, but, because there is no specific participant, beneficiary, or enrollee for purposes of populating the In-network Rate File, the plan or issuer must report the base negotiated rate that would apply prior to application of any participant, beneficiary, or enrollee-specific characteristics. In this example, the Medicare rate for Item A is $150, before applying adjusters for participant, beneficiary, or enrollee-specific characteristics. Therefore, the plan would report a negotiated rate for Item A when received from Provider X of $180 ($150 multiplied by 120 percent) and must include this rate in the In-network Rate File.

Finally, under a reimbursement arrangement that adjusts payments or reconciles provider payments after providing care, such as in many value-based purchasing models, the plan or issuer must also provide the base negotiated rate for the specific provider in the In-network File. For instance, in a value-based purchasing model, payers may adjust negotiated rates for a particular provider if the provider meets certain contractual goals, which may be related to quality, volume, and efficiency of care. The Departments clarify that quality or value dependent weighting factors or adjusters are not required to be included in the negotiated rate made public under the final rules.

As noted earlier in this preamble, nothing in the final rules prevents a plan or issuer from providing supplementary materials, including footnotes, disclaimers, data dictionaries, and other explanatory language, as accompaniments with the machine-readable files. For example, a plan or issuer may choose to provide clarifying information related to how the negotiated rate, if reported as a base negotiated rate, may change depending on quality or value-dependent weighting factors, or participant, beneficiary, or enrollee-specific factors such as the severity of illness, age, or gender. Because base rates unadjusted for participant, beneficiary, or enrollee-specific factors are required to be reported for reference-based pricing arrangements, the Departments note that it is a best practice to include a disclaimer noting that the rate could change subject to participant, beneficiary, or enrollee-specific characteristics.

Some commenters noted that simply listing the negotiated rates without context regarding overall cost would not help consumers make informed decisions. The commenter further noted that consumer decision-making could be harmed if relying on negotiated rate information without context regarding provider billing practices. Other commenters stated that non-negotiated billed charges would be useful as an additional category of pricing information for the public, especially for

the uninsured and those seeking out-of-network care. Another commenter agreed that information on provider-billed charges is important for transparency, but this commenter suggested that providers, not issuers, would be the appropriate source of this information.

As discussed later in this preamble, the Departments are of the view that inclusion of billed charges in the In-network Rate File is unnecessary to achieve the goals of the final rules because in-network providers are not permitted to balance bill participants, beneficiaries, or enrollees as in-network providers have agreed to accept the negotiated rate as payment in full (less any participant, beneficiary, or enrollee cost-sharing liability) for the item or service. However, inclusion of billed charges in the Allowed Amount File will provide meaningful information when coupled with allowed amount information because it will allow consumers to estimate their potential balance billing liability when receiving items and services furnished by out-of-network providers if balance billing is allowed in their state. Therefore, inclusion of billed charges in the In-network Rate File would not provide additional value for consumers.

Moreover, the Departments are of the view that inclusion of the billed charge could be more misleading in the In-network Rate File because the billed charge is very rarely what the consumer or the payer ends up paying for a particular claim and may not have a clear relationship with the negotiated rate or underlying fee schedule. While the Departments agree that inclusion of billed charges in the In-network Rate File would provide another data point for developers in developing the tools, adding billed charges would also increase both the size and complexity of the In-network Rate File. Because it appears that inclusion of this data element could obscure other pricing information and would not increase transparency of actual prices paid by participants, beneficiaries, enrollees, or payers, the Departments decline to add a billed charge data element requirement to the In-network Rate File at this time.

As discussed earlier in this preamble, the final rules finalize a requirement for plans and issuers to associate the pricing information disclosed on each of the three machine-readable files with three data elements that identify the provider and the location where the service was provided: NPI, TIN, and Place of Service Code. For the In-network Rate File, the Departments proposed that the negotiated rate should be the rate that applies to each item or service that is associated with the last date of contract term for each provider NPI. The final rules modify this requirement to clarify that the applicable rates publicly disclosed in the In-network Rate File should be the rates that apply to each item or service that is associated with the last date of the contract term or the contract expiration date for each provider as identified by NPI, TIN, and Place of Service Code.

Allowed Amount File

For the Allowed Amount File, the third content element is historical out-of-network allowed amounts for covered items and services. The proposed rules would require plans and issuers to include in the Allowed Amount File each unique out-of-network allowed amount in connection with covered items or services furnished by a particular out-of-network provider during the 90-day time period that begins 180 days prior to the publication date of the Allowed Amount File. As with the In-network Rate File, where a plan or issuer reimburses providers for an item or service based on a formula or reference based-pricing (such as a percentage of a Medicare reimbursement rate), the plan or issuer would be required to provide the calculated dollar amount of the allowed amount for each provider. Allowed amounts would have to be associated with the provider's NPI, TIN, and Place of Service code.

The Departments designed this reporting requirement to elicit payment data that reflects recent out-of-network allowed amounts in connection with claims for out-of-network covered services. The Departments assumed these amounts would provide payment data that is useful to consumers because it is reflective of the most recent reimbursements. Specifically, the Departments proposed to require reporting based on dates of service within 180 days of the Allowed Amount File publication date to ensure that data is composed of recent claims (rather than older claims from multiple time periods) and to avoid the reporting of payments from inconsistent periods of time. The Departments took the view that payment data from defined periods of time would enable users to make meaningful comparisons across plans and coverage options.

When disclosing an out-of-network allowed amount under this requirement, the Departments proposed to require a plan or issuer to disclose the actual amount the plan or issuer paid to the out-of-network provider, plus the participant's, beneficiary's, or enrollee's share of the cost. For instance, if the out-of-network allowed amount for a covered service was $100, and the plan or issuer paid 80 percent of the out-of-network allowed amount ($80) per the terms of the plan or coverage, so that the participant, beneficiary, or enrollee was responsible for paying twenty percent of the out-of-network allowed amount ($20), the plan or issuer would report an out-of-network allowed amount of $100. This unique payment amount would be associated with the particular covered item or service (identified by billing code) and the particular out-of-network provider who furnished the item or service (identified by NPI, TIN, and Place of Service Code).

The Departments clarify that, in contrast to the In-network Rate File, no special considerations for reporting alternative payment arrangements are necessary for the Allowed Amount File because plans and issuers are required to disclose actual amounts paid in the Allowed Amount File and can therefore account for retrospective reconciliations and weighting factors that require special considerations. For the Allowed Amounts File, the Departments expect plans and issuers that reimburse in-network providers using alternative payment methodologies to adhere to the standard requirement of providing allowed amounts on historical claims paid to out-of-network providers for each covered item or service during the applicable reference period. Plans and issuers generally do not reimburse out-of-network providers, with whom they do not maintain a contractual relationship, under an alternative payment arrangement. However, to the extent a plan or issuer uses an alternative payment arrangement to reimburse out-of-network providers, the plan or issuer would still be required to report the allowed amount paid to the out-of-network provider. The Departments will address, through the technical implementation guidance, how a plan or issuer will be able to represent data in the Allowed Amount File, as necessary. The Departments anticipate that plans and issuers that reimburse providers using reference-based pricing without a network will have larger than average Allowed Amount Files, as all of the payments would be made to out-of-network providers and would therefore be subject to this requirement.

Some commenters supported disclosure of the ''historical'' payments made by plans and issuers to out-of-network providers. One commenter acknowledged that bulk de-identified data that informs a consumer of historical out-of-network allowed

amounts may be relevant to consumer decision-making regarding a particular provider or procedure. One commenter pointed out that if the Departments failed to adopt this requirement in tandem with the In-network Rate File requirement, providers could withdraw from networks to avoid transparency requirements.

By contrast, other comments were less supportive of the Allowed Amount File proposal. Several commenters stated that publishing historical out-of-network allowed amounts would not meet the Departments' purported goal of helping consumers understand costs and would possibly lead to consumer confusion. Commenters expressed concern that the Allowed Amount File could result in consumers receiving misleading information, which would lead to negative financial consequences for consumers because the file would not provide all information about potential out-of-network costs, such as those that could be incurred through balance billing, if allowed in their state. One commenter stated that inclusion of billed charges would allow the development of open source charge schedules. One commenter pointed out that the information in the machine-readable files would not address scenarios where a participant, beneficiary, or enrollee receives out-of-network care in an in-network facility. Still other commenters expressed concerns about the reliability of the data as historical allowed amounts with out-of-network providers may not provide an accurate portrait of future cost information because issuers do not have contracts with out-of-network providers. Similarly, another commenter stated that health plans should not be responsible for publishing rates for providers with whom they do not maintain a relationship.

One commenter recommended the Departments withdraw the proposal, making the argument that small health plans are unlikely to have a sufficient number of claims billed for any one procedure from a particular provider to make the file meaningful. In lieu of requiring the Allowed Amount File, another commenter suggested the Departments instead place the onus on out-of-network providers or suppliers to provide consumers with information about the costs of their services.

The Departments continue to be of the view that release of this information is appropriate and necessary to empower consumers to make informed decisions about their health care, spur competition in health care markets, and to slow or potentially reverse the rising cost of health care items and services. As noted earlier in this preamble and in the preamble to the proposed rules, limiting access to data to a subset of consumers would not promote the transparency goals of PPACA and the final rules, and would reduce the potential for the final rules to drive down health care costs by increasing competition. If the Departments were to eliminate the Allowed Amount File requirement or reduce its scope, it would significantly reduce the benefits of the final rules for uninsured consumers and insured consumers evaluating out-of-network treatment options.

The information in the Allowed Amount File, especially as filtered through innovative platforms and tools, will help consumers make more informed decisions regarding changes to their health coverage (for example, the purchase of new coverage or switching to a new plan). Furthermore, this information may help insured consumers make more informed health care decisions when seeking out-of-network treatment; and may help uninsured consumers make health care decisions and potentially allow them to negotiate more effectively with providers. Finally, the creation of Allowed Amount Files may help researchers and regulators monitor plan benefit design and help spur innovation.

While there is some potential for some consumers to be confused by the information in the Allowed Amount Files, the Departments do not agree that the files will provide misleading information to consumers. The Departments expect most consumers to access this information through tools created by third-party application developers and other stakeholders, which will be able to provide additional context for the average consumer.

The Departments proposed to require plans and issuers to report out-of-network allowed amounts for services furnished at least 90 days in the past to help ensure the availability of reasonable volumes of out-of-network allowed amount data in the Allowed Amount File. The Departments expressed the view that a 90-day lag between the end of a reporting period and the publication of required out-of-network allowed amount data will allow plans and issuers sufficient time to adjudicate and pay claims from out-of-network providers for the relevant reporting period. Claims processing times may vary between plans and issuers, and external factors may increase processing timelines. For example, the Departments noted in the proposed rules that many out-of-network providers do not send claims directly to plans and issuers but instead require participant, beneficiary, or enrollee to file out-of-network claims. This could mean that an out-of-network claim may not reach a plan or issuer for 6 to 12 months after a service is rendered. Such delays could negatively affect the volume of out-of-network allowed amount data and the ultimate usefulness of this data. For this reason, the Departments sought comment regarding whether requiring plans and issuers to report out-of-network allowed amounts for items and services furnished at least 90 days in the past is sufficient to ensure the proposed disclosures will yield sufficient volumes of historical data to be useful to consumers who wish to shop for services based on price. The Departments requested comment on whether there should be more time between the end of the reporting period and publication of the data, such as 120 days, 180 days, or longer, which would increase the likelihood that out-of-network claims from the relevant reporting period have been adjudicated and paid by the time of publication.

The Departments did not receive comments directly in response to this comment solicitation and are finalizing the Allowed Amount File historical lookback period as proposed. The final rules, therefore, adopt a requirement for the Allowed Amount Files to include data for the 90-day period beginning 180 days before the file publication date. For example, a file published on June 30, 2021, should include data for a 90-day period beginning on January 1, 2021. The Departments will monitor the implementation of this requirement for the Allowed Amount Files and may revisit the lookback period if the 90-day reporting period beginning 180 days before file publication fails to yield sufficient out-of-network data on allowed amounts.

The Departments specifically sought comment on whether the required disclosures of historical out-of-network allowed amounts would provide useful information that can assist consumers in locating services at an affordable cost, or whether there could be additional information that would be both useful to anticipated users and practical for plans and issuers to disclose for this purpose. For instance, the Departments stated in the preamble to the proposed rules that the Departments considered requiring plans and issuers to disclose amounts out-of-network providers have charged participants, beneficiaries, and enrollees for covered services in the Allowed Amount File. The Departments noted they understood that such charged amounts would be included in any

claim for out-of-network benefits and could be helpful to consumers shopping for services based on price. The Departments sought comment on this data element.

As summarized earlier in this preamble regarding the In-network Rate File, some commenters who supported the inclusion of non-negotiated billed charges in the In-network Rate File also supported inclusion of billed charges in the Allowed Amount File. These commenters noted that billed charge information would be especially useful for the uninsured or those seeking out-of-network care. Another commenter agreed that information on provider-billed charges is important for transparency, but this commenter stated that providers, not issuers, would be the appropriate source for this information.

Regarding these comments, the Departments agree that that a billed charges data element is important to ensure that the public disclosures required through the out-of-network Allowed Amount File are as useful to consumers as possible, including in the scenario where an insured consumer receives items or services from an out-of-network provider. Although the Departments are aware that the amount an out-of-network provider will ultimately balance bill (if allowed in their state) a consumer for an item or service does not always equal the difference between the billed charge and the allowed amount, the Departments are of the view that this information would aid consumers in understanding their potential out-of-pocket liability. In the jurisdictions that do not prohibit or limit balance billing, information on billed charges could aide consumers in their health care decision-making as it is possible that consumers may choose to receive or forgo a particular item or service from a particular provider based on the additional out-of-pocket liability they could be expected to pay through a balance billing charge from a provider.

Consumers may be able to shop for a particular out-of-network provider based on total cost of an item or service. For example, in a state that allows providers to balance bill, a consumer has a coinsurance of 40 percent for Service X when Service X is furnished by an out-of-network provider. Out of network Provider A's billed charge for Service X is $200, and the consumer's plan allows an amount of $100 to be paid to the provider. Therefore, the consumer is responsible for a coinsurance amount of $40 ($100 allowed amount multiplied by the consumer's 40 percent coinsurance) and the consumer may be balance billed an additional $100 ($200 billed charge minus the $100 allowed amount). In comparison, out-of-network Provider B's billed charge for Service X is $120 and the consumer's plan allows the same amount of $100 to be paid to the provider. If the consumer receives Service X from Provider B, they will be responsible for the same coinsurance amount of $40 ($100 allowed amount multiplied by the consumer's 40 percent coinsurance). However, if the consumer receives Service X from Provider B, the consumer may only be balance billed $20 ($120 billed charge minus $100 allowed amount), which would be an $80 savings to the consumer compared with receiving the Service X from Provider A. Note that this example assumes that both Provider A and Provider B will balance bill consumers, which is not always true even in states that allow balance billing. Consumers should also contact providers to inquire whether they will balance bill before making health care purchasing decisions using this information. Therefore, with information on both allowed amounts and billed charges, the consumer may choose to receive Service X from Provider B because their total out-of-pocket costs will likely be lower.

The Departments note that it is possible that plans and issuers will populate the Allowed Amount File with multiple billed charges for the same item or service furnished by the same out-of-network provider. If this is the case, the billed charge in the Allowed Amount File will present an expected range and give consumers access to a reasonably accurate estimate of how much they can expect to be balance billed by an out-of-network provider, but the billed charge cannot provide to the consumer the exact amount they can expect to be balance billed when receiving items and services furnished by the out-of-network provider.

For these reasons, the Departments are of the view that inclusion of the billed charges in the Allowed Amounts File will help provide a more complete picture of the full amount a provider could receive for a particular item or service, either from plans and issuers or directly from a participant, beneficiary, or enrollee. Furthermore, the Departments are of the view that requiring this information is consistent with the goal of providing consumers an understanding of their potential out-of-pocket liability in advance, similar to an EOB provided in advance, as billed charges are included on a participant's, beneficiary's, or enrollee's EOB and are often the first data available for understanding a participants, beneficiary's, or enrollee's out-of-pocket liability.

The Departments are aware that plans and issuers have information regarding providers' billed charges, even if they do not necessarily have information regarding specific balance billing amounts. The Departments are therefore of the view that the inclusion of billed charges in the Allowed Amount File will not substantially increase the burdens of the final rules. Nonetheless, the Departments are aware that adding billed charges will also increase both the size and complexity of the Allowed Amounts File. The Departments do not intend to increase the burden of developing and maintaining these files unless the inclusion of the additional data element is essential for providing meaningful pricing information to consumers. Because it is the Departments' view that this data element will increase transparency of actual prices paid by participants, beneficiaries, enrollees, and payers, the Departments are finalizing the Allowed Amounts File with the modification to add billed charges as an additional data point required to be disclosed through the file.

The final rules define billed charges as total charges for an item or service billed to a plan or issuer by a provider. Plans and issuers are required to publicly disclose billed charges associated with each unique allowed amount that would be required under the final rules. The final rules further clarify that plans and issuers must report each unique combination of allowed amounts and billed charges for each out-of-network provider, and their associated Place of Service Code, provider NPI, and provider TIN. For example, an out-of-network provider (under a single NPI, TIN, and Place of Service Code) submits 25 claims (or any other number of claims to meet the 20 unique claim threshold requirement discussed in more detail later in this preamble) to a plan or issuer for the service Y. The 25 claims have three [179] different billed charges ($100, $150 and $200) and two different allowed amounts ($50 and $150) for item Y. The plan or issuer should have one entry that represents each unique combination of billed charges and allowed amounts submitted by the out-of-network provider. Therefore, in this example, the Departments would expect

[179] The Departments note that it is possible for a provider to have different allowed amounts for the same item or service covered by the same out-of-network provider because the plan or issuer does not have a contractual relationship with that out-of-network provider, by definition. For similar reasons, it is also possible for the billed charged submitted by the same out-of-network provider to for the same item or service to be variable.

the plan or issuer to represent in the Allowed Amounts File no fewer than three unique entries, and no more than six unique entries for item Y from this out-of-network provider. For example:

- Entry A has a billed charge of $100 and an associated allowed amount of $50;
- Entry B has a billed charge of $150 and an associated allowed amount of $50;
- Entry C has a billed charge of $200 and an associated allowed amount of $50;
- Entry D has a billed charge of $100 and an associated allowed amount of $150;
- Entry E has a billed charge of $150 and an associate allowed amount of $150;
- Entry F has a billed charge of $200 and an associated allowed amount of $150.

The Departments do not expect to see 25 different entries, unless they represented 25 distinct combinations of billed charges and associated allowed amounts from the out-out network provider for Item Y.

In the Allowed Amount File, the file structure is envisioned as a parent/child data relationship, where certain data elements are included under or belong to other data elements, as a child to a parent. In the Allowed Amount File, the billed charge data element would serve as a child to the parent allowed amount element. Therefore, under each unique allowed amount for a particular item or service from a particular provider, the amount of each provider-billed charge is listed as a unique dollar amount.

One commenter requested the Departments clarify what is meant by ''allowed amounts for covered items or services furnished by particular out-of-network providers,'' questioning whether through inclusion of the word ''particular'' the Departments intended to reference specialized out-of-network providers upon which plans and issuers might place coverage limitations. The Departments clarify that inclusion of the word ''particular'' as a modifier of ''out-of-network providers'' was not intended to be a reference to specialized out-of-network providers upon which plans and issuers might place coverage limitations. Rather, use of the word ''particular'' indicates that Allowed Amount Files must include the historical allowed amounts for covered items and services furnished to each out-of-network provider to whom such payments were made during the reference period. The Departments clarify that under the final rules, and as contemplated in the proposed rules, plans and issuers are expected to include historical allowed amounts for every covered item or service furnished by each out-of-network provider so long as the unique claims threshold for the out-of-network provider is met.

The Departments further clarify that plans and issuers are only required to include in the Allowed Amount File those covered items and services furnished by an out-of-network provider for which the plan or issuer has adjudicated claims and determined it will pay an allowed amount. If the plan or issuer has not adjudicated claims and determined it will pay an allowed amount for items or services furnished by an out-of-network provider, the plan or issuer is not required to include those allowed amounts or billed charges in the Allowed Amount File.

In response to the comment that the information in the files would not address the scenario where a participant, beneficiary, or enrollee receives out-of-network care in an in-network facility, the Departments clarify that the expectation is that this information would be captured in the Allowed Amounts File. If a participant, beneficiary, or enrollee receives out-of-network care, even if the facility is in the participant's, beneficiary's, or enrollee's network, the provider will generate a claim and send a billed charge to the payer that will establish an allowed amount for the claim; the Departments expect this allowed amount to appear in the Allowed Amounts File in this scenario. As noted elsewhere in this preamble, the Departments will provide technical implementation guidance (as well as individualized technical assistance, as needed) to ensure that plans and issuers are able to make public the disclosures required through the final rules.

The Departments do not agree with the commenter who asserted that, because some small health plans will not have a sufficient number of any one procedure from a particular provider to make the file meaningful, the Allowed Amount File requirement should be withdrawn. The relevant commenter did not provide a number of claims that it believed would make the file meaningful. In contrast, the Departments are of the view that the files will be meaningful to the public regarding all covered items and services from a particular provider regardless of the specific numbers of claims at issue, even if a particular provider bills relatively few claims to a particular plan or issuer. As discussed elsewhere in this preamble, for privacy and security reasons, the Departments are requiring disclosure for all covered items and services from a particular provider that meets the unique claims threshold established by the final rules. If a small health plan does not have sufficient claims for a covered item or service to meet the unique claims threshold for a particular provider, then that health plan is not permitted to publicly disclose information for that particular item or service paid to the particular provider. The Departments are of the view that most health plans and issuers will meet the unique claims threshold for a large proportion of items, services, and providers to make the files sufficiently meaningful to justify this requirement.

In the preamble to the proposed rules, the Departments noted that providing this information could raise health privacy concerns. The Departments are committed to protecting PHI and other sensitive information. To address these privacy concerns, as discussed in this preamble, the Departments proposed that plans and issuers would not be required to provide out-of-network allowed amount data in relation to a particular provider and a particular item or service when compliance would require a plan or issuer to report out-of-network allowed amounts to a particular provider in connection with fewer than 10 different claims for payment. The Departments also noted that disclosure of such information would not be required if compliance would violate applicable health information privacy laws. In addition to proposing this exemption, the Departments proposed to require plans and issuers to include only unique out-of-network allowed amounts to mask the total episodes of care for a particular provider and item or service. In the proposed rules, the Departments expressed the view that these mitigation strategies, in addition to flexibilities proposed to allow the aggregation of reported data (as described later in this preamble), were sufficient to protect patients from identification based on information in the Allowed Amount File. The Departments solicited comment on whether additional privacy protections would be required.

The Departments specifically requested comment on whether a higher minimum claims threshold, such as a threshold of 20 claims, would better mitigate privacy concerns and minimize complexity in complying with Federal or state privacy laws without compromising the integrity of the compiled information. The Departments also sought comment on additional approaches that could decrease the potential for aggregated health information that would be disclosed under the proposed rules to be

identified, especially with respect to smaller group health plans.

In response, some commenters expressed concerns about maintaining HIPAA protections on the Allowed Amount File due to the small number of claims associated with specific services for out-of-network providers. Several commenters stated the threshold of 10 unique claims to require public disclosure of unique historical allowed amounts would be too low to protect consumers' PHI. One commenter requested that the Departments clarify how they arrived at the 10 claims threshold. Some commenters recommended different minimum thresholds. Some commenters recommended a minimum threshold of 50 claims. On the other hand, other commenters did not support increasing the threshold, noting that the files do not contain identifiable data and so would not pose a risk. One commenter stated that the files should be released including the lowest number of claims necessary to achieve the goal of protecting participant, beneficiary, and enrollee privacy and recommended keeping the proposed threshold of 10 claims. Another commenter requested that the Departments not make the threshold any higher, and even consider lowering the cutoff to five claims, to maintain access to price transparency data for rural Americans.

Based upon comments received the final rules adopt a 20 unique claim threshold. The Departments are of the view that the 20 unique claim threshold balances the concerns expressed by commenters who suggested the Departments increase the threshold to 50 claims with the concerns of commenters who expressed the opinion that the proposed 10 claim threshold (or an even lower threshold) would be sufficient to ensure the files include a meaningful amount of data. The Departments are of the view that 20 unique claims are sufficient to balance the privacy concerns against the needs for transparency through the Allowed Amounts File. This 20 unique claim threshold is more stringent than CMS' cell size suppression policy, which requires cells containing values of 1 through 10 to be suppressed in CMS data sets.[180] Increasing the unique claim threshold from 10 to 20 claims will not significantly reduce the amount of data that are required to be made public through the Allowed Amount File. However, if the Departments were to increase the unique claim threshold to 50 claims, as suggested by some commenters, the Departments are concerned that this could significantly reduce the amount of data that are required to be made public through the Allowed Amount File, which could undermine the goal of price transparency.

The Departments are of the view that increasing the unique claim threshold from 10 to 20 claims will better balance the policy goal of maximum transparency with the need to protect participants, beneficiaries, and enrollees from the possibility of being re-identified through the data included in the Allowed Amount File. In addition to this strategy, the Departments expect that the flexibility discussed later in this preamble under the special rule to permit aggregation of reported data will help protect participants, beneficiaries, and enrollees from identification based on information in the Allowed Amount File. Finally, the Departments reiterate that the disclosure of the information is not required if disclosure would violate applicable health information privacy laws. The Departments note that this exception does not mean that these disclosures are not required where a law that would otherwise prohibit the disclosure permits disclosure if required by law.

Prescription Drug File

The Departments finalize negotiated rates for prescription drugs as the third content element in the Prescription Drug File. The Departments received several comments related to whether negotiated rates for prescription drugs should be disclosed through the machine-readable files, and if so, which price or prices related to prescription drugs should be required to be included. Many commenters provided general support for the public release of negotiated rates for prescription drugs. One commenter asserted that releasing negotiated rates for prescription drugs would result in lower costs for health plans and consumers, which could lead to a reduction in manufacturer discounts of upwards of three percent.

Several commenters did not support disclosure of negotiated rates for prescription drug prices through the machine-readable files. Commenters recommended that the In-network Rate File should not include prescription drugs for several reasons. These reasons include: The complexity of prescription drug pricing (prices are determined by a formula that is determined at the point-of-sale and can change on a daily basis; the information would not be relevant to consumer decision-making; and the existence of established drug pricing tools that provide support for consumer decision-making. Some commenters stated that the unique nature of prescription drug pricing would make the release of negotiated rates difficult and further noted that the rates negotiated between PBMs and pharmacies are considered confidential. Another commenter stated that the Departments should only require disclosure of prescription drug prices when the information disclosed is directly related to the cost a plan participant, beneficiary, or enrollee would need to pay out of pocket so as not to undermine group health plans' and health insurance issuers' ability to negotiate lower drug costs. Some commenters claimed that plans and issuers have no control over prescription drug costs and may not be able to provide this information. Instead, commenters asserted that information related to prescription drug costs should come from PBMs or prescription drug manufacturers.

In 2018, retail prescription drug spending represented approximately nine percent ($335 billion) of overall health spending.[181] In 2017 large group health plans and issuers accounted for the largest share of prescription drug spending amongst other payers, despite generally having a younger and healthier population than public payers.[182] The Departments maintain that plans and issuers have an essential role,[183] and vested interest in controlling prescription drug spending. Moreover, as prescription spending continues to rise,[184] so does the trend of prescription rebates.[185] According to

[180] The CMS Cell Size Suppression Policy is outlined on the CMS website at the following location: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.*

[181] ''National Health Expenditures 2018 Highlights.'' Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/files/document/highlights.pdf.*

[182] Cubanski, J., and Rae, M. ''How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?'' Kaiser Family Foundation. May 20, 2019. Available at: *https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/.*

[183] ''How are prescription drug prices determined?'' American Medical Association. April 9, 2019. Available at: *https://www.ama-assn.org/delivering-care/public-health/how-are-prescription-drug-prices-determined.*

[184] ''National Health Expenditure Projections 2019–28.'' Office of the Actuary. Centers for Medicare & Medicaid Services. March 24, 2020. Available at: *https://www.cms.gov/files/document/national-health-expenditure-projections-2019-28.pdf.*

[185] According to the Academy of Managed Care Pharmacy, a prescription drug rebate is a monetary amount returned to a payer from a prescription drug manufacturer based on pharmaceutical use by a covered person or purchases by a provider. ''AMCP Guide to Pharmaceutical Payment Methods, 2013

Continued

surveyed health plan and PBM personnel, PBMs passed through 78 percent of manufacturer rebates to health plans in 2012 and 91 percent in 2016.[186] And while some plans and issuers may use these rebates to dampen premium increases,[187] there remains an unclear prescription drug supply chain that masks the true costs of prescription drugs. The Departments are of the view that it would not advance the goals of the final rules to exclude a category of items and services that comprises such a significant proportion of health care spending.

The Departments agree that prescription drug pricing is complex but are of the view that complexity is not a valid reason for inaction. There are many different players in the prescription drug supply chain that may have some control over costs, including plans and issuers, manufacturers, wholesalers, pharmacies, and PBMs.[188] As commenters stated, it is often the case that PBMs negotiate the price of a prescription drug for a plan or issuer based on a contract the plan or issuer maintains with the PBM; however, it is ultimately the plan or issuer who is responsible for deciding how the costs of prescription drugs are passed along to a participant, beneficiary, or enrollee. The Departments, therefore, are of the view that plans and issuers are aware of the negotiated rate for a prescription drug for which their participants, beneficiaries, or enrollees may have cost-sharing liability, or can be informed of this negotiated rate by their contracted PBM.

The Departments do not agree that prescription drug pricing information, such as negotiated rates, will confuse consumers. As discussed elsewhere in this preamble, the Departments recognize that the information included in the machine-readable files may not be easy for an average consumer to navigate and expect that third-party developers will use this information to make tools available that make this information more useful for the average consumer.

The Departments agree with commenters who acknowledged the existence of many tools that provide prescription drug prices. However, the Departments are of the view that existing prescription drug pricing tools are insufficient as they lack competitive pricing information across all PBMs, and health plans and issuers.[189] Once prescription drug pricing is made more fully available, health care providers will have greater opportunity to factor pricing information into their prescribing decisions. Many health care providers benefit financially when they can reduce costs and improve their patients' medication adherence.[190] This benefit to providers can also have a significant impact on overall health care spending.

For these reasons, and those discussed more fully below, the Departments are finalizing, with modifications from the proposed rules, requirements to disclose pricing information for prescription drugs through a machine-readable file. However, reflecting the unique attributes of prescription drug pricing, the final rules respond to comments by adopting requirements that are more detailed than what was included in the proposed rules, including the inclusion of a third machine-readable file for prescription drug pricing information.

The final rules require plans and issuers to produce a third machine-readable file for reporting prescription drug pricing information, the Prescription Drug File, whereas the proposed rules would have required plans and issuers to include negotiated rates for covered prescription drugs in the In-network Rate File. The Departments have made this change to ensure that prescription drug pricing information is produced in a manner that is most useful to the public. As noted earlier in this preamble, there are upwards of 100,000 NDCs for prescription drugs. Divorcing negotiated rates for prescription drugs from negotiated rates for other items and services allows the pricing information for medical items and services to be discernible from pricing information for prescription drugs. Further, a PBM may administer pharmacy benefits for a plan or issuer in addition to any other services it may provide to a plan or issuer. Therefore, keeping prescription drugs pricing data separate from pricing data for other items and services is generally better aligned with plan and issuer operations and will reduce the burden associated with combining data from different sources. As discussed in the Information Collection Requests (ICR) section of this preamble, the Departments estimate that the Prescription Drugs File requirement will not add significantly to the development and maintenance costs of the machine-readable files because the cost and burdens related to prescription drugs will largely be transferred from the In-network Rate File to the Prescription Drug File. Additionally, the Departments anticipate that removal of prescription drugs from the In-network Rate Files will significantly reduce the size of those files, which could reduce the costs associated with maintenance and storage of each individual file. The Departments are of the view that removing prescription drugs from the In-network Rate File and requiring this information to be included in a separate Prescription Drug File is consistent with the Departments' goal of separating fundamentally different types of data into distinct files. Because, as many commenters observed, prescription drug prices are unique, the Departments are of the view that this information would be more appropriately represented through a third machine-readable file. Furthermore, the updated machine-readable file structure will support consumers, researchers, and third-party developers in reviewing, ingesting, aggregating, and analyzing the data.

The Disclosure of Prescription Drugs Pricing Information

Under the proposed rules, group health plans and health insurance issuers would be required to publicly disclose negotiated rates in the In-network Rate file. The Departments defined negotiated rates in the proposed rule as the amount a group health plan or health insurance issuer, or a third party on behalf of a group health plan or health insurance issuer, has contractually agreed to pay an in-network provider for covered items and services, pursuant to the terms of an agreement between the provider and the group health plan or health insurance issuer, or a third party on behalf of a group health plan or health insurance issuer. As discussed in the Definitions section of this preamble, the final rules adopt this definition as proposed, with modifications to provide additional clarity.

In the preamble to the proposed rules, the Departments acknowledged that cost-sharing liability for prescription drugs is often based on an amount other than the negotiated rate, such as manufacturer list prices or undiscounted list prices such as AWP or

Update.'' Available at: *https://www.amcp.org/sites/default/files/2019-03/Full-Pharmaceutical-Guide-%283.0%29.pdf*; *see also* ''The Prescription Drug Landscape, Explore.'' PEW Charitable Trusts. March 8, 2019. Available at: *https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored.*

[186] *Id.*

[187] *Id.*

[188] ''How are prescription drug costs really determined?'' Biotechnology Innovation Organization. Available at: *https://www.drugcostfacts.org/prescription-drug-costs.*

[189] Galewitz, P. ''Doctors Slow To Adopt Tech Tools That Might Save Patients Money On Drugs.'' NPR. July 5, 2019. Available at: *https://www.npr.org/sections/health-shots/2019/07/05/738283044/doctors-slow-to-adopt-tech-tools-that-might-save-patients-money-on-drugs.*

[190] *Id.*

WAC. The Departments further acknowledged that, because of the application of rebates and other discounts, the inclusion of just the negotiated rate for prescription drugs could mislead consumers because the rate paid by the plan could ultimately be lower than the price paid by the consumer at the point-of-sale, as it is the Departments' understanding that these rebates and other discounts typically are not passed on to the consumers at the point of sale. The Departments expressed the concern that including only the negotiated rate for prescription drugs used to determine cost-sharing liability could perpetuate the lack of transparency surrounding prescription drug pricing. To this end, the Departments solicited comment on which pricing information related to prescription drugs should be disclosed.[191]

Despite the Departments' concerns regarding negotiated rates for prescription drugs outlined in the preamble to the proposed rules, commenters responded that negotiated rates, in addition to other information, are an important data point necessary to achieving useful transparency into coverage and out-of-pocket costs for prescription drugs. Several commenters recommended that the machine-readable file include both the negotiated price and the undiscounted ''list'' price, upon which coinsurance and deductibles are often based, in order to promote competition. Other commenters suggested that plans and issuers should disclose to enrollees when they do not pass through manufacturer rebates and discounts at the point-of-sale or factor these amounts into enrollee cost sharing. Another commenter recommended the Departments consider requiring a ''net price'' for prescription drugs rather than the negotiated rates. This commenter stated that, it is vital that this ''negotiated rate'' also include the ''net price'' (which accounts for all price concessions, including direct and indirect remuneration fees (DIR) and/or similar policies/terminology, such as ''true up'' practices under employer-sponsored and private plans to accurately estimate participant, beneficiary, and enrollee cost-sharing liability for prescription drugs). One commenter noted that if the public disclosure did not include information related to rebates, the file could be misleading and could lead to a continuing overemphasis on prescription drug list prices without recognition of the role played by rebates.

Another commenter recommended that the Departments allow plans and issuers to report the most appropriate available price type based on the plan's benefit design. This commenter suggested that plans should also be required to identify the price reported, such as AWP or WAC or the contracted pharmacy reimbursement amount (for example, the Part D negotiated price).

The Departments have closely reviewed the comments to determine the prescription drug pricing information plans and issuers should provide in the Prescription Drug File in order to achieve the goals of transparency. Based on this review, the final rules are adopting as content element three for the Prescription Drug File a requirement for plans and issuers to publicly disclose two amounts for prescription drugs in the Prescription Drug File: The negotiated rate and the historical net price.

Prescription Drug Negotiated Rate Disclosure

As evidenced by the comments and the Departments' independent research, there is wide variability in how negotiated rates are assigned for prescription drugs. For instance, some commenters noted that negotiated rates for prescription drugs include rebates, price concessions, and other ''true-ups, while others likened the negotiated rates to the undiscounted list price used for determining cost-sharing liability. Therefore, plans and issuers may use varying types of prices when reimbursing providers for prescription drugs. For example, it is the Departments' understanding that for generic prescription drugs, the Maximum Allowable Cost (MAC)—an amount the plan or issuer uses as the maximum amount they will pay for a particular prescription drug product—may be the amount that plans and issuers use to pay providers for a prescription drug. Plans and issuers may reimburse providers for other prescription drugs using a UCR amount or an amount based on the undiscounted list price, such as AWP or WAC. It is the Departments' understanding that contracts negotiated between plans and issuers (or their contracted PBM) and providers generally do not include specific negotiated rates for prescription drugs, but instead include formulas that determine the type of price that will be used to reimburse providers for a particular prescription drug product. The negotiated rate may differ by drug or class of drug in the contract as the lesser of several types of prices based on one of the benchmarks described above—that is, WAC, AWP, MAC, or UCR. Because prices for prescription drugs can fluctuate on a daily basis, the price that is used to reimburse the provider can also fluctuate based on application of the contract terms.

In addition to better appreciating the wide variability in how negotiated rates are assigned, the Departments also now understand based on comments and independent research, that, contrary to the Departments' understanding as explained in the preamble to the proposed rule, no matter what benchmark or formula is used to determine the negotiated rate, the negotiated rate is frequently also the rate upon which cost-sharing liability is based for prescription drugs.

Based on the circumstances described above, the Departments therefore agree with commenters that a certain amount of flexibility is required for plans and issuers as it relates to the benchmarks and inputs required for the disclosure of negotiated rates for prescription drugs. To allow for flexibility, as proposed, the final rules do not assign a benchmark or necessary inputs to the definition of negotiated rates. The final rules include a broad definition for negotiated rates to mean the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a TPA or PBM.

As noted above, the negotiated rate can be one of several different rates and can fluctuate on a daily basis depending on the terms of the contract between plans or issuers (or the PBM for the plan or issuer) and the provider, which

[191] The Departments note that this discussion in the preamble to the proposed rules occurred in the context of the third content element (negotiated rates) for the internet-based self-service tool. However, as negotiated rates were a proposed content element for the machine-readable files, the Departments are of the view that the comments received regarding negotiated rates in the context of the internet-based self-service tool are equally applicable to the prescription drug disclosures plans and issuers are being required to make through the machine-readable files. The definition of ''negotiated rate'' for prescription drugs applies to both the internet-based self-service tool and machine-readable file provisions. Regarding the machine-readable files, the Departments proposed that plans and issuers be required to include in-network negotiated rates and out-of-network allowed amounts for all covered items and services. In the Departments' view, the use of the same term regarding both requirements underscores the relevance of these comments to all disclosure requirements applicable to items and services, including those applicable to prescription drugs. Furthermore, several commenters did not clearly separate their comments regarding the internet-based self-service tool and the machine-readable files and provided broad comments that applied to all relevant sections of the proposed rules.

includes pharmacies and other prescription drug dispensers. Therefore, the Departments clarify that, where a plan or issuer uses a formula as described above to determine the rate that will be used to reimburse providers for a prescription drug, the negotiated rate that should be included in the Prescription Drug File should be the rate that would be used by the plan or issuer to reimburse providers on the date that the file is extracted.

Notably, the final rules do not finalize a requirement to include the manufacturer list price, as contemplated in the proposed rules. The manufacturer list price is a manufacturer-specified metric for drug prices that is commonly used by both Federal and commercial health care programs as a benchmark for negotiated rates. The manufacturer list price in this context is often the WAC, which is defined in statute as, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of pricing data with respect to a drug or biological.[192]

Like negotiated rates, the list price does not include discounts, dispensing fees, rebates, or other retrospective pricing adjustments. The manufacturer list price is not plan- or issuer-specific. If the Departments were to require plans and issuers to include the manufacturer list price in the Prescription Drug File, the information included in the files would be the same or similar across all plans and issuers. Further, manufacturer list price information is already aggregated, available through several companies, and could be incorporated into third party applications to be made accessible to consumers. WAC prices for drugs and biologics are collected and published by several companies, including First Databank and Medi-Span. Additionally, CMS publishes a monthly National Average Drug Acquisition Cost (NADAC), which provides a national benchmark for the prescription drug prices paid by retail pharmacies.[193] Because information on manufacturer list prices would be largely redundant across plans and issuers, and because this information is publicly available through other existing resources, the Departments concluded this information would be of limited value for the public.

The Departments do not intend to increase the burden of developing and maintaining the machine-readable files unless the inclusion of the additional data element is essential to provide meaningful, transparent pricing information to the public. Inclusion of the manufacturer list price would not significantly advance transparency as this information is already available publicly, and it would increase the burden of developing the Prescription Drug File. The Departments expect that third-party developers will access and incorporate publicly available databases, such as those including manufacturer list pricing information, where that information is relevant to providing meaningful information to consumers.

The Departments are of the view that it is important for transparency for negotiated rates to be included in the Prescription Drug File. Consumers, both insured and uninsured, can use this information to better understand the cost of prescription drugs and to advocate for less expensive alternatives. The Departments are also of the view that making the negotiated rate public in a manner that is highly visible to consumers, researchers, innovators and regulators could potentially place pressure on manufacturers to lower their list prices, which could, in turn, lower negotiated rates upon which consumer cost-sharing liability is based.

Nonetheless, as stated in this preamble and in the preamble to the proposed rules, requiring disclosure of only the negotiated rate for prescription drugs could perpetuate the lack of transparency surrounding prescription drug pricing. As commenters noted, the negotiated rate is not generally tied to the amount a plan or issuer will ultimately pay for the prescription drug or prescription drug service due to the use of post-point-of-sale rebates, discounts, and other price concessions that reduce the price that plans and issuers pay for prescription drugs. To address this issue and to introduce greater transparency surrounding prescription drug pricing, in response to comments, the Departments are also finalizing a requirement that plans and issuers must publicly disclose historical net prices, as discussed in detail below.

Prescription Drug Historical Net Price Disclosure

For purposes of the final rules, historical net price means the retrospective average amount a plan or issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. Net price is the price for a prescription drug after discounts are deducted, and is paid at different points in the prescription drug distribution chain (for example, the plan or issuer to the pharmacy, the pharmacy to a wholesaler, and the wholesaler to the manufacturer).[194] For the purposes of the final rules, the Departments are concerned with the price ultimately paid by a plan or issuer to a drug manufacturer.[195] Essentially, rebates, discounts, chargebacks, fees, and other additional price concessions are adjustments made after the point-of-sale that affect the total price paid by the plan or issuer (or through a contract with the PBM) to the manufacturer for a prescription drug product. As a general matter, a price concession is a discount or rebate available to a purchaser of a product or service, wherein the discount or rebate is conditioned upon the purchaser complying with the contractual terms of the rebate or discount offer.[196] More specifically, a rebate is an amount that the prescription drug manufacturer returns to a payer based on utilization by consumers enrolled through a plan or issuer or based on purchases by a provider.[197] A chargeback is a type of discount process through a prescription drug wholesaler where manufactures reimburse wholesalers who offer drugs to purchasers at discounted prices, and the discount negotiation occurs between the manufacturer and the purchaser.[198] Finally, fees include any payment adjustments, incentives, or other discounts that are not included in the negotiated price for a drug (for example, prompt pay discounts, pharmacy network fees, performance-based fees, and incentive fees).[199] The Departments

[192] 42 U.S.C. 1395w–3a(c)(6).

[193] ''National Average Drug Acquisition Cost.'' Centers for Medicare & Medicaid Services. September 15, 2020. Available at: *https://data.medicaid.gov/Drug-Pricing-and-Payment/NADAC-National-Average-Drug-Acquisition-Cost-/a4y5-998d.*

[194] ''AMCP Guide to Pharmaceutical Payment Methods, 2013 Update'' Academy of Managed Care Pharmacy. 2013. Available at: *https://www.amcp.org/sites/default/files/2019-03/Full-Pharmaceutical-Guide-%283.0%29.pdf.*

[195] The Departments note that each plan or issuer (or the PBM acting under contract with the plan or issuer) may utilize a different combination of price concessions.

[196] ''AMCP Guide to Pharmaceutical Payment Methods, 2013 Update. Academy of Managed Care Pharmacy. 2013. Available at: *https://www.amcp.org/sites/default/files/2019-03/Full-Pharmaceutical-Guide-%283.0%29.pdf.*

[197] *Id.*

[198] *Id.*

[199] ''Final Medicare Part D DIR Reporting Requirements for 2017.'' Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-May-30th.*

note that manufacturers also may offer additional price concessions to certain providers or directly to consumers in the form of coupons. The final rules only require disclosure of reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer (or the PBM under contract with the plan or issuer).

As noted earlier, several commenters commented on the nature of the prescription drug pricing information that should be captured to achieve the goals of price transparency. Some commenters noted the net price would be important to price transparency efforts because it would put consumers on notice when the net price is less than their cost-sharing amount and it would capture the actual prices of prescription drugs after the application of price concessions, which would provide transparency regarding actual prescription drug costs. The Departments agree with these commenters that disclosure of information about the net price for prescription drugs (and therefore rebates and other price concessions that are included in the net price) is necessary to achieve the goals of the final rules.

Therefore, the final rules adopt a requirement to make public a historical net price, as defined by the final rules. Furthermore, rather than require disclosure of the actual net price, the final rules establish and adopt a definition of historical net price that balances the need for transparency against concerns expressed by other commenters that release of net prices could affect issuers and PBMs' ability to negotiate drug prices, including rebates and other price concessions. Specifically, the final rules define historical net price as the retrospective average amount a plan or issuer paid an in-network provider, including any in-network pharmacy or other prescription drug dispenser, for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug or prescription drug service. The Departments note that for the purposes of the final rules, the definition of historical net price only includes those price concessions received by the plan or issuer (or under the contract between the PBM and the plan or issuer). Because of timing delays related to application of rebates, discounts, chargebacks, fees, and other price concessions, plans and issuers are required to provide historical or retrospective data, rather than prospective or current pricing data regarding the net price of prescription drugs. In the case prescription drug net prices, historical data will provide valuable information for stakeholders, as the actual prices plans and issuers ultimately pay for prescription drugs cannot be known until after the application of time-delayed rebates, discounts, chargebacks, fees, and other price concessions. As discussed later in this section, plans and issuers will be required to include historical net prices for a 90-day period beginning 180 days before the date a particular Prescription Drug File is published. The final rules also require the historical net price, as defined earlier in this section, to be disclosed through the Prescription Drug File.

As discussed earlier in this preamble, the Departments are aware that an estimated allocation of rebates, discounts, chargebacks, fees, and any other additional price concessions may be necessary to represent the historical net price. Product-specific and non-product specific rebates, discounts, chargebacks, fees, and other price concessions must be allocated by dollar value if the total amount of the price concession is known to the plan or issuer at the time of file publication. It is the Departments' understanding that most discounts, such as those related to market sharing and rebates based on volume, are calculated within time periods as short as one to three months. Therefore, the Departments expect the total amounts for these types of discounts, rebates, and other price concessions will be known at the time of file publication. Where the total amount of a price concession is known at the time of file publication, plans and issuers must allocate the price concession by the total dollar amount.

The Departments also understand that some product-specific and non-product specific price concessions are based upon outcomes- or value-based payment arrangements that calculate rebates over a longer period of time—usually six months to more than three years. Because these price concessions will not be known at the time of file publication, the Departments are requiring plans and issuers to estimate the historical net price using a reasonable allocation and good faith estimate of the total concession amount. Therefore, if the total amount of the price concession is not known to the plan or issuer at the time of file publication, then rebates, discounts, chargebacks, fees, and other price concessions should be reasonably allocated using an estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period.

Rebates may reflect discounts negotiated with drug manufacturers that lower drug prices for the plan or issuer. Rebates may not directly benefit participants, beneficiaries, or enrollees, however, as the decision of whether and how to share savings from rebates is at the discretion of the plan or issuer. Nonetheless, there is evidence that rebates are positively correlated with increased manufacturer list prices for prescription drugs, which is typically the basis for a consumer's cost-sharing liability.[200] A recent analysis found that, on average, from 2015 to 2018, a $1 increase in rebates was associated with a $1.17 increase in manufacturer list prices.[201] Therefore, due to the positive correlation between rebates and manufacturer list prices, a policy that results in a reduction to rebates may result in a reduction in the manufacturer list price (and also overall prescription drug prices). A policy that requires plans and issuers to make public historical net prices could expose the extent of rebates and other price concessions, and this transparency in historical net price could cause a reduction in the use of rebates and other price concessions, and, therefore, a reduction in the manufacturer list price.[202] The resulting reductions in manufacturer list price could lead to lowered out-of-pocket costs for both uninsured consumers who must pay the manufacturer list price and insured consumers with deductibles and coinsurance. Because negotiated rates for prescription drugs are largely based upon the manufacturer list price, the reduction in the manufacturer list price will likely be reflected in the negotiated rate. Further, because negotiated rates are used to determine cost-sharing liability for prescription drugs, a reduction in such rates will likely result in lower consumer costs through a reduction to deductibles and coinsurance.

The Departments are of the view that requiring both the negotiated rate and the historical net price, as defined by the final rules, will produce sufficient transparency regarding prescription drug pricing information to support consumer health care purchasing

[200] Sood, N., et al. ''The Association Between Drug Rebates and List Prices.'' U.S.C. Schaeffer Center for Health Policy and Economics. February 11, 2020. Available at: *https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/*.

[201] *Id.*

[202] *Id.*

decisions and provide other stakeholders insight into actual prescription drug pricing. Inclusion of both the negotiated rate and historical net price addresses the Departments' concern, expressed in the preamble to the proposed rules, that merely requiring disclosure of the rate that is used to determine an individual's cost-sharing liability (that is, as clarified in the final rules, the negotiated rate) could perpetuate the lack of transparency in prescription drug pricing.

Additionally, in the preamble to the proposed rules, the Departments specifically solicited comment on whether and how the public disclosure requirements should account for rebates, discounts, and dispensing fees to ensure individuals have access to meaningful cost-sharing liability estimates for prescription drugs.[203] Upon review of the comments, the Departments are of the view that public disclosure of the historical net price, which takes into account rebates, discounts, dispensing fees, and other price concessions, in addition to the negotiated rate, upon which cost sharing is based, provides the appropriate combination of pricing information to achieve the goals of transparency and ensure that individuals have access to meaningful prescription drug pricing information. First, the negotiated rate will help support consumer health care purchasing decisions. Second, the historical net price will support the public in gaining enhanced knowledge of actual drug prices. Enhanced knowledge of actual drug historical net prices could also support consumer health care purchasing decisions, as consumers could use the information to determine whether their out-of-pocket costs are commensurate with the rebates, discounts, and other price concessions received by their plan or issuer. The historical net price will also make consumers and other stakeholders aware of situations where cost-sharing liability for a prescription drug exceeds the amount their plan or issuer ultimately paid for the prescription drug. In these situations, participants, beneficiaries, and enrollees will be able to make an informed decision regarding whether to utilize their plan or coverage when purchasing the prescription drug. Furthermore, plans and issuers could be incentivized to pass through a larger or more significant share of the rebates and other discounts that they receive from drug manufacturers if those discounts are effectively disclosed via historical net price information.

[203] 84 FR 65464, 65472 (Nov. 27, 2019).

The Departments acknowledge that there are potential adverse consequences of requiring plans and issuers to make public rebates and other price concessions, directly or indirectly, through the historical net price. For instance, stakeholders such as PBMs and prescription drug manufacturers could attempt to find ways to obscure rebates and other price concessions such that they would not be required to be publicly disclosed under the final rules. However, the Departments are of the view that such attempts would likely be discouraged by the nature of the disclosures themselves and would otherwise be unsuccessful if attempted. A benefit of requiring the widespread public disclosure of pricing information for prescription drugs is that the transparency data itself can be used to identify where plans and issuers (or third parties acting on their behalf) may be attempting to circumnavigate disclosure requirements. Researchers and other entities who aggregate and analyze the data will be able to compare pricing data across plans and issuers. This can help identify plans and issuers whose data is an outlier and identify them for further scrutiny by regulators. The current lack of transparency in prescription drug pricing does not allow this type of oversight and monitoring. While it is possible that stakeholders will act in ways that conflict with the intent of the public disclosures, it is also very likely that transparency itself will help state and local regulators to identify these anti-competitive practices. Indeed, it is possible that the public disclosures could help to uncover other unknown anti-competitive business practices that exist today. For these reasons, the Departments are of the view that the benefits of public disclosure of prescription drug pricing information outweigh the potential risk that certain stakeholders may seek to take advantage of the disclosure requirements in ways that would increase prescription drug costs.

A commenter observed that if the Departments were to include the net price, it would be important to clarify that that the information is not necessarily predictive of future transactions because information about rebates is not known with certainty before a drug is dispensed. The Departments recognize that prospective net prices for prescription drugs could be complicated to estimate accurately due to the nature of prescription drug pricing. Nonetheless, the Departments are of the view that the historical net price will be a sufficiently accurate guide for potential prescription drug prices and will fulfill the objectives of the final rules.

The final rules adopt a requirement to include in the Prescription Drug File the historical net price over a 90-day reporting period for each NDC for dates of service within 180 days of the Prescription Drug File publication date. This approach will ensure that data is composed of the historical net price for relatively recent claims (rather than older claims from multiple time periods) and will avoid the conflation of payments from different periods of time. The Departments are of the view that historical net prices from defined periods of time will enable users to make meaningful comparisons across plans and coverages. Additionally, the Departments chose this reporting reference period to be consistent with the period proposed and being finalized through the final rules for reporting of allowed amounts through the Allowed Amounts File. The Departments are of the view that consistency across machine-readable file requirements, where applicable, will reduce potential confusion among file users as well as reduce burdens for plans and issuers. The Departments are of the view that the 180-day lookback period (which is expected to capture many of the market-share and volume rebates and other price concessions) and requirement to make a reasonable allocation will balance the need to be transparent in current prices with the delayed timing of the application of certain rebates and other price concessions.

To reasonably allocate any particular non-product specific or product-specific rebate, discount, chargeback, fee, or other additional price concession by dollar value of the drug where the totals amount is fully known at the time of file publication, plans and issuers should divide the rebate or discount amount by the total dollar value of drugs on which the rebate is calculated, and then apply that percentage to all applicable drugs. For example, if a rebate amount of $20,000 is received during the 3-month file reference period in connection with $100,000 in sales on two drugs during the same period, the rebate is allocated as a 20 percent discount to the prices of those two drugs. Sales for Drug A totaled $60,000 and sales for Drug B totaled $40,000. A rebate of $12,000 ($60,000 multiple by 20 percent) is allocated to Drug A, resulting in a historical net price populated in the Prescription Drug File of $48,000. Similarly, a rebate of $8,000 is allocated to Drug B, resulting in a historical net price populated in the Prescription drug file of $32,000. The Departments are

aware that this allocation methodology will not always perfectly allocate the rebate amounts because of the complexities of rebate calculation, or because of timing issues. However, the Departments are of the view that this simplified approach balances the goal of providing actionable drug pricing information to the public while limiting the burdens on plans and issuers in producing the information.

To reasonably allocate any particular non-product specific or product-specific rebate, discount, chargeback, fee, or other additional price concession where the total amounts are not fully known at the time of file publication, plans and issuers must make a good faith, reasonable estimate of the price concession using an historical adjustment amount. To make this estimate, plans and issuers shall determine the average value of price concessions for the relevant product over a time period prior to the current reporting period and of equal duration to the current reporting period and use that amount to apply an estimated adjustment amount in the current reporting period. For example, Plan X has $100,000 in total sales for 20,000 units—averaging $5 per unit—of Drug A during the current reporting period, which is January 1, 2020, through March 31, 2020. However, Plan X will not know the total amount of product-specific rebate to expect for sales of Drug A for at least another six months. To address this timing issue, Plan X can apply a reasonable estimate to allocate an adjustment to the current reporting period. For instance, Plan X can look back to the total rebates received for the product during a comparable time period. In this example, Plan X reviews its historical data and determines the rebates received for Drug A, from the period between January 1, 2019, and March 31, 2019, totaled $10,000 for sales of 30,000 units totaling $160,000. The average price per unit was $5.33 and the average discount per unit was $0.33 resulting in an average final net price of $5 for Drug A. Plan X then applies this historical rebate percentage to the current reporting period for Drug A. Plan X subtracts $6,250 ($100,000 total sales for the current reporting period multiplied by the estimated 6.25 percent historical rebate percentage) from the $100,000 total sales for a total net price of $93,750 and an average net price for Drug A, rounded to the nearest hundredth, of $4.69. Plan X reports in the Prescription Drug File an average historical net price for Drug A of $4.69 for the current reporting period.

In the discussion of the Allowed Amounts File in the preamble to the proposed rules, the Departments noted that providing the Allowed Amounts information could raise health privacy concerns. The Departments are of the view that similar concerns could be raised regarding the historical net price information in the Prescription Drug File. For example, there may be instances—such as in a small group plan or with respect to an NDC for a rare chronic condition—where, through deduction, disclosure of historical net price information may enable users to identify the participant, beneficiary, or enrollee who received a particular prescription drug because a very small number of claims are used to derive the historical net price of a particular NDC at a particular pharmacy or other prescription drug dispenser. Additionally, as noted in relation to the Allowed Amount File, there may also be instances when the historical net price public disclosure requirement would be inconsistent with Federal or state laws governing health information that are more stringent than HIPAA regarding the use, disclosure, and security of health data that was produced pursuant to a legal requirement, such that plans and issuers would be required to further de-identify data. For example, some of the claims for payment used to derive the historical net price could relate to services provided for substance use disorders, which could implicate disclosure limitations under 42 CFR part 2 governing the confidentiality of patient records related to treating a substance use disorder. The Departments are committed to protecting PHI. To address privacy concerns, the final rules adopt an approach consistent with the out-of-network Allowed Amount File. The final rules do not require plans and issuers to provide historical net price data in relation to a particular pharmacy or other prescription drug dispenser and a particular NDC when compliance would require a plan or issuer to report an historical net price for a particular pharmacy or other prescription drug dispenser calculated with fewer than 20 different claims for payment. Furthermore, the Departments note that disclosure of historical net prices will not be required if compliance would violate applicable health information privacy laws. The Departments are of the view that these mitigation strategies, in addition to the historical net price being an average of amounts paid to a particular provider for a particular NDC during the reference period, are sufficient to protect patients from identification based on information in the Prescription Drug File. The Departments note that the low volume exemption applies only to the requirement to include the historical net price and does not affect the requirement to include the negotiated rates in the Prescription Drug File.

Regarding prescription drugs, the Departments received a comment that requested discounts under section 340B of the PHS Act be included in the applicable machine-readable file, noting that providing this information is important to ensure consumers can access those savings. However, this commenter acknowledged that health plans often do not have access to information about when a section 340B discount is paid and so recommended the Departments develop and implement a process to help health plans identify this information.

Discounts under the section 340B Drug Pricing Program are only available to eligible providers (known as covered entities as outlined in section 340B of the PHS Act) and regulations under section 340B of the PHS Act are outside of the scope of the final rules.

2. Required Method and Format for Disclosing Information to the Public

As explained in section II.C.1.c of this preamble, the final rules adopt the requirement that plans and issuers produce the In-network Rate File, the Allowed Amount File, and the Prescription Drug File. The Departments are finalizing a requirement that the In-network Rates, Allowed Amounts, and Prescription Drug Files must be disclosed as machine-readable files. The final rules define ''machine-readable file'' to mean a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost. The requirement ensures that the machine-readable file can be imported or read by a computer system without those processes resulting in alterations to the ways data and commands are presented in the machine-readable file. The Departments proposed to require each machine-readable file to use a non-proprietary, open format to be identified by the Departments in technical implementation guidance (for example, JavaScript Object Notation (JSON), Extensible Markup Language (XML), or Comma Separate Value(s) (CSV)). A portable document format (PDF) file, for example, would not meet this definition due to its proprietary nature.

Contemporaneous with the proposed rules, the Departments published a PRA package (OMB control number: 0938–1372 (Transparency in Coverage (CMS–

10715)) that further described the specific data elements that would be disclosed in the proposed machine-readable files. Updated cost and burden estimates related to the collection requirements are discussed in the ICR section of this preamble and are included in in the corresponding PRA package, including changes to costs and burdens and additional collection instruments as a result of modifications to the proposed rule made through the final rules.

The Departments proposed requiring group health plans and health insurance issuers to publish their negotiated rates and historical allowed amount data in two machine-readable files, one including required negotiated rate data with in-network providers, and a second including required out-of-network allowed amount data. The Departments proposed requiring plans and issuers to publish the data in two separate machine-readable files to account for the dissimilarity between the negotiated rates paid to in-network providers under contract and the more variable allowed amounts paid to out-of-network providers. The Departments solicited comment on whether building and updating one file could be less burdensome for plans and issuers than maintaining multiple files, and whether having the data in a single file could facilitate use by third-party developers. The Departments were particularly interested in comments regarding whether a single file for disclosure of all the required information would likely be extremely large, making it less than optimal for anticipated users, such as software application developers and health care researchers.

Some commenters supported keeping the In-network Rates File and out-of-network Allowed Amount File separate. One commenter noted the structure would allow quick development of data aggregation efforts and consumer-friendly tools. Additionally, the commenter stated that keeping the files separate would support file ingestion. Another commenter stated that each file would contain fundamentally different data, and the costs associated with storing and maintaining a large combined file would be very large.

The Departments agree that the information being required to be publicly disclosed through the machine-readable files related to negotiated rates and allowed amounts is sufficiently distinct to justify separating the information into separate files. In particular, the out-of-network allowed amounts information must be derived from historical claims data, which is fundamentally different in kind from simply listing applicable rates for each service. Furthermore, the Departments also agree with comments indicating that splitting the files would help reduce the maintenance and storage burdens of the files. Throughout this preamble, the Departments have stressed the importance of ensuring the public disclosures required through the final rules are accessible, especially to internet-based and mobile application developers, to support development of innovative consumer-facing tools, as well as to other entities, such as researchers, and regulators, to support efforts to better understand and support the competitiveness of health care markets.

The requirement to publish more than one machine-readable file which will facilitate the disclosure of data that is different in character, scope, and other factors, which will help facilitate data ingestion for users of the machine-readable files, including third-party developers, researchers, regulators, and other interested parties. This approach will also help facilitate file ingestion, data aggregation, and data analysis by researchers whose projects could lead to important market insights that could inform efforts to further address the wide variation in health pricing, and by regulators who would be able to leverage the data in their oversight activities.

As discussed earlier in this preamble, the final rules adopt a third Prescription Drug File in recognition of the unique pricing attributes of prescription drug products. Prices related to prescription drug products that plans and issuers would have been required to include in the In-network Rate File under the proposed rules will now be required to be publicly disclosed through the third Prescription Drug File. As discussed earlier in this preamble, the Departments estimate that requiring a third file for prescription drugs will not add significantly to the burdens and costs of developing and maintaining the machine-readable files calculated in relation to the final rules because costs and burdens calculated for prescription drugs as included in the In-network Rate File will be transferred to the Prescription Drug File. Additionally, the Departments anticipate that removal of prescription drugs from the In-network Rate File will significantly reduce the size of that file, which could reduce the costs associated with maintenance and storage for the In-network Rate File. The Departments clarify that not all prescription drug pricing information required to be disclosed through the final rules is required to be included in the Prescription Drug File. Rather, the Prescription Drug File is required to include prescription drug pricing information for in-network providers, including pharmacies and other prescription drug dispensers, while the Allowed Amount File is required to include prescription drug pricing information for out-of-network providers, including pharmacies and other prescription drug dispensers. The Departments also clarify that the In-network Rate file may also contain prescription drug information to the extent the prescription drug is a part of a bundled payment arrangement.

Some commenters argued that the method and format for providing information to the public is not feasible. One commenter did not support the policy that the machine-readable files should be provided in a public use file format, claiming the files would be millions of rows long and very difficult to review. Another commenter expressed concern that the volume of data would make it impossible to post all of the information in two files and further stated that there is no single set of codes that describe every item or service, so it would be impossible to post this data without very specific, standard definitions. Given the lack of standard definitions, this commenter argued that there is no systematic way to compile and display the information requested, so claim compilation would have to be done manually. The commenter further stated that, even if there were standard definitions, it would be impossible to provide them in ''plain language.''

Based on consultations with industry and IT development professionals, the Departments do not agree with commenters who stated that development of the machine-readable files would not be feasible as envisioned by the proposed rules. The Departments are aware that these files could be very large and could be difficult for laypersons to navigate. However, the Departments are of the view that the files' primary benefit to health care consumers will be the availability of web-based tools and mobile applications developed for consumer use by third-party developers, aggregation and analysis conducted by researchers, and oversight efforts by regulators. The required machine-readable files will be optimal for ingestion, data aggregation, and data analysis, all of which are functions performed by third-party internet-based developers, researchers, and regulators who use large data sets in a manner that will lead to benefits for consumers. Additionally, notwithstanding that the Departments have designed these

transparency requirements so that it is not necessary that individual consumers use or ingest the data in the machine-readable files, the Departments are of the view that many individual health care consumers do possess the necessary expertise to access and navigate the files. The final rules also impose a requirement to include plain language to identify each item and service included in each file. This requirement will help ensure consumers, third party application developers, researchers, regulators, and other interested parties are able to easily understand the information.

The Departments have determined that the potential benefits for consumers of requiring the disclosure of required data through machine-readable files outweigh the potential for consumer confusion at the individual consumer level. Additionally, the Departments expect that third party application developers, researchers, regulators, and other file users will have the expertise to aggregate, standardize, and interpret the pricing information included in the file and translate the pricing information into products, research, and market oversight and reforms that will ultimately benefit consumers.

The Departments also do not agree that the volume of data would make the machine-readable files too large to post publicly, regardless of whether the data is posted in two or three files. The Departments' rough estimate of file size, based, in part, upon numbers provided by commenters, suggests a file size of approximately 5 gigabytes.[204] CMS currently makes available for download on its website some large public use file (PUF) data sets that are several gigabytes. For example, the Part D Prescriber PUF, [205] available on the CMS website, is over three gigabytes in size. The Departments acknowledge that because of the large file size, file users will likely need to use database or statistical software to download the machine-readable files as importing into Microsoft Excel would result in incomplete loading of data. However, this approach is similar to that used for some of the larger PUF data sets available on the CMS website, including the Part D Prescriber PUF, which must be opened using specialty software.

Assuming that plans' and issuers' negotiated rates are in a digitized format, even if the negotiated rates are not stored in a single database, this information can be systematically compiled and maintained by the plan or issuer. In recognition that there is no single set of billing codes for non-prescription drug services, the Departments are providing flexibility in the final rules by not prescribing which code or set of codes plans and issuers must use to publicly disclose their data. Rather, the Departments are requiring that plans and issuers associate each in-network applicable rate or out-of-network allowed amount with a CPT, HCPCS code, DRG, or other common payer identifier. In the case of prescription drugs, the Departments are requiring plans and issuers to associate each negotiated rate and historical net price with an NDC. The Departments' expectation is that the type of billing code plans and issuers use to populate the machine-readable files will be consistent with the billing codes that plans and issuers use in their operations when actually determining provider reimbursement and cost-sharing liability.

The Departments further note that nothing prevents plans and issuers from including in the files a mixture of billing code types so long as the billing codes included in the file are reflective of the plan's or issuer's operations. To facilitate identification of the billing code type, there will be an indicator in the file format described by the technical implementation guidance that will allow plans and issuers to specify the particular type of billing code entered for each data entry in the machine-readable files. The final rules also require that plans and issuers include plain language descriptions for each billing code. The Departments note that in the case of items and services that are associated with common billing codes (such as the HCPCS codes), plans and issuers are permitted to use the codes' associated short text description.

The final rules further clarify that, in the case of NDCs for prescription drugs, the plain language description must be the proprietary and nonproprietary name assigned to the NDC by the FDA. The Departments have made this change to align with the change to require only the NDC billing code to be used for prescription drugs. Requiring the proprietary and nonproprietary name assigned to the NDC by the FDA further standardized the product identifiers for prescription drugs and will facilitate comparisons across prescription drug pricing information for plans and issuers.

For all other items and services, as the Departments explicitly stated in the proposed rules and elsewhere in this preamble, plans and issuers can meet the ''plain language'' description requirements by using their chosen code's short text description. However, the Departments note that including the short text description for each code is a minimum requirement and nothing in the final rules prevents plans and issuers from providing a more consumer-friendly plain language description for each covered item or service. Plans and issuers may be incentivized to provide more consumer-friendly information in machine-readable files because it may permit them to include disclaimer or clarifying language in the files, where applicable. Furthermore, if a plan or issuer uses plain language descriptions for billing codes in its operations that are more consumer-friendly than the established short text descriptions, the Departments expect plans and issuers to include in the machine-readable files the plain language descriptions they use in their operations.

The Departments received comments that supported the Departments' development of specific technical standards for the files to which plans and issuers must adhere. One commenter recommended the Departments provide guidance to plan sponsors who are able to provide some, but not all, of the file data elements. Another commenter stated that the proposed rules do not make clear how to report items and serviced provided through capitated and bundled payment arrangements in the files; noting that this information is necessary for consumers to measure provider value. One commenter responded positively to the Departments' provision of technical implementation guidance for the files, but requested a robust public comment solicitation far in advance of the applicability date for the rules.

The Departments are of the view that providing specific technical direction in separate technical implementation guidance, rather than in the final rules, will better enable the Departments to respond to technical issues and developments, as well as compliance questions related to novel or rare payment arrangements. Therefore, as proposed, the Departments are developing technical implementation guidance for plans and issuers to assist them in developing the machine-readable files.

The technical implementation guidance will be available online

[204] As a reference point, a typical commercial two-hour Blu-ray film is approximately 15–25 gigabytes. ''White Paper Blue-ray Disc Format General.'' Blue-ray Disc Association. 2018. Available at *http://www.blu-raydisc.com/Assets/Downloadablefile/White_Paper_General_5th_20180216.pdf.*

[205] The Part D Prescriber Public Use File (PUF) is available on the CMS website at the following location: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/PartD2017.*

through GitHub, a website and cloud-based service that helps developers store and manage their code, as well as to track and control changes to their code. The GitHub space offers the Departments the opportunity to collaborate with industry, including regulated entities, and third-party developers to ensure the file format is adapted for reporting of the required public disclosure data for various plan and contracting models. For example, the Departments have updated the schematics of the file formats in response to comments received about and bundled payments and capitated payment arrangements, as well as other alternative contracting models. Plans and issuers will be able to access the GitHub schemas at any time and collaborate with the Departments in real-time.

The Departments' goal in using GitHub is to facilitate this collaborative effort all allow plans and issuers to meet the public disclosure requirements of the final rules while addressing their unique IT system, issuer, and plan attributes. To the extent a plan or issuer's unique attributes (for example, IT system, plan benefit design, or reimbursement model) are not addressed sufficiently through the technical implementation guidance, the Departments intend to provide targeted technical assistance to ensure all plans and issuers are able to meet the public disclosure requirements under the final rules. The technical implementation guidance will provide instructions on how to obtain this technical assistance should the need arise.

The technical implementation guidance hosted on GitHub will include a repository set of schemas describing the data formats (encoded as JSON, XML, and CSV) for all three machine-readable files: The In-network Rate File, the Allowed Amount File, and the Prescription Drug File. The technical implementation guidance will be available as part of the PRA package developed for the ICRs included in the final rules. As part of the PRA process, stakeholders have an additional opportunity to submit comments related to the PRA for 30 days following the publication of the final rules.

In the proposed rules, the Departments requested comment on whether the final rules should adopt a single non-proprietary format for the machine-readable files, specifically JSON files. The Departments understand that this format generally is easily downloadable, and it could simplify the ability of file users to access the data.

The Departments received one comment in support of requiring JSON as the standardized file format for the required machine-readable files. However, the Departments' internal technical experts agreed that the speed of technology developments weighs heavily in favor of maintaining flexibility to adopt a suitable file format as a non-substantive, operational requirement that will be identified in the relevant implementation guidance for the required machine-readable files. Additionally, this flexibility will allow the Departments to adapt the file technical specifications for new and emerging technologies. Therefore, the Departments decline to require in regulation a more specific file format for the machine-readable files.

The Departments reiterate that, as finalized, all machine-readable files must conform to a non-proprietary, open-standards format that is platform-independent and made available to the public without restrictions that would impede the re-use of the information. Therefore, because a PDF file format is proprietary, it would not be an acceptable file format in which to produce the files. A plan or issuer's file will be acceptable so long as it includes all required data elements required for the respective file (that is, all applicable rates in the In-network Rate File, allowed amounts and billed charges in the Allowed Amounts File, and negotiated rates and historical net process in the Prescription Drug File) and is formatted in a manner consistent with the technical implementation guidance the Departments are developing.

The final rules therefore adopt, with modification, the required method and format for disclosure of information through the machine-readable files. The Departments note several non-substantive modifications to the regulatory text, which are being adopted in the final rules to clarify and streamline the text. To further highlight the file technical implementation guidance, the regulation text of the final rules has been modified non-substantively to specify that the machine-readable files must be made available in a form and manner specified in guidance issued by the Departments. In the proposed rules, the regulation text stated more broadly that the machine-readable files must be made available in a form and manner determined by the Departments. Additionally, the proposed rule included two sentences that simply restated what must be publicly disclosed through the two proposed machine-readable files.[206] The Departments have removed these sentences from this this section of the regulatory text because they duplicate language contained in the previous sections of the regulatory text, do not add any additional value to this section of the regulatory text, and could cause confusion.

3. Required Accessibility Standards for Disclosure of Information to the Public

The Departments proposed to require a plan or issuer to make available on an internet website the required machine-readable files, and that the files must be accessible free of charge, without having to establish a user account, password, or other credentials, and without having to submit any personal identifying information such as a name, email address, or telephone number. The Departments also proposed to allow plans and issuers flexibility to publish the files in the locations of their choosing based upon their superior knowledge of their website traffic and the places on their website where the machine-readable files would be readily accessible by the intended users. The Departments are finalizing these requirements as proposed. The Departments also considered requiring plans and issuers to submit the internet addresses for the machine-readable files to CMS, and having CMS make the information available to the public. A central location could allow the public to access the information in one centralized location, reducing confusion and increasing accessibility. However, the Departments opted to propose flexible rules allowing plans and issuers to publish the files in the locations they have chosen based upon their determinations regarding where the files will be most easily accessible by the intended users. The Departments also considered that requiring plans and issuers to notify CMS of the internet address for their machine-readable files would increase the burdens on plans and issuers. The Departments requested comment on whether the proposed requirement to allow issuers to display the files in the location of their choice is superior to requiring plans and issuers to report the internet-based addresses of their files to CMS for public display. The Departments were specifically interested in whether the burden associated with reporting file locations to CMS would be outweighed by the risk that members of the public would be unable to easily locate plans' and issuers' machine-readable files.

Several commenters supported the Departments' proposal to make the machine-readable files easily and publicly available. One commenter

[206] *See* 84 FR 65464, 65519 (Nov. 27, 2019).

supported making the files available free of charge and stated that individuals should not be required to register a user account, password, or enter other credentials, or to submit PII to access the files. Several commenters suggested alternative methods or more stringent requirements for making public the information required to be disclosed through the machine-readable files. One commenter expressed a preference for CMS to maintain a centralized location on the CMS website from which the public can access links to the files. The commenter noted that if the Departments elected not to maintain a centralized database, the Departments should require plans and issuers to prominently display a link to the files in the main menu of the homepage on their respective websites. Similarly, another commenter asserted that the final rules should require issuers to report the location of their files and provide a data dictionary to facilitate oversight and enforcement of plans and issuers.

Other commenters suggested the Departments create a centralized database to house the data required to be disclosed through the machine-readable files. One commenter recommended the information required to be disclosed through the files be loaded into a publicly available searchable database that anyone can access prior to receiving a medical service. Similarly, another commenter recommended that HHS aggregate the data to create a centralized database. By contrast, another commenter recommended the Departments should not create a central location for negotiated rate information and historical data, making the argument that the private sector is best suited to deliver this information to consumers.

As proposed, the machine-readable files must be made publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of PII to access the file. Additionally, the proposed rules specified that the files must be made available in the form and manner specified by the Departments. While the Departments considered comments related to the manner of the public file disclosures (such as prominent display on a plan or issuer's homepage), the Departments are also mindful of the need to provide flexibility to plans and issuers so that they are able to house the files in a location that meets their unique technical specifications. At this time, the Departments are of the view that reporting of the links to the file locations is not necessary to achieve the goals of the final rules. However, the Departments note that nothing in the final rules prevents a Federal or state regulatory body, such as a state Department of Insurance (DOI), from collecting this information from issuers subject to their jurisdiction.

The Departments are aware and understand commenters' interest in HHS aggregating and centralizing all of the data required to be publicly disclosed through the machine-readable files. However, the Departments are of the view that HHS is not best suited for this role. As noted throughout this preamble, the Departments expect making negotiated rate and allowed amount information available through the machine-readable files will spur third-party internet-based developers to innovate, resulting in consumer-facing tools. The Departments anticipate that these consumer-facing tools developed by third parties could act as centralized databases, aggregating the pricing information for many plans and issuers. The Departments are of the view that the private sector is better suited to developing internet-based tools using this information than the Departments, and further, that the competition spurred by several different third parties operating in this space could benefit consumers seeking to find the third-party tool that is best suited to their individual consumer needs.

The final rules adopt, as proposed, the accessibility requirements for the machine-readable files. The final rules clarify that the accessibility requirements apply to all three machine-readable files finalized within the final rules: The In-network Rate File (referred to in the proposed rules as the Negotiated Rate File), the Allowed Amount File, and the Prescription Drug File.

4. Required Timing of Updates of Information To Be Disclosed to the Public

The proposed rules would have required group health plans and health insurance issuers to update the information required to be included in each machine-readable file monthly. The Departments also proposed to require plans and issuers to clearly indicate the date of the last update made to the In-network Rate Files and Allowed Amount Files in accordance with guidance issued by the Departments.

The Departments recognized in the proposed rules that information in In-network Rate Files (referred to in the proposed rules as the Negotiated Rate Files) could change frequently and considered whether to require plans and issuers to update their In-network Rate Files more often than monthly to ensure that consumers have access to the most up-to-date negotiated rate information. Accordingly, the Departments sought comment on whether the final rules should require plans' and issuers' In-network Rate Files to be updated more frequently. The Departments also sought comment on an alternate proposal that would require plans and issuers to update negotiated rate information within 10 calendar days after the effective date of new rates with any in-network provider, and on whether the update timelines for negotiated rate information and historical out-of-network payment data should be the same.

For the reasons discussed elsewhere in this section of this preamble, the final rules adopt, as proposed, the requirement for a plan or issuer to update the information required to be included in each machine-readable file monthly. The final rules clarify that this requirement to update the machine-readable files monthly applies to all three machine-readable files being finalized through the final rules: The In-network Rate File, the Allowed Amount File, and the Prescription Drug File.

Several commenters stated that the requirement to update the In-network Rate Files and Allowed Amount Files monthly is operationally burdensome and the benefits of this requirement are limited because the information will not change significantly on a monthly basis. Some commenters recommended the Departments change the required frequency of updates to every six months, while others suggested that the final rules require updates to the In-network Rate File less frequently than monthly (for example, quarterly or semi-annually), but recommended that the Allowed Amount File should be updated monthly. Another commenter recommended a phased-in approach where the files would be updated twice a year in the first year of implementation and quarterly thereafter. In contrast, one commenter recommended the files be updated in real-time as soon as updates to rates are made.

Based on consultation with government-affiliated IT experts and the design of the file schemas, the Departments are of the view that building the first machine-readable file will facilitate the automation of the process to build future files. In other words, the ability to produce subsequent files should be streamlined after completing initial development. Therefore, the Departments do not find

persuasive the contention that requiring file updates monthly will significantly increase the overall costs and burdens related to producing the files. The Departments, however, do not agree that the files should be updated in real-time as soon as updates are made. With the monthly update requirement, the Departments are seeking to balance the need to ensure the data is current and accurate for consumers with minimizing burdens on plans and issuers.

As noted in the proposed rules, the Departments acknowledge there will be some costs with making updates to the files, including costs to ensure the quality of data and costs associated with posting the information on a public website. The Departments are of the view that requiring plans and issuers to update the files on a monthly basis will sufficiently limit the burden while ensuring that the most current data generally available. However, requiring updates to the files more or less frequently would not adequately balance these interests. Requiring updates to the files more frequently (such as on a daily basis), would add potentially unnecessary burdens for plans and issuers. Requiring updates to the files less frequently would potentially result in consumers relying on outdated information for health care purchasing decisions. While negotiated rates, in particular, may not change frequently for any one contract with a provider or group of providers, the Departments understand that payer-provider contracts are updated on a rolling basis and throughout the year. Therefore, updates throughout the year are needed in order to ensure that the information disclosed remains up-to-date.

The final rules also require that the Prescription Drug File be updated on a monthly basis. The Departments understand the complexities of prescription drug pricing and are aware that drug prices can fluctuate as frequently as daily. However, the Departments have determined that aligning the frequency of updates of all machine-readable files will mitigate the burden associated with maintaining the files for plans and issuers, and will best balance the need for disclosing current and accurate information against that burden. The Departments are aware that the number of pricing updates in the monthly Prescription Drug File will likely be more than the number of monthly pricing updates for medical services in the In-network Rate File. However, the Departments are of the view that if plans and issuers can update their pharmacy claims processing systems in real-time to account for fluctuating prices and adjudicate claims for prescription drugs, then the burden to pull current pricing information into the Prescription Drug File should be manageable.

The Departments will monitor the implementation of the machine-readable file requirements and consider updates in future rulemaking if it is determined that monthly updates are not adequately balancing the need for accurate and current information against the burdens for plans and issuers.

5. Special Rules To Prevent Unnecessary Duplication and Allow for Aggregation

Similar to the proposed cost-sharing information disclosure requirements for participants, beneficiaries, and enrollees, the Departments proposed a special rule to streamline the publication of data that would be included in the proposed machine-readable files. This special rule has three components: One for insured group health plans where a health insurance issuer offering coverage in connection with the plan has agreed to provide the required information, another for plans and issuers that contract with third parties to provide the information on their behalf, and a special rule allowing aggregation of out-of-network allowed amount data.

a. Insured Group Health Plans

The Departments proposed that, to the extent coverage under a group health plan consists of group health insurance coverage, the plan would satisfy the proposed machine-readable file requirements if the issuer offering the coverage were required to provide the information pursuant to a written agreement between the plan and issuer. Accordingly, if a plan sponsor and an issuer enter into a written agreement under which the issuer agrees to provide the information required under the proposed rules, and the issuer fails to provide full or timely information, then the issuer, but not the plan, has violated the final rule's disclosure requirements. This special rule would only apply, however, to insured group health arrangements where the contractually-obligated issuer is independently subject to the final rules.

The Departments received comments expressing strong support of the special rule to streamline public disclosure and avoid unnecessary duplication of disclosures for insured group health insurance coverage. These commenters recommended the policy be retained in the final rules. Accordingly, the final rules retain this special rule as proposed.

b. Use of Third Parties To Satisfy Public Disclosure Requirements

The Departments recognize that self-insured group health plans may rely on written agreements with other parties, such as service providers, to obtain the necessary data to comply with the final rules' disclosure requirements. Furthermore, it is the Departments' understanding that most health care coverage claims in the U.S. are processed through health care clearinghouses and that these entities maintain and standardize health care information, including information regarding negotiated rates and out-of-network allowed amounts.[207] As a result, the Departments noted in the proposed rules that a plan or issuer may reduce the burden associated with making negotiated rates and out-of-network allowed amounts available in machine-readable files by entering a business associate agreement and contracting with a health care claims clearinghouse or other HIPAA-compliant entity to disclose this data on its behalf.[208] Accordingly, the Departments proposed to permit a plan or issuer to satisfy the public disclosure requirement of the proposed rules by entering into a written agreement under which another party (such as a TPA or health care claims clearinghouse) will make public the required information in compliance with this section. However, if a plan or issuer chooses to enter into such an agreement and the party with which it contracts fails to provide full or timely information, the plan or issuer will have violated the final rules' disclosure requirements.

Generally, commenters supported the use of clearinghouses or TPAs to store all of the information that must be disclosed under the proposed rules. One commenter suggested that all HIPAA-compliant third parties, not just clearinghouses, be allowed to satisfy the public disclosure requirements. Some commenters raised concerns related to using clearinghouses noting that the feasibility of using clearinghouses is dependent on the clearinghouse receiving all of the necessary data from health insurance issuers and providers who possess the data. The commenter strongly recommended the final rules require entities that possess the data to

[207] The Departments are adopting the definition of health care clearinghouse under 45 CFR 160.103 for purposes of these rules. Under that definition, health care clearinghouse means a public or private entity that performs one of two functions that involve the receiving and processing of health information data from a non-standard format to a standard format or non-standard data elements to standard data elements and vice versa.

[208] 45 CFR 164.502(a)(3) and 164.504(e)(2).

share the information in a timely manner with the relevant clearinghouses. The commenter also noted the costs charged by clearinghouses associated with data storage and noted that the prices must be reasonable and not discriminatory (for example, against smaller plans).

Several commenters recommended the Departments' special rule include protection for plan sponsors if they fail to meet the public disclosure requirements due to an inability, while acting in good faith, to obtain the data from a third-party service provider or when a contracted third-party withholds information or fails to submit information in a timely manner. One of these commenters also requested the Departments establish a policy that liability for failure to comply rests with a contracted third party in the event a plan sponsor can show that, acting in good faith, it is unable to comply with the disclosure requirements due to withholding of information by the third party.

This special rule, as finalized, continues to permit a plan or issuer to satisfy the public disclosure requirements of 26 CFR 54.9815–2715A3(b), 29 CFR 2590.715–2715A3(b), and, 45 CFR 147.212(b) of the final rules by entering into a written agreement under which another party (such as a TPA or health care claims clearinghouse) will make public the required information in compliance with this section. The final rules identify TPAs and health care claims clearinghouses as examples of the types of parties a plan or issuer may contract with, but these are not the only types of entities that may enter into such arrangements and the Departments expect that they will comply with any applicable privacy protection requirements, including applicable privacy protections under HIPAA.

Plans and issuers are not required to enter into such agreements in order to comply with the public disclosure requirements of the final rules. As the Departments noted in the preamble to the proposed rules, if a plan or issuer chooses to enter into such an agreement it is ultimately the responsibility of the plan or issuer to ensure that the third party provides the information required by the final rules. As noted earlier in this section, the special rule for insured plans is only available to plans that contract with an entity that is an issuer separately subject to final rules. This requirement ensures that the Departments retain a mechanism to enforce the final rules. Accordingly, this special rule relating to the use of third parties to satisfy these requirements continues to provide that the plan or issuer would violate the requirements of the final rules if the third party fails to provide full or timely information.

Another commenter recommended the Departments create a special rule or ''safe harbor'' for plans that are unable to disclose negotiated rate information due to antitrust laws, which prevent the plan from accessing information about its partners' contracts when engaged in a partnership alliance agreement. The commenter described a partnership alliance as shared partner networks in other geographic areas in order to meet the needs of multi-state employer groups.

As discussed earlier in this preamble, the Departments acknowledge that the Sherman Antitrust Act prohibits any contract, combination, or conspiracy in restraint of trade or commerce.[209] Specifically, the law prohibits any ''person'' from entering into any such contract, trust, or similar arrangement.[210] Nothing under the proposed or final rules creates, compels, or endorses agreements or conspiracies between or among persons to form illegal arrangements or trusts in restraint of trade or commerce. Antitrust law does not proscribe or limit action by the Federal Government, to improve competition and lower costs to consumers, even if these actions may involve disclosures that, if made by private parties under a collusive agreement, might invite antitrust scrutiny.[211] Because the Departments are of the view that antitrust law will not prevent plans and issuers from making the public disclosures required under the final rules, there is no need for the Departments to create a special rule for plans that are unable to disclose negotiated rate information due to antitrust laws.

One commenter expressed a concern that multiemployer plans generally do not have access to the rate information needed to provide the cost-sharing disclosures required under the proposed rules, yet plans could be subject to significant penalties for failure to comply. The Departments note that insured multiemployer plans would qualify for the special rule for insured plans under which an issuer providing coverage for a plan enters into an agreement to provide the required information, which is being finalized through the final rules. If a multiemployer plan sponsor enters into a written agreement with an issuer under which the issuer agrees to provide the information required under the final rules, and the issuer fails to provide full or timely information, then the issuer, but not the plan, has violated the transparency disclosure requirements and may be subject to enforcement mechanisms applicable to plans under the PHS Act.[212] Therefore, insured multiemployer plans that contract with an issuer to provide the information required under the final rules would not be subject to enforcement actions under this mechanism; rather, the issuers with whom they have contracted will be subject to enforcement action under the final rules for failure to meet the transparency disclosure requirements.

Under the second special rule, multiemployer plans may also contract with a TPA or other third party (for example, a clearinghouse) to meet the transparency disclosure requirements under the final rules. However, this commenter is correct that if a plan or issuer chooses to enter into such an agreement, and the party with which it contracts fails to provide full or timely information, the plan or issuer would violate the transparency disclosure requirements.

The notion that accountability for compliance rests with a plan or issuer when the issuer or plan enlists a contractor or vendor for a business function is not inconsistent with other applicable regulations.[213] While claims processing is the main function for which an issuer or plan has contracted in this example, other responsibilities, such as responding to Federal audits and report requirements, may fall within the scope of the duties required by contract. The Departments clarify that nothing in the final rules prevents an issuer or plan from ensuring contracts with TPAs or other third parties include clear terms specifying functions required to meet the disclosure requirements of the final rules, as well as establish service level agreements and performance metrics to hold the entities with whom the issuer or plan decides to contract accountable.

Because multiemployer plans may be able to take advantage of the special rules established under the proposed rules, the Departments do not view additional special considerations necessary to address the ability of such

[209] 15 U.S.C. 1.

[210] *Id.*

[211] For example, *see* 84 FR 65464, 65464–65 (Nov. 27, 2019).

[212] Section 2723 of the PHS Act.

[213] For example, plans remain liable for violations of claims regulations under 26 CFR 54.9815–2719 and 29 CFR 2590.715–2719; and QHPs issuers who contract with downstream or delegated entities must maintain compliance with all applicable standards under 45 CFR 156.340(a).

plans to comply with the transparency requirements of the final rules.

c. Aggregation for Allowed Amount Files

In order to further mitigate privacy concerns and to eliminate unnecessary duplication, the Departments proposed to permit plans and issuers to satisfy the public disclosure requirements of the proposed rules by making available out-of-network allowed amount data that has been aggregated to include information from more than one plan or policy. As previously discussed, a plan or issuer may satisfy the disclosure requirement by disclosing out-of-network allowed amounts. Accordingly, under such circumstances, the proposed rules would have permitted plans and issuers to aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract.

To the extent a plan or issuer provided aggregated out-of-network allowed amount information, the Departments proposed to apply the minimum claims threshold to the aggregated claims data set, but not at the plan or issuer level. Based on commenters' requests for clarification, the Departments have determined that the proposed approach to apply the minimum claims threshold to the full aggregated claims data set could undermine the goal of the minimum claims threshold. The out-of-network Allowed Amount File must include a unique plan identifier for each plan or coverage included in the file under 26 CFR 54.9815–2715A3(b)(1)(ii)(A), 29 CFR 2590.715–2715A3(b)(1)(ii)(A), and 42 CFR 147.212(b)(1)(ii)(A). Therefore, even if the data for each plan or coverage were to be aggregated for purposes of determining whether the minimum claims threshold applies to a particular covered item or service, the data in the Allowed Amounts File would be distinguishable at the level of the plan identifier. The Departments are of the view that this could be problematic if all plans or coverage included in an aggregated Allowed Amount File meet the minimum claim threshold for an item or service when combined, but some or all individual plans do not independently meet the minimum claim threshold of 20 claims.

For instance, data for two plans are aggregated in the same Allowed Amount File under this rule. Plan A has 20 claims for Service X, while Plan B only has six claims for Service X. In aggregate, the plans meet the 20-claim threshold with 26 total claims for Service X. However, individually, only Plan A has met the minimum claim threshold. Under the proposal, data for Service X would be required to be included for both Plan A and Plan B, along with both the plan identifiers. The outcome of this requirement would be that Plan B would include data identifiable at the plan level for Service X. The Departments are of the view that allowing Plan B data to be included in the file for Service X would undermine the minimum claim threshold, increasing risk that individual patients' claims histories could be identified. To prevent this outcome, data for each plan or coverage included in an aggregated Allowed Amount File must independently meet the minimum claims threshold for each item or service and for each plan or coverage included in the aggregated Allowed Amount File. To highlight this requirement, the Departments are finalizing this provision of the proposed rules with a minor modification clarifying that the flexibility to aggregate out-of-network allowed amounts for more than one plan or coverage in a single machine-readable file is still subject to the minimum claims threshold applicable to individual plans or coverage as described under paragraph (b)(1)(ii)(C) of the same section.

One commenter requested clarification of a plan's obligation if a third party aggregates the Allowed Amount File. The commenter specifically requested clarification regarding whether the plan or third party would be responsible for posting the file, and whether there will be any special labeling requirements for an aggregated file, including if the file will need to include a disclosure that it includes aggregated data.

Nothing in the final rules prevents the Allowed Amount File from being hosted on a third-party website or prevents a plan administrator from contracting with a third party to post the file. The Departments have added text to the final rules to make clear that this flexibility exists and to provide that if a plan chooses not to also host the file separately on its own public website, it must provide a link on its website to the location where the file is publicly available. The Departments will provide additional information on the form and manner, including labeling, through the file technical implementation guidance.

III. Overview of the Final Rule Regarding Issuer Use of Premium Revenue Under the Medical Loss Ratio Program: Reporting and Rebate Requirements—The Department of Health and Human Services

As stated in the preamble to the proposed rules, consumers with health insurance often lack incentives to seek care from lower-cost providers, for example when consumers' out-of-pocket costs are limited to a set copayment amount regardless of the costs incurred by the issuer. Innovative benefit designs can be used to increase consumer engagement in health care purchasing decisions. HHS proposed to allow issuers that empower and incentivize consumers through the introduction of new or different plans that include provisions encouraging consumers to shop for services from lower-cost, higher-value providers, and that share the resulting savings with consumers, to take credit for such ''shared savings'' payments in their MLR calculations. HHS believes this approach preserves the statutorily-required value consumers receive for coverage under the MLR program, while encouraging issuers to offer new or different plan designs that support competition and consumer engagement in health care.

Formula for Calculating an Issuer's Medical Loss Ratio (45 CFR 158.221)

Section 2718(b) of the PHS Act requires a health insurance issuer offering group or individual health insurance coverage (including grandfathered health insurance plans) to provide rebates to enrollees if the issuer's MLR falls below specified thresholds (generally, 80 percent in the individual and small group markets and 85 percent in the large group market). Section 2718(b) of the PHS Act generally defines MLR as the percentage of premium revenue (after certain adjustments) an issuer expended on reimbursement for clinical services provided to enrollees and on activities that improve health care quality. Consistent with section 2718(c) of the PHS Act, the standardized methodologies for calculating an issuer's MLR must be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.

Several states have considered or adopted legislation over the last few years to promote health care cost transparency and encourage issuers to design and make available plans that ''share'' savings with enrollees who shop for health care services and choose to obtain care from lower-cost, higher-value providers.[214] In addition, at least five states and a number of self-insured group health plans have incorporated such ''shared savings'' provisions into

[214] 24–A Maine Rev. Stat. Ann. Sec. 4318–A (adopted Jun. 19, 2017); Neb. Rev. Stat. Sec. 44–1401 *et seq.* (adopted Apr. 23, 2018); Utah Code Ann. Sec. 31A–22–647 (adopted Mar. 19, 2018); AZ SB 1471 (2018); N.H. HB 1784–FN (2018); MA H2184 (2017).

all or some of their health plans.[215] Under some plan designs, the savings are calculated as a percentage of the difference between the rate charged by the provider chosen by the consumer for a medical procedure and the average negotiated rate for that procedure across all providers in the issuer's network. Under other plan designs, the ''shared savings'' are provided as a flat dollar amount according to a schedule that places providers in one or more tiers based on the rate charged by each provider for a specified medical procedure. Under various plan designs, the ''shared savings'' may be provided in form of a gift card, a reduction in cost sharing, or a premium credit. HHS is of the view that such unique plan designs would motivate consumers to make more informed choices by providing consumers with tangible incentives to shop for care at the best price. As explained elsewhere in the preamble to the proposed rules, there is ample evidence that increased transparency in health care costs would lead to increased competition among providers.[216] HHS is of the view that allowing flexibility for issuers to include savings they share with enrollees in the numerator of the MLR would increase issuers' willingness to undertake the investment necessary to develop and administer plan features that may have the effect of increasing health care cost transparency, which in turn could lead to reduced health care costs.

HHS has in the past exercised its authority under section 2718(c) of the PHS Act to take into account the special circumstances of different types of plans by providing adjustments to increase the MLR numerator for ''mini-med'' and ''expatriate'' plans,[217] student health insurance plans,[218] as well as for QHPs that incurred Exchange implementation costs [219] and certain non-grandfathered plans (that is, ''grandmothered'' plans).[220] This authority has also been exercised to recognize the special circumstances of new plans [221] and smaller plans.[222] Consistent with this approach, HHS proposed to exercise its authority to account for the special circumstances of new and different types of plans that provide ''shared savings'' to consumers who choose lower-cost, higher-value providers by adding a new paragraph 45 CFR 158.221(b)(9) to allow such ''shared savings'' payments to be included in the MLR numerator. HHS made this proposal so that issuers would not be required to pay MLR rebates based on a plan design that would provide a benefit to consumers that is not currently captured in any existing MLR revenue or expense category. HHS proposed that the amendment to 45 CFR 158.221 would become effective beginning with the 2020 MLR reporting year (for reports filed by July 31, 2021). HHS invited comments on this proposal.

After considering the public comments, HHS is finalizing the amendment to 45 CFR 158.221(b) as proposed.

The majority of comments on the proposed amendments to the MLR program rules supported the proposal to add a new paragraph to 45 CFR 158.221(b). Supporters noted that allowing issuers to include ''shared savings'' payments in their MLR calculation aligns issuer and enrollee incentives, aligns with MLR's purposes, is innovative, provides enrollees with value, increases consumer engagement and empowerment, and will promote better enrollee decision-making and reduce total health care costs. Several supportive commenters also noted that the proposal may encourage more issuers to offer such ''shared savings'' programs, as allowing ''shared savings'' payments to be included in the MLR numerator will remove any existing barriers to such programs and facilitate the use of innovative benefit designs that increase consumer engagement in health care purchasing decisions, while disallowing this approach punishes issuers that offer innovative ''shared savings'' programs and disincentivizes issuers from adopting such programs. Several commenters stated that there is evidence that patients are more likely to shop for care when information on prices is coupled with incentives, and that such shopping can generate significant savings for issuers and lead health care providers to lower their prices in order to remain competitive in the marketplace.[223]

HHS agrees with the comments in support of the proposal and is finalizing this amendment as proposed to provide additional flexibility to states and issuers and encourage the economic effects the commenters highlighted.

Some commenters requested clarification regarding certain aspects of the ''shared savings'' plans. Several commenters requested that HHS develop uniform standards and a definition for ''shared savings,'' which according to commenters would, among other things, help prevent fraud and abuse; and that HHS clarify the criteria for low-cost, high-value providers. One commenter asked HHS to provide sub-regulatory guidance to specify in what form the savings can be shared, how issuers will report their ''shared

[215] *See* the State of Kansas' SmartShopper program for state employees enrolled with BCBSKS, available at: *https://healthbenefitsprogram.ks.gov/docs/default-source/site-documents/sehp/vendor-documents/bcbs/smartshopper_state_of_kansas_steps.pdf?sfvrsn=cfa4e44_8;* the state of Kentucky employee member handbook for Livingwell CDHP's SmartShopper program, available at: *https://personnel.ky.gov/KEHP/2020%20LivingWell%20CDHP%20Medical%20Benefit%20Booklet.pdf* and *https://www.smartshopper.com/legacy?utm_expid=.WJ_v45PuTXuo1k6ioPp4tA.1&utm;* the State of Massachusetts employee member handbook for Fallon Health Select Care's SmartShopper program, available at: *https://www.mass.gov/doc/fallon-select-care-handbook-fy21/download;* the State of New Hampshire employee medical benefit, the Site of Service and Vitals SmartShopper Programs, available at: *https://das.nh.gov/riskmanagement/active/medical-benefits/cost-savings-programs.aspx#vitals-smartshopper;* Utah Public Employees Health Program Cost Tools, available at: *https://www.pehp.org/save.*

[216] Austin, D. A., and Gravelle, J. G. ''Congressional Research Service Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector.'' Congressional Research Service. July 24, 2007.''Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf.*

[217] *See* 45 CFR 158.221(b)(3) for ''mini-med'' plans and 45 CFR 158.221(b)(4) for ''expatriate'' plans; *see also* the Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protections and Affordable Care Act; Interim Final Rule; 75 FR 74864, 74872 (Dec. 1, 2010).

[218] *See* 45 CFR 158.221(b)(5); *see also* the Student Health Insurance Coverage; Final Rule, 77 FR 16453, 16458–16459 (Mar. 21, 2012).

[219] *See* 45 CFR 158.221(b)(7); *see also* the Exchange and Insurance Market Standards for 2015 and Beyond; Final Rule; 79 FR 30240, 30320 (May 27, 2014).

[220] *See* 45 CFR 158.221(b)(6); *see also* 79 FR 30240, 30320 (May 27, 2014). *See* 45 CFR 158.221(b)(6); *see also* 79 FR 30240, 30320 (May 27, 2014); *see also* 45 CFR 158.221(b)(6); *see also* 79 FR 30240, 30320 (May 27, 2014). ''Grandmothered'' plans is a term for certain non-grandfathered coverage in the small group and individual health insurance markets. Since 2014, CMS has permitted, subject to applicable State authorities, health insurance issuers to continue certain coverage that could not otherwise remain in place without significant changes to comply with PPACA. Such health insurance coverage would not be treated as out of compliance with sections 2701–2707 and 2709 of the PHS Act and section 1312(c) of PPACA (group health plans must still comply with section 2704 and 270505 of the PHS Act). *See* Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies, available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Limited-Non-Enforcement-Policy-Extension-Through-CY2020.pdf* and *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2021.pdf.*

[221] *See* 45 CFR 158.121; *see also* 75 FR 74864, 74872–74873 (Dec. 01, 2010) and the HHS Notice of Benefit and Payment Parameters for 2018 Final Rule; 81 FR 94058, 94153–94154 (Dec. 22, 2016).

[222] *See* 45 CFR 158.230 and 158.232; *see also* 75 FR 74864, 74880 (Dec. 01, 2010).

[223] For example, one commenter shared that since 2015, its ''shared savings'' program issued over 149,000 incentive reward payments, generating over $85 million in savings. *See https://beta.regulations.gov/document/CMS-2019-0163-14320.*

savings,'' how double-counting can be prevented, and whether ''shared savings'' payments are taxable income. Other commenters suggested that HHS provide maximum flexibility for issuers and states to innovate and develop ''shared savings'' programs they determine are best suited for their populations.

While HHS appreciates these suggestions and is also concerned with preventing fraud and abuse, HHS is of the view that state legislators and regulators are currently in a better position than HHS to work with the issuers in their states to define the ''shared savings'' programs that they support, issue standards and criteria for the programs for their respective constituents, and decide in what form the savings can be made. These considerations include the operational details of any ''shared savings'' program, such as creating standards and definitions, developing acceptable payment methods, and addressing fraud concerns. HHS notes that several issuers have already developed and implemented such programs and that a few states have done the same. The amendment being finalized in this rulemaking is specific to the recognition of ''shared savings'' payments in issuer MLR calculations and is intended to encourage more state and issuer innovation with these types of programs. Accordingly, HHS will provide technical guidance in the MLR Annual Reporting Form Instructions to clarify the reporting of ''shared savings'' payments specifically for MLR purposes. With respect to the comment regarding how double-counting can be prevented, HHS notes that 45 CFR 158.170 prevents double-counting by requiring each expense to be reported in only one category or to be pro-rated between categories for MLR purposes. Finally, whether ''shared savings'' payments to enrollees are taxable will vary based on certain specific facts and circumstances. Some forms of ''shared savings'' may be taxable; however, HHS defers to the Department of the Treasury to address the taxability of such payments as necessary.

Opponents of the proposal stated that it fails to ensure that the savings are actually used for health care or quality improvement activities (QIA), that HHS is subverting the statutory scheme by allowing issuers to spend less on enrollees' care and quality initiatives without returning the premium dollars saved to all enrollees, and that the proposal would allow issuers to further boost profits and diminish the MLR standards and issuer accountability. Some opponents of the proposal argued that since any plan type can offer ''shared savings,'' adding a ''shared savings'' payment component to a policy does not make it a ''different'' type of plan and it should not be treated as such. Others were concerned that the proposal would incentivize issuers to artificially drive down negotiated rates with providers and that these savings may not make their way back to enrollees. One commenter opposed extending ''shared savings'' programs to self-insured ERISA plans. Another commenter pointed out that the National Association of Insurance Commissioners (NAIC) did not mention the proposal in its comments and the MLR statute provides that the NAIC shall establish the definitions and methodologies for MLRs.

HHS agrees that ''shared savings'' are neither an incurred claim nor a QIA. Instead, in support of this amendment to 45 CFR 158.221(b), HHS is relying on the statutory directive under section 2718(c) of the PHS Act that the MLR standardized methodologies shall be designed to take into account the special circumstances of different types of plans and newer plans, such as plans that offer ''shared savings'' payments to enrollees that seek care from lower-cost, higher-value providers. HHS believes that any issuer that includes in its plan design(s) a ''shared savings'' component is offering a ''different'' type of plan and a ''newer'' plan, as a ''shared savings'' program is a new and unique feature. HHS notes that the amendment finalized in these rules helps provide policyholders with value for their premium dollars, as intended by section 2718 of the PHS Act. HHS disagrees that the amendment somehow subverts the statutory scheme as issuers that implement these programs are sharing the savings and returning dollars to enrollees who participate in these programs, and issuers must still otherwise meet the applicable MLR threshold or provide a rebate to enrollees. For the same reasons, HHS does not share certain commenters' view that the amendment weakens the MLR standards and enables issuers to improperly boost profits, as the amendment simply allows issuers to account for the portion of the ''shared savings'' that is passed to participating enrollees and that consequently does not increase issuers' profits. With respect to comments regarding the impact on provider negotiated rates and enrollee access to savings, HHS is unsure how the amendment would incentivize issuers to artificially drive down negotiated rates with providers. However, if as a result of this amendment, provider rates decrease, such a result would in fact benefit enrollees. In addition, because only actual payments made to enrollees can be included in an issuer's MLR calculation under the amendment, issuers will benefit for MLR calculation and reporting purposes only if the savings are actually shared with enrollees. With respect to the comment regarding self-insured ERISA plans, HHS notes that this amendment does not apply to or impact, either self-funded ERISA plans, or self-funded non-ERISA plans, as these plans are not subject to the MLR reporting and rebate requirements under section 2718 of the PHS Act. Last, with respect to comments regarding the NAIC recommendations to HHS, section 2718(c) of the PHS Act directed the NAIC, subject to certification by the Secretary, to establish uniform definitions and standardized methodologies to guide MLR reporting and calculations. The NAIC met its statutory obligation when it provided recommendations to HHS in 2010 in the form of a model regulation.[224] The NAIC's recommendations informed the Secretary's decisions about the Federal definitions and methodologies for calculating MLRs.[225] In this rulemaking, HHS is taking further action to recognize the special circumstances of the different and newer plans that include ''shared savings'' programs with the addition of new paragraph (b)(9) to 45 CFR 158.221.

Some commenters expressed concerns that ''shared savings'' programs in general could actually compromise the quality of care by driving consumer choices based on cost without regard for quality, and that these programs could encumber and curtail medically necessary clinical services in serving the financial interest of the payer. Some commenters requested that HHS only allow ''shared savings'' where there is evidence that the participating enrollees actually receive better care at reduced costs. One commenter stated that the proposal fails to define higher-value, which varies based on each enrollee's circumstances. One commenter questioned the feasibility of measuring whether reward systems generate actual savings.

[224] ''Regulation for Uniform Definitions and Standardized Methodologies for Calculation of the Medical Loss Ratio for Plan Years 2011, 2012, and 2013 per section 2718(b) of the Public Health Service Act,'' MDL–190. Available at: *https://www.naic.org/store/free/MDL-190.pdf?4*.

[225] *See* the Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act; Interim Final Rule, 75 FR 74864 (Dec. 1, 2010); *see also* 45 CFR part 158.

HHS disagrees that programs that reward enrollees for critically examining their options and pursuing cost-effective care interfere with the provision of medically necessary clinical services. However, HHS agrees that quality as well as cost should be determinants of what qualifies for inclusion in any given issuer's ''shared savings'' program. That is why the amendment to 45 CFR 158.221 includes both a cost and quality component; it permits issuers to include in the MLR numerator ''shared savings'' payment made to enrollees choosing to obtain care from a lower-cost and higher-value provider. However, HHS did not propose and is not finalizing elements or criteria issuers must address or otherwise include in their respective ''shared savings'' programs. The amendment finalized in this rulemaking is specific to recognizing ''shared savings'' payments in issuer MLR calculations. As detailed above, HHS believes state legislators and regulators are currently in the best position to work with issuers in their states to develop standards and criteria for ''shared savings'' programs for their respective constituents. HHS further believes that issuers are in the best position to perform the necessary provider credentialing activities that will ensure that network providers that are included in their ''shared savings'' programs are high-value, high-quality providers. Since higher-value can vary by enrollee demographics and provider type, issuers must determine what this means for their enrollees and providers and maintain all documents and other evidence necessary to support that determination consistent with the maintenance of records requirements contained in 45 CFR 158.502. Issuers are sophisticated entities that understand that if their enrollees obtain lower-quality care, their costs over the long-term will increase rather than decrease as their enrollees will likely need additional and possibly corrective medical care. HHS therefore believes that issuers' incentives are aligned with those of their enrollees when it comes to designing ''shared savings'' programs.

HHS received a few comments urging that issuers be allowed to include some or all of the costs of implementing the requirements of these price transparency rules as a QIA in the numerator of the MLR calculation. A few commenters urged HHS to allow issuers to include some or all of the costs of creating the cost estimator tool required by the price transparency aspects of the proposed rules.

Price transparency implementation costs do not constitute an improvement to the quality of health care and thus do not qualify as QIA and cannot be included in the numerator of the MLR calculation.

Lastly, several commenters expressed support for or opposition to the MLR reporting and rebate requirements in general. HHS appreciates these comments but notes that they are outside the scope of the amendments to the MLR program rules contained in the proposed rule.

IV. Applicability

A. In General

1. Entities Subject to the Final Rules

The Departments proposed requiring group health plans, including self-insured plans, and health insurance issuers of individual and group health insurance coverage to disclose pricing information, with certain exceptions as discussed in more detail in this preamble. The Departments are of the view that consumers across the private health insurance market will benefit from the availability of pricing information that is sufficient to support informed health care decisions. Although the Departments considered making the requirements applicable to a more limited segment of the private health insurance market, the Departments are of the view that consumers across the market should receive and benefit from the same access to standardized, meaningful pricing information and estimates. Moreover, applied broadly, these changes have a greater potential to reform health care markets.

Additionally, the preamble to the proposed rules discussed how pricing information related to items and services that are subject to capitation arrangements under a specific plan or contract could meet transparency standards by disclosing only the consumer's anticipated liability. The Departments sought comment on whether there are certain reimbursement or payment models (such as ACOs or staff model HMOs) that should be partially or fully exempt from these requirements or should otherwise be treated differently. Further, the Departments sought comment on how consumers may become better informed about their cost-sharing requirements under these reimbursement or payment models.

The Departments also considered limiting applicability to issuers of individual health insurance coverage and insured group health insurance coverage, but concluded that limiting applicability would be inconsistent with section 2715A of the PHS Act. The Departments are concerned that a more limited approach might encourage plans and issuers to simply shift costs to sectors of the market where the final rules would not apply and where consumers have diminished access to pricing information. Additionally, the Departments are concerned that a more limited approach may distort the health care market by creating perverse incentives for plans and issuers to avoid participating in certain markets that require compliance with these requirements.

The Departments are aware that certain plans and health coverage are not subject to the transparency provisions under section 2715A of the PHS Act and, therefore, are not be subject to the final rules. This includes grandfathered health plans, excepted benefits, health care sharing ministries, and short-term, limited-duration insurance (STLDI).

Grandfathered health plans are health plans that were in existence as of March 23, 2010, the date of enactment of PPACA, and that are only subject to certain provisions of PPACA, as long as they maintain their status as grandfathered health plans under the applicable rules.[226] Under section 1251 of PPACA, section 2715A of the PHS Act does not apply to grandfathered health plans. Therefore, the proposed rules would not have applied to grandfathered health plans (as defined in 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140).

In accordance with sections 2722 and 2763 of the PHS Act, section 732 of ERISA, and section 9831 of the Code, the requirements of title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code do not apply to any group health plan (or group health insurance coverage offered in connection with a group health plan) or individual health insurance coverage in relation to its provision of excepted benefits. Excepted benefits are described in section 2791 of the PHS Act, section 733 of ERISA, and section 9832 of the Code. Section 2715A of the PHS Act is contained in title XXVII of the PHS Act, and, therefore, the proposed rules would not have applied to a plan or coverage consisting solely of excepted benefits.

The Departments also proposed that the rules would not apply to STLDI. Under section 2791(b)(5) of the PHS Act, STLDI is excluded from the definition of individual health insurance coverage and is therefore exempt from section 2715A of the PHS

[226] 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140.

Act.[227] Therefore, the proposed rules would not have applied to STLDI coverage.

The Departments also proposed that the rules would not apply to health reimbursement arrangements, or other account-based plans, as defined in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i), that simply make reimbursements subject to a maximum fixed dollar amount for a period, with the result that cost-sharing concepts are not applicable to those arrangements.

In contrast, the Departments proposed that the final rules would apply to grandmothered plans, meaning certain non-grandfathered health insurance coverage in the individual and small group markets with respect to which CMS has announced it will not take enforcement action even though the coverage is out of compliance with certain specified market requirements.[228] The Departments sought comment on whether grandmothered plans may face special challenges in complying with these transparency reporting provisions and whether the proposed rules should apply to grandmothered plans.

The final rules adopt these provisions as proposed. The final rules apply these requirements to group health plans, and health insurance issuers offering non-grandfathered group or individual health insurance coverage, with certain exceptions. Thus, the final rules apply to grandmothered plans. The Departments are finalizing, as proposed, that these requirements will not apply to certain plans and coverages that are not subject to the transparency provisions under section 2715A of the PHS Act, including grandfathered health plans, excepted benefits, and STLDI. Additionally, the final rules will not apply to health reimbursement arrangements, or other account-based plans, as defined in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i), as these account-based arrangements simply make certain dollar amounts available, with the result that cost-sharing and price setting concepts are not applicable to those arrangements.

The majority of commenters supported applying these requirements to issuers of individual health insurance coverage and group health insurance coverage, as well as group health plans. Commenters supported allowing consumers across the market to access important pricing information. Some commenters suggested additional plans and coverages that should be required to comply with these requirements, as discussed later in this preamble. The Departments did not receive comments regarding application of the final rules to grandmothered plans.

One commenter stated that the proposed rules would create an uneven playing field that would unfairly advantage plans and issuers offering stand-alone dental or vision coverage over plans that incorporate such benefits into major medical coverage. For example, the commenter stated that a plan offering essential health benefits would have to include in a machine-readable file negotiated rates for pediatric dental services. However, a plan offering stand-alone dental coverage would not have to publish pricing information. For these reasons, the commenter recommended that vision, dental, and hearing benefits, if offered as part of a plan or coverage subject to the transparency requirements, should be excluded from information disclosed through the internet-based self-service tool and machine-readable files.

In response to this comment, the Departments note that section 2721(b), (c)(1) through (3) of the PHS Act provides an exemption from title XXVII of the PHS Act for ''any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) *in relation to its provision of excepted benefits.*'' (*See also* section 732 (b), (c) of ERISA, and section 9831(b), (c) of the Code) (emphasis added).[229] To the extent that a plan or issuer provides a participant, beneficiary, or enrollee with the opportunity to opt out of limited scope dental or vision benefits, those benefits are considered as not an integral part of the plan and, accordingly, are considered excepted benefits.[230] Therefore, under the final rules, plans and issuers that offer excepted benefits, such as limited scope dental or vision benefits, along with their major medical coverage are not required to disclose the information required by the final rules regarding their provision of those excepted benefits. Accordingly, the final rules do not create an uneven playing field that would unfairly advantage plans and issuers offering stand-alone dental or vision coverage over plans that incorporate such benefits into major medical coverage.

The Departments received a mix of comments regarding whether the final rules should apply to alternative contracting and alternative payment model structures, such as ACOs or HMOs. One commenter recommended a narrower scope for ACOs and other capitated payment arrangements, including only requiring transparency tools to display amounts that are not service dependent (for example, flat copayments), as well as accumulator information about deductibles and out-of-pocket maximums. As discussed elsewhere in this preamble, some commenters expressed concern regarding how the final rules would apply to reference-based pricing models, direct primary care, bundled or capitated payment arrangements, and value-based insurance design. Additionally, some commenters expressed concern regarding how the final rules would apply to plans with rental networks and quality-adjusted and risk-adjusted contracts (under which prices can only be calculated after the fact). These commenters recommended that these kinds of arrangements be exempt from the final rules' requirements.

On the other hand, other commenters suggested that there is no justification for excluding plans that reimburse their providers based on capitation from the requirements of the final rules as this would result in an incomplete data set, and issuers of risk adjustment-covered plans already assign values to services to administer benefits with deductibles and co-insurance, for risk adjustment purposes under 45 CFR 153.710(c), and for internal reporting. One commenter recommended that the final rules should apply to ACOs and other capitated arrangements and that these arrangements should be required to disclose their underlying financial incentive arrangements, not just consumer's anticipated liability. The commenter also noted that any exemptions may incentivize plans to move to these pricing models, which the commenter characterized as opaque and potentially consumer-unfriendly. Several commenters agreed that pricing information related to items and services subject to capitation arrangements could meet transparency standards only through the disclosure of the consumer's anticipated liability.

Some commenters raised the concern that the proposed rules would have a particularly negative impact on smaller entities that are less likely to have the financial reserves and technological

[227] *See* 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103.

[228] Pate, R. ''Insurance Standards Bulletin Series.'' Centers for Medicare & Medicaid Services. January 31, 2020. Available at: *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2021.pdf.*

[229] *See also* section 2763 of the PHS Act.

[230] 26 CFR 54.9831–1(c)(3)(ii), 29 CFR 2590.732(c)(3)(ii), and 45 CFR 146.145(b)(3)(ii).

resources to build and maintain systems to operationalize disclosure requirements. Some commenters requested that the final rules be optional or that smaller plans and TPAs be exempted from the requirements. For example, a few commenters recommended providing an exception to the price transparency requirement for small issuers, TPAs, and plans with revenue below the $41.5 million small entity threshold or with 100,000 commercial participants, beneficiaries, and enrollees or fewer. They suggested that an exception to the final rules would allow small issuers to adopt elements of the requirements of most relevance to their participants, beneficiaries, and enrollees while not forcing them to create a much more expensive option that may be of limited appeal.

In considering these concerns, the Departments weighed the competing goals of ensuring that consumers have access to pricing information, the burden on plans, including self-insured plans, and issuers of individual health insurance coverage and group health insurance coverage, and encouraging innovative plan design. As finalized, all issuers of non-grandfathered individual and group health insurance coverage and self-insured plans (that are not account-based plans), are required to comply with the final rules. Finalizing these rules to be applicable to plans as proposed is the most straightforward approach as it is impossible to define and predict all possible modifications, plans, or models. Furthermore, doing so mitigates creating incentives to adopt certain plan designs over others. The Departments believe that this is not likely to stifle innovation. Rather, the Departments are of the view that this approach creates a level playing field for non-grandfathered individual and group health insurance coverage and self-insured plans (that are not account-based plans) to create innovative plan designs and increase consumers' access to pricing information that is sufficient to support informed health care decisions. The Departments are of the view that exempting plan designs, such as alternative contracting and alternative payment model structures, would create an opportunity for plans and issuers to avoid sharing important pricing information with consumers. The Departments maintain the view that consumers across the market should come to expect and receive the same access to standardized, meaningful pricing information and estimates for all plans affected by the final rules. In addition, as detailed earlier in this preamble, issuers of risk adjustment-covered plans that include capitation arrangements are required under the final rules to submit a derived amount, potentially using the same internal methodology the issuer uses to assign a price value to the item or service for purposes of submitting risk adjustment data under 45 CFR 153.710(c).

A few commenters supported exempting grandfathered health plans, HRAs or other account-based plans, excepted benefits, and STLDI from the proposed rules. However, a majority of commenters were concerned that the final rules, as proposed, would not apply to plans or arrangements that may have the highest potential cost-sharing obligations, such as STLDI and health care sharing ministries. These commenters were concerned that STLDI plans often have dollar limits on covered benefits, limits on prescription drug coverage and covered doctor visits, and excluded benefits, which often means consumers enrolled in these plans can face higher cost-sharing liability when seeking medical care than patients covered by individual health insurance coverage, as defined under section 2791(b)(5) of the PHS Act. They stated that it is even more important for these patients to have access to their cost-sharing liability under the final rules before receiving care or even signing up for a STLDI plan, so they are aware of their coverage limits and are prepared to receive bills from the hospital and other health care providers for amounts that exceed their coverage. One commenter stated that whether such plans are considered ''individual health insurance'' is not relevant for such a determination, as the proposed rules would not apply to just individual health insurance, but would also apply to group coverage and grandmothered plans.

The Departments appreciate the concerns raised by commenters regarding these plans. However, the final rules adopt these policies as proposed. As noted earlier in this section of this preamble, certain types of coverage and arrangements such as STLDI, excepted benefits and health care sharing ministries, are not subject to the transparency provisions under section 2715A of the PHS Act and, therefore, are not subject to the final rules. However, the Departments encourage all plans that are not subject to the final rules to work to increase the transparency and availability of pricing information, to enable consumers to make informed health care decisions.

One commenter sought clarification of the liability of individual employers concerning Multiple Employer Welfare Arrangements (MEWAs) and Taft-Hartley plans. Section 715 of ERISA incorporates section 2715A of the PHS Act into part 7 of ERISA. Generally, employers are only responsible for ensuring compliance with the requirements of ERISA for a Taft-Hartley plan (also known as a multi-employer plan), if they are a member of the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, or are otherwise a fiduciary of the plan. For MEWAs that are employee welfare benefit plans, the bona fide group or association that sponsors the MEWA assumes and retains responsibility for operating and administering the MEWA, including ensuring compliance with Part 7 of ERISA. In cases where the MEWA itself is not a plan, each employer that provides benefits through a MEWA and, therefore, maintains its own plan, is separately responsible for compliance with ERISA requirements, and thus with the requirements of the final rules.

Some commenters recommended adding additional plans and coverages to the list of health coverage not subject to these transparency requirements. One commenter recommended adding expatriate health plans because the Expatriate Health Coverage Clarification Act of 2014 exempts expatriate health plans from most of the provisions of PPACA, including sections 1311(e)(3) of PPACA and section 2715A of the PHS Act, both of which the Departments cite in asserting statutory authority to propose these transparency requirements. Another commenter recommended that Denominational Health Plans be specifically exempted from the final rules. This commenter noted that Denominational Health Plans can only offer coverage to a limited segment of the population—eligible employees in the denomination—based on church requirements, beliefs, and polity. Therefore, most of the individuals to which this information would be disclosed would not be eligible to enroll in these plans even if they wished to do so. Other commenters recommended extending the final rules to health coverage to which 2715A of the PHS Act does not apply. For example, a commenter recommended that the Departments add Medicaid Managed Care Organization plans and Medicare-Medicaid Plans to the list of health plans not subject to the transparency requirements. The commenter noted that the combination of Medicaid payment rates and low cost-sharing requirements limit the

usefulness of this information in the Medicaid context.

The Departments are finalizing the final rules as proposed and, therefore, all plans subject to section 2715A of the PHS Act must comply with these requirements. The Departments agree with commenters that sections 1311(e)(3) of PPACA and 2715A of the PHS Act do not apply to expatriate health plans [231] and, therefore, such plans are not subject to the requirements in the final rules. Furthermore, the Departments' authority for the final rules derive from section 2715A of the PHS Act, which only applies to group health plans and health insurance issuers offering group or individual health insurance coverage, and not Medicaid Managed Care Organization plans, Medicare-Medicaid Plans, and Denominational Health Plans.

Interaction of Final Rules With 45 CFR 156.220

The Departments recognize that health insurance issuers offering group or individual health insurance coverage as QHPs through an Exchange are already subject to reporting requirements under 45 CFR 156.220 that implement the transparency in coverage requirements of section 1311(e)(3) of PPACA. Pursuant to 45 CFR 156.220, issuers of QHPs offered through an individual market Exchange or a Small Business Health Options (SHOP) Exchange, including stand-alone dental plans, must submit specific information about their plans' coverage to the appropriate Exchange, HHS, and the state insurance commissioner, as well as make the information available to the public in plain language.

The Departments acknowledge the similar purposes served by 45 CFR 156.220 and the final rules. The Departments, however, note the final rules do not alter requirements under 45 CFR 156.220. Accordingly, QHP issuers must comply with both rules' requirements. If necessary and to the extent appropriate, HHS may issue future guidance to address QHP issuers' compliance with both 45 CFR 156.220 and the final rules.

2. Applicability Dates

Except as otherwise provided for in the proposed MLR requirements,[232] the Departments proposed that all the proposed requirements would become applicable for plan years (or in the individual market, policy years) beginning on or after one year after the finalization of the final rules. The Departments requested feedback about this proposed timing. In particular, the Departments were interested in information regarding the time necessary to develop cost estimation tools and machine-readable files. The Departments are finalizing a modified applicability timeline for the machine-readable files at 26 CFR 54.9815–2715A3, 29 CFR 2590.715–54.9815–2715A3, and 45 CFR 147.212. The requirements to publish the machine-readable files will become effective for plan years (or in the individual market, for policy years) beginning on or after January 1, 2022. The Departments, in response to comments, are finalizing an applicability date that is generally one-year later than the proposed applicability date for complying with the internet-based self-service tool requirements. Specifically, plans and issuers will be allowed to phase in the requirements at 26 CFR 54.9815–22715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211 regarding the items and services included in the internet-based self-service tool. Plans and issuers will be required to provide pricing information for a minimum of 500 items and services identified by the Departments beginning with plan years (or in the individual market, policy years) on or after January 1, 2023. Plans and issuers will be required to provide the pricing information through the internet-based self-service tool for all items and services by plan years (or in the individual market, policy years) beginning on or after January 1, 2024.

The Departments are finalizing applicability dates that do not tie applicability timelines to the beginning of plan years (or in the individual market policy years) that begin one year after the effective date of the rules, as proposed. Because most plan and policy years begin on January 1st, the Departments are of the view that this change in the applicability date likely will not shorten the amount of time plans and issuers have to comply with the machine-readable file requirements, as it has been the Departments' intent, including under the proposed rules, to require calendar year plans and policies to come into compliance with the final rules by January 1, 2022. The changed timeline is therefore unlikely to lead to increased burdens or costs. The Departments are finalizing a 3-year applicability timeline for the internet-based self-service tool requirements. Under the proposed rules, plans and issuers would have had to comply with all relevant proposed requirements beginning with plan or policy years beginning on or after January 1, 2023. Under the final rules, full compliance with all requirements associated with the internet-based self-service tool will not be required until plan or policy years beginning on or after January 1, 2024. For these reasons, the final rule's applicability dates for the self-service tool requirements are also unlikely to lead to increased burdens or costs.

Many commenters submitted comments regarding the proposed applicability date of the proposed rules. The majority of commenters strongly recommended delaying the proposed applicability date for the internet-based self-service tool and machine-readable file requirements of the rules for at least one year and up to five years from publication of the final rules.

Commenters recommended delaying the applicability date of the final rules because complying with the requirements will require negotiations with administrative service providers, and the design, building, and testing of websites. Other commenters cited the challenges in accessing some of the required information from third parties and the technical challenges plans will likely face as additional reasons to delay the applicability dates of these requirements. Additionally, commenters noted that the proposed rules would require disclosure of large volumes of data, which will have to be coordinated among various parties and for which systems will need to be put into place to ensure timely, accurate disclosure. Some commenters noted that a delay would be needed due to complex operational and compliance issues related to contracting with TPAs, ownership of data, and building and operating new IT systems.

Commenters also cited vendor supply/demand challenges; extensive technology design, development, and deployment work; amending agreements with third parties; financing required to meet the requirements of the final rules; and time needed to test the tools for consumer use as reasons to delay the applicability date. One commenter noted that their current price estimator tools took considerable time and resources to develop, and large portions of a tool's underlying logic or feature set may not be compatible with the approach envisioned in the proposed rules. Moreover, testing, evaluating, and resolving these types of issues will require significant investment in IT development, numerous iterations of quality assurance and consumer testing, extensive education and training for plan staff, and development of new consumer-facing materials, among other

[231] 42 U.S.C. 18014.

[232] As noted above, HHS proposed and finalized that the amendment to the MLR regulation will become effective beginning with the 2020 MLR reporting year (for reports filed by July 31, 2021).

challenges. Another commenter recommended that employers/plan sponsors should not have to comply with the final rules until the first day of the first plan year that is two years after the date on which the rules are published. Similarly, commenters requested a lengthy phase-in period to give employers, third parties, issuers, and health care providers time to modify their contractual agreements to provide all of the data the proposed rules would require to be disclosed.

A few commenters stated the Departments severely underestimated the time needed to implement the machine-readable files. The commenter noted that the timeline to implement the machine-readable files is very short, which could compromise the integrity of the files and lead to unintended consequences for consumers. Another commenter noted that, if not eliminated, the requirement to make machine-readable files available should be applicable no earlier than plan or policy years beginning three years after the date the rules are finalized.

As discussed in the economic impact analysis, the Departments are of the view that developing the machine-readable files should be straightforward for most plans and issuers and that plans and issuers will incur limited additional administrative burdens or costs after the one-time initial file development. The development activities needed to establish the machine-readable files involve gathering, formatting, and making publicly available already existing data that plans and issuers use in their everyday operations. Plans and issuers need to keep this information current for operational purposes, and the additional costs and burdens of ensuring that the machine-readable files are updated monthly is expected to decrease in subsequent years and ultimately become minimal, as the Departments expect plans and issuers to automate the updating and verification processes in the years following initial development.

The Departments are of the view that providing for a phased-in approach with regard to the number of items and services required for the internet-based self-service tool will provide more time for plans and issuers to plan for any increased costs, work with various vendors, perform user testing, and build appropriate technology to handle the disclosure of data through the internet-based self-service tool. Therefore, the final rules require plans and issuers to include in the internet-based self-service tool (and by request, through the paper method) 500 items and services identified by the Departments for plan years (in the individual market, for policy years) beginning on or after January 1, 2023, and all items and services for plan years (in the individual market, for policy years) beginning on or after January 1, 2024. The Departments are of the view that providing more time to implement the internet-based self-service tool while generally maintaining the timeline for the machine-readable files, strikes the appropriate balance between minimizing burdens for issuers and maximizing price transparency for the public. Providing information to the public through the machine-readable files sooner will also accelerate researchers' and third-party developers' access to pricing information and potentially provide additional resources and incentives for plans to build out their own consumer-tools.

Many commenters also encouraged the Departments to allow for a phased-in approach for the internet-based self-service tool and machine-readable files. Some commenters suggested finalizing a rule that allows for a phased-in approach for different group health plans and health insurance issuers of individual and group health insurance coverage to come into compliance with the final rules. Some commenters recommended finalizing a rule that allows for a phased-in approach by allowing smaller entities an extended implementation timeframe (*that is,* an additional 3 to 5 years) due to the disproportionate IT burden that will be placed on these smaller entities. Additionally, commenters were concerned that the rules may create a competitive advantage for larger issuers and TPAs.

A few commenters recommended that the rules be implemented in a more gradual fashion by requiring a price transparency tool that covers a narrower data set initially, for example, one that includes only the most common shoppable services. These commenters asserted that, over time, this scope could be broadened to be fully inclusive, but an initial narrow focus could increase the chance that patients have critical, actionable information as soon as possible.

Other commenters recommended a phased approach that would focus first on the functionality providing the most value to consumers to establish a baseline standard of price transparency across plans, while allowing time for the industry to solve more difficult technical challenges. Another commenter recommended allowing employers that have highly customized benefit structures additional time to implement the internet-based self-service tool. One commenter recommended allowing for a transition period for issuers and plans to use their current tools to meet the requirements.

A few commenters recommended including quality metrics. These commenters noted that requiring quality information in the disclosures would take additional time. In particular, one commenter was concerned that in the absence of quality data, price transparency could actually increase spending. The commenter therefore recommended delaying the implementation of the final rules until quality information, such as information related to patient satisfaction and experience, adherence to clinical standards and evidence-based medicine, and patient safety and clinical outcomes, could be incorporated. Another commenter stated that, if pharmacy quality information could be included, the Departments would need to provide for several years to transform existing consensus-based processes to identify appropriate quality metrics to include health plans serving different populations. Another commenter urged the Departments to perform a study on the effects of price transparency and the potential consequences on consumers seeking care to better understand how best to integrate quality information alongside prices to allow consumers to evaluate the services that best respond to their individual needs.

As the Departments explain in section II.C.1 of this preamble, government and private sector actors are working to develop and implement reliable and reasonable quality measures that can be applied to produce quality rating information that consumers may access and consider alongside pricing. As commenters acknowledged, delaying the final rules for the purpose of requiring the integration of quality information with price information would require several additional years. While the Departments appreciate the value of quality information to informed health care decision-making, the Departments are of the view that price transparency in health coverage must not be delayed for years when some quality information is already available or under development. Indeed, the Departments expect that the ready availability of pricing information will create greater consumer interest in quality information and other data relevant to health care decision-making, and that the market will respond to provide such information through innovative resources such as online tools and mobile applications. The Departments anticipate that innovators will seek ways to best present and

integrate pricing and quality data. However, the Departments also will consider what next steps are appropriate and feasible within the Departments' current authorities, including the possibility of conducting a study to evaluate how to best integrate quality information alongside prices. For these reasons and those noted earlier in this preamble, the Departments decline to require plans and issuers to include quality information in the disclosures required by the final rules.

The Departments are finalizing the applicability dates of the final rules as described earlier in this preamble. The Departments are of the view that the additional time and flexibility regarding the internet-based self-service tool will help address the concerns commenters raised regarding smaller entities' ability to comply with these requirements.

B. Enforcement and Good Faith Special Applicability

The preamble to the proposed rules did not discuss how the proposed rules would be enforced. State regulators, in their comments to the proposed rules, sought greater clarity on how the proposed rules' requirements would be enforced as specifically applied to health issuers in the individual and group markets. Section 1311(e)(3) is located in title I of PPACA and, under section 1321(c)(2) of PPACA is subject to the enforcement scheme set forth in section 2723 of the PHS Act. Similarly, section 2715A of the PHS Act is subject to the enforcement scheme set forth in section 2723 of the PHS Act. Therefore, states will generally be the primary enforcers of the requirements imposed upon health insurance issuers by the final rules.[233] The Departments expect to work closely with state regulators to design effective processes and partnerships for enforcing the final rules.

The proposed rules included a special applicability provision to address circumstances in which a group health plan or health insurance issuer, acting in good faith, makes an error or omission in its disclosures. Specifically, a plan or issuer would not fail to comply with the proposed rules solely because it, acting in good faith and with reasonable diligence, made an error or omission in a disclosure, provided that the plan or issuer corrects the information as soon as practicable. Additionally, to the extent such an error or omission was due to good faith reliance on information from another entity, the proposed rules included a special applicability provision under which, to the extent compliance would require a plan or issuer to obtain information from any other entity, the plan or issuer would not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knew, or reasonably should have known, that the information was incomplete or inaccurate. Under the proposed rules, if a plan or issuer had knowledge that such information was incomplete or inaccurate, the plan or issuer would be required to correct the information as soon as practicable.

Furthermore, the proposed rules also included a special applicability provision to account for circumstances in which a plan or issuer fails to make the required disclosures available due to its internet website being temporarily inaccessible. Accordingly, the proposed rules provided that a plan or issuer would not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

The Departments solicited comments regarding whether, in addition to these special applicability provisions, additional measures should be taken to ensure that plans and issuers that have taken reasonable steps to ensure the accuracy of required information disclosures are not exposed to liability by virtue of providing such information as required by the proposed rules.

In general, commenters supported the good faith special applicability provisions (also referred to as ''safe harbors'') and recommended certain clarifications. One commenter requested clarification regarding how the Departments would determine whether a plan or issuer acted in ''good faith'' and with ''reasonable diligence.'' Another commenter requested additional guidance on what it would mean to ''correct'' information, and specifically whether this requirement would apply on a prospective or retrospective basis. Another commenter recommended the Departments allow health plans 30 days to update accumulated amounts in the internet-based self-service tool.

The Departments are finalizing the ''good faith'' safe harbor as proposed. While ''good faith'' is not explicitly defined in the final rules, it is an established legal and business term that is generally understood to involve honesty in fact and the observance of reasonable commercial standards of fair dealing, according to the Uniform Commercial Code.[234] Efforts to correct omitted or erroneous information should proceed promptly after the plan or issuer is informed of the error. At a minimum, correcting information should include replacing the incorrect information, and may include notifying those affected of the error and the correction, using digital or written communications to notify affected participants, beneficiaries, and enrollees, and posting a notice on the internet website of the expected time before the error will be corrected.

The Departments received few comments on the good faith special applicability provision to account for circumstances in which a plan or issuer fails to make the required disclosures available due to its internet website being temporarily inaccessible. One commenter recommended that the website inaccessibility safe harbor be expanded to cover situations in which the internet-based self-service tool or machine-readable files are temporarily inaccessible, including because the internet website is inaccessible. This clarification would cover other technical issues, for example, that may affect only these resources, even though the remainder of the issuer's or plan's website is accessible.

Several commenters recommended that the Departments expand the ''safe harbor'' to account for additional circumstances. Commenters recommended that a safe harbor be created for plans that do not have direct access to negotiated in-network rates and allowed amounts, or information regarding reference based re-pricing in real time, and that may be unable to obtain some of the required information despite good faith efforts. For example, commenters recommended exempting employers, plan sponsors, and self-insured plans that rely on TPAs from liability if they have made good faith efforts to obtain the required data but have failed to do so. Commenters also recommended exempting plan sponsors that have been unable to procure third-party vendors from liability if these plans sponsors have acted in good faith. One commenter recommended that the Departments finalize a good faith special applicability provision to protect

[233] DOL has jurisdiction to enforce the final rules as they apply to group health plans subject to ERISA. Treasury has jurisdiction over certain church plans. HHS has jurisdiction over non-Federal governmental plans and over health insurance issuers where the HHS Secretary determines that a state has failed to substantially enforce the requirements. OPM has jurisdiction over the Federal Employees Health Benefits Plans.

[234] ''Uniform Commercial Code. General Definitions.'' Cornell Law School Legal Information Institute. Available at: *https://www.law.cornell.edu/ucc/1/1-201#Goodfaith.*

health plans and issuers that provide cost estimates that meet the requirements of the final rules if the estimates do not match the amounts actually paid by participants, beneficiaries, or enrollees. This commenter also requested that this safe harbor be extended to the cost-sharing estimate requirements.

Commenters also recommended that the Departments consider a safe harbor provision for covered entities that clearly provides that issuers and plans are not responsible for the downstream privacy and security of PHI shared by a participant, beneficiary, or enrollee with a third-party application consistent with the recent guidance issued by the HHS OCR.[235] Another commenter recommended the creation of additional safe harbor provisions to allow and encourage health care organizations to share threat information about security risks and incidents linked to third-party applications.

One commenter noted that disclosure of pricing information through the machine-readable files and cost-sharing tool raises concerns for plan sponsors about the potential for increased litigation under ERISA based on the release of payer-specific negotiated rates. The commenter encouraged DOL to effectively and expressly address this issue so that any disclosure requirement is crafted in a way that does not increase fiduciary liability for employer plan sponsors. The commenter recommended that DOL consider proposing a ''safe harbor'' to protect employers from downstream litigation risk related to the public disclosure of negotiated rates and disclosure of negotiated rates through the cost-sharing tool. Such a ''safe harbor'' could provide that so long as an employer can demonstrate it ''considered'' negotiated rates as part of its decision-making process in selecting an administrative service organization (ASO) for its plan, so that it would not be deemed to have acted imprudently as a fiduciary for purposes of ERISA with respect to the selection of the ASO by virtue of the negotiated rates. While the Departments appreciate this comment regarding increased litigation under ERISA, this request is beyond the scope of this rulemaking.

Finally, several commenters requested a deemed compliance standard for employers or plans that already offer transparency tools designed to assist participants with cost estimates and obtaining up-to-date cost-sharing information or for plans and issuers that voluntarily submit their data to multi-payer claims databases. Other commenters noted that some existing state laws require plans to provide the ability for enrollees to look up their out-of-pocket costs for several hundred procedures online or by phone. These commenters recommended—to reduce burden on issuer implementation and avoid duplication of effort—that health plans that comply with existing state laws requiring treatment cost-estimator functionality be deemed in compliance with any similar Federal requirements. Another commenter recommended this safe harbor be extended to the machine-readable files.

The Departments understand that states have been at the forefront of transparency initiatives and some have required disclosure of pricing information for years. However, it is important to note that states do not have authority to require such disclosures by plans subject to ERISA, which compose a significant portion of the private market.[236] As a result, a significant portion of consumers do not have access to information on their plans, even in states that have implemented transparency requirements. The Departments are also aware that many plans and issuers have moved in the direction of increased price transparency. Despite these price transparency efforts, the Departments understand that there continues to be a lack of easily accessible pricing information for consumers to use when shopping for health care services. The final rules are meant, in part, to address this lack of easily accessible pricing information, and represent a critical part of the 'Departments' overall strategy for reforming health care markets by promoting transparency, competition, and choice.

The Departments will take these additional safe harbor recommendations into consideration for future rulemaking. The Departments are not including in the final rules any safe harbor rule that would substitute the offering of existing tools or compliance with existing state transparency laws. The Departments have concluded that additional price transparency efforts are necessary to empower consumers, promote competition in the health care industry, and reduce the overall rate of growth in health care spending. The additional safe harbors recommended by commenters would not allow for the consistent baselines and standards that the Departments seek to establish with the final rules. As noted above, one of the goals of the final rules is to empower plans and issuers in the commercial health care market to innovate and compete in an industry where innovation and competition currently appear to be limited. By requiring public disclosure of pricing data a year after the effective date of the rules, the final rules will encourage issuers, TPAs, and third-party developers and innovators to create or enhance their shopping tools, including the self-service tools also required by these final rules. The development of these tools in turn will create additional consumerism, which will lead to lower prices throughout the health care market. This impact is only achievable, however if all applicable plans and issuers are held to the same standards and timelines. Furthermore, limiting the applicability of the final rules would undermine the Departments' overall strategy for reforming health care markets by promoting transparency, competition, and choice across the health care industry.

The Departments are of the view that, ultimately, plans and issuers are responsible for complying with the requirements outlined in the final rules. The Departments understand that plans may have to make adjustments to their contracts and as such, the Departments have factored that into the burden estimates and timing requirements for implementation explained elsewhere in the final rules. As plans and issuers are responsible for complying with the requirements outlined in the final rules, they should carefully examine the capacity of any partners they may contract with to provide the required information. Finally, as discussed earlier in this preamble, the Departments recognize the privacy concerns raised by commenters, but are of the view that the final rules, which include an exemption for providers with fewer than 20 different claims for payment and do not require any disclosure of PII or PHI through an API, and the continuing obligation of plans and issuers to comply with applicable privacy requirements, do not raise sufficient privacy concerns to require an additional privacy-related safe harbor.

V. Economic Impact Analysis and Paperwork Burden

A. Summary/Statement of Need

This regulatory action is taken, in part, in light of Executive Order 13877

[235] ''HHS FAQ.'' United States Department of Health and Human Services. Available at: *https://www.hhs.gov/hipaa/for-professionals/faq/3009/does-a-hipaa-covered-entity-bear-liability.html.*

[236] Panis, C. W. A., and Brien, M. J. ''Self-Insured Health Benefit Plans 2019: Based on Filings through Statistical Year 2016.'' Deloitte. January 7, 2019. Available at: *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2019-appendix-b.pdf.*

directing the Departments to issue an ANPRM, soliciting comments consistent with applicable law, requiring providers, health insurance issuers, and self-insured group health plans to provide or facilitate access to information about expected out-of-pocket costs for items or services to patients before they receive care. As discussed previously in this preamble, in response to Executive Order 13877, the Departments published the proposed rules entitled ''Transparency in Coverage.'' Despite the growing number of initiatives and the growing consumer demand for, and awareness of, the need for pricing information, there continues to be a gap in easily accessible pricing information for consumers to use to shop for health care items and services. The final rules add new requirements to 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 147 aimed at addressing this gap, and are a critical part of the Administration's overall strategy for reforming health care markets by promoting transparency and competition, creating choice in the health care industry, and enabling consumers to make informed choices about their health care. As discussed later in the RIA, the Departments acknowledge that more than 90 percent of plans, issuers, and TPAs currently provide some form of internet-based self-service tool to their consumers. However, as stated in section I.B of the final rules, the Departments understand that utility and accuracy among existing issuer cost estimator tools varies widely. Based on issuer demonstrations of their tools given to the Departments, some estimators reflect a combined range of possible costs; others give estimates based off historical pricing or claims data from various sources, while others are restricted in the types of procedures they include. Moreover, some existing issuer tools do not take into account a participant's, beneficiary's, or enrollee's accumulators.[237] The Departments are of the view that it is important to establish a minimum set of standards of what is acceptable so that consumers can take advantage of the information market-wide. Consistency will give consumers confidence that the information presented by these tools will not change arbitrarily. Reliability assures consumers that information in these tools accurately reflects plans' and issuers' best estimates of costs. The availability of these tools across all markets will ensure that no participant, beneficiary, or enrollee is denied access to the benefits of this rule and the Departments are of the view that this consistency is vital for success and utilization. As discussed previously in section I.B, state transparency requirements are generally not applicable to self-insured group health plans, and as a result, a significant portion of consumers may not have access to information on their plans and their health care costs. The Departments encourage additional functionality and innovation to be built around the requirements of the final rules, but believe a baseline is required to give the participant, beneficiary, or enrollee some confidence that no matter which plans tool they used, it would at least offer the same basic information. By requiring group health plans and health insurance issuers to disclose to participants, beneficiaries, or enrollees such individual's cost-sharing information for covered items or services furnished by a particular provider, the final rules provide them sufficient information to determine their potential out-of-pocket costs related to needed care and encourages them to consider price when making decisions about their health care.

B. Overall Impact

The Departments have examined the impact of the final rules 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 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)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year).

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. An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). The Departments have concluded that the final rules are likely to have economic impacts of $100 million or more in at least 1 year, and, therefore, meet the definition of ''economically significant rule'' under Executive Order 12866. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with the final rules. OMB reviewed this regulation in accordance with the provisions of Executive Order 12866.

Two commenters suggested that the proposed rules failed to comply with Executive Order 12866. Executive Order 12866 defines rules likely to have an economic impact in excess of $100 million as ''significant'' and requires that the agencies conduct an assessment of potential costs. The commenters suggested that the economic impact analysis and cost assessment the agencies provided for the proposed rules were short of the concrete, well-founded analysis required of the economic analysis directed by Executive Order 12866 that must accompany a proposed rulemaking as far-reaching, and potentially costly, as the proposed rules. One commenter suggested that the proposed rules were inconsistent with

[237] *See also* ''Are healthcare's cost estimate tools making matters worse for patients?'' Becker's Hospital CFO Report. Available at *https://www.beckershospitalreview.com/finance/are-healthcare-s-cost-estimate-tools-making-matters-worse-for-patients.html* (citing Gordon, E. ''Patients Want To Price-Shop For Care, But Online Tools Unreliable.'' NPR. November 30, 2015. Available at *https://www.npr.org/sections/health-shots/2015/11/30/453087857/patients-want-to-price-shop-for-care-but-online-tools-unreliable*) (''Some estimators reflect a combined range of possible costs, while others are based off historical pricing or claims data from various sources. Many online estimate tools are restricted in the types of procedures they include. . . .'').

both Executive Order 12866 and Executive Order 13563, both of which direct agencies to carefully consider alternatives to regulations an agency has deemed necessary, and to select the least burdensome approach available. The commenter maintained that the agencies did not adequately consider alternatives and are proposing an unnecessarily and excessively burdensome approach.

After consideration and discussion of the comments related to proposed cost estimates received in response to the proposed rules, the Departments chose to reevaluate the cost estimates associated with the provisions in the final rules. The Departments also consulted with internal and external IT professionals to gain a better insight into what individuals and tasks would be needed to design, develop, and deploy the internet-based self-service tool and the three machine-readable files required by the final rules. Based on this consultation and additional research, the Departments have chosen to increase the cost estimates to account for the updated understanding of the costs posed by the final rules, as well as the additional requirements included in the final rules. The Departments further discuss changes to the final cost estimates later in this preamble and in the associated ICR sections.

The final rules will enable participants, beneficiaries, and enrollees to obtain information about their potential cost-sharing liability for covered items and services that they might receive from a particular provider by requiring plans and issuers to disclose cost-sharing information as described at 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211. As discussed earlier in section I.B. of the final rules, there has been a shift in the health care market from copayments to coinsurance. Coupled with increases in plans and coverages with high deductibles, generally requiring sizeable out-of-pocket expenditures prior to receiving coverage under the terms of the plan or policy, participants, beneficiaries, and enrollees are now shouldering a greater portion of their health care costs than before. For example, over the period from 2008 to 2018, the average health care costs incurred by families covered by large employers—including premium contributions and out-of-pocket spending on health care services—have increased 67 percent from $4,617 to $7,726 annually. Over the same period, the average out-of-pocket costs alone have increased from $1,779 to $3,020 annually.[238] The Departments are of the view that disclosure of pricing information is crucial for participants, beneficiaries, or enrollees to engage in informed health care decision-making and believe that with greater price transparency and access to more accurate and actionable pricing information, participants, beneficiaries, and enrollees will be able to consider the value of an item or service when making decisions related to their health care.

In addition, as described at 26 CFR 54.9815–2715A1, 54.9815–2715A2, and 54.9815–2715A3, 29 CFR 2590.715–2715A1, 2590.715–2715A2, and 2590.715–2715A3, and 45 CFR 147.210, 147.211 and 147.212, the final rules require group health plans and health insurance issuers to make public in-network rates, including amounts in underlying fee schedules, negotiated rates, and derived amounts for in-network providers; historical allowed amounts paid to out-of-network providers and billed charges for all covered items and services; and negotiated rates and historical net prices for prescription drugs. The Departments are of the view that these requirements, through providing greater transparency and access to pricing information, will provide consistency and confidence across all internet-based self-service tools. Access to data provided by the three machine-readable files will ensure that all consumers have the pricing information they need in a readily accessible format, which could inform their choices, in addition to potentially impacting cost disparities and improvements to the overall functioning of the health care market. The Departments are of the view that greater price transparency and the availability of price information to the public will empower the 26.1 million uninsured consumers[239] to make more informed health care decisions and allow consumers who wish to shop among plans and coverage options to better understand the potential cost of their care. Public availability of this information will also allow third-party IT developers to provide consumers with more accurate information on provider, plan, and issuer value, as well as prescription drug pricing information, ensuring that such information is available to consumers where and when it is needed. Furthermore, providing the in-network rates along with out-of-pocket costs will also show what future costs could be for a participant, beneficiary, or enrollee for the same service, depending on the progress of his or her deductible. This information will help consumers make informed decisions related to their health care needs now and in the future.

The Departments received many comments regarding the underlying economic principles of the proposed rules. Many commenters were concerned the rules as proposed could disrupt contract negotiations between providers and health plans and result in providers acting in anticompetitive ways (such as collusion, consolidation, or price fixing), resulting in increased rates (a so-called ''race to the top''). Some of these commenters were particularly concerned with the potential of the Departments' proposals to spur anticompetitive behavior in highly concentrated markets. Several of these commenters cited the FTC's concerns about the potential negative impacts of price transparency on competition in the health insurance markets, including the possibility that providers (or sellers) will coordinate their behavior or bid less aggressively, leading to higher prices. Commenters also cited similar concerns expressed by the Department of Justice (DOJ) and the Congressional Budget Office (CBO) about the unintended consequences of releasing competitive proprietary information such as the in-network rates of plans and issuers. Commenters further stated increased costs would negatively impact consumer choice and reduce the affordability of health insurance coverage of low- and middle-income consumers. One commenter expressed concern that plans and issuers could also coordinate to reduce provider payment levels below market competitive rates, which could negatively impact patient access to quality care. In contrast, one commenter suggested that concerns about potential collusion among providers are unfounded as local markets are currently populated by a limited number of providers who tend to have knowledge of each other's rates and

[238] Rae, M., Copeland, R., and Cox, C. ''Tracking the rise in premium contributions and cost-sharing for families with large employer coverage.'' Peterson-KFF. August 14, 2019. Available at: *https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/?utm_campaign=KFF-2019-Health-Costs&utm_medium=email&_hsenc=p2ANqtz-_72_RHB9Twe8BpbqOg28rdlGqxq_SBgV6rB-kbC4PuYMItIOSxHQLmh_D3OH4GOnUKZXa8&utm_source=hs_email&hsCtaTracking=04848753-3235-436e-a0de-ae8238ad00ad%7Cc1097ae0-0521-4e9a-8e45-e5a87f67af4a.*

[239] ''Income, Poverty and Health Insurance Coverage in the United States: 2019.'' United States Census Bureau. September 15, 2020. Available at: *https://www.census.gov/newsroom/press-releases/2020/income-poverty.html.*

consumers currently receive pricing information through EOBs. The commenter also expressed the opinion that the argument put forth by issuers that in-network rates are trade secrets is self-serving and benefits them at the expense of consumers and the public.

One issuer stated that its experience in state markets where health care price transparency was implemented (Massachusetts, New Hampshire, and Maine) do not provide evidence that transparency efforts produce reduced health care prices and that state price transparency efforts negatively affected issuers' ability to negotiate lower rates. However, another commenter cited a study of the New Hampshire transparency initiative that found ''a significant reduction in negotiated prices.'' [240]

Some commenters suggested that the Departments should ensure that strong protections are in place to prevent price fixing or unsustainably low reimbursement for care before requiring public disclosure of in-network and out-of-network rates. For example, to address concerns about price fixing, one commenter suggested working closely with the FTC and other appropriate Federal and state authorities to monitor health care provider markets for any incidence of collusion, potentially leading to the prosecution of entities for violations that raise costs for patients and plan sponsors.

By contrast, several commenters expressed the view that the public disclosure of payer-specific in-network rates and transparency would promote competition in the health insurance markets and will drive down costs, which could result in lower, more reasonable health care prices. One commenter cited a paper that reviewed outcomes after the implementation of price transparency efforts and found evidence for behavioral changes that could place pressure on providers to lower rates.[241] Specifically, the paper found evidence of shopping activity among consumers, especially younger consumers, evidence of development activity by third-party application developers using this information, and evidence that employers will use the data to negotiate better rates. Another commenter noted that employers and health plans would be able to leverage the information to negotiate rates that are more reasonable and encourage patients to access higher-value providers.

As noted previously in sections I.B and I.C of this preamble, the Departments are of the view that greater price transparency and the public disclosure of pricing information is necessary to enable consumers to use and understand pricing data in a manner that will increase competition, improve markets, reduce disparities in health care prices, and potentially lower health care costs. The Departments continue to be of the view that effective downward pressure on health care pricing cannot be fully achieved without increased price transparency and the public disclosure of pricing information. As discussed in section E.3 of this preamble, the Federal Government maintains laws and processes to investigate reports of collusive or other anticompetitive practices.

Section 1311(e)(3) of PPACA and section 2715A of the PHS Act, as well the authority vested in the Departments, grant participants, beneficiaries, enrollees, and the public the right to know the prices of health care items and services, which will enable them make informed health care purchasing decisions. Without access to price information, consumers are unable to accurately assess and choose the least costly care and coverage options among all available options, and choice cannot be meaningful without adequate information about those choices. Currently, insured participants, beneficiaries, or enrollees, as well as uninsured consumers, do not have access to adequate and accessible pricing information related to care and coverage. The potential benefit of consumer access to this information is enormous. Furthermore, the Departments are aware of consumer demand for this information. According to a May 2019 poll conducted by the Harvard Center for American Political Studies, 88 percent of U.S. registered voters (out of a sample of 1,295) stated they would support an initiative by the government to mandate issuers, hospitals, doctors and other providers to disclose the cost of their services and discounted or negotiated rates between these groups.[242] Furthermore, 65 percent of these individuals would favor these initiatives even if in the short term they lead to an increase in prices by some providers.[243] The vast majority of comments the Departments received in response to the proposed rules were from individuals who expressed general support for the transparency proposals and expressed frustration at the lack of information available about health care pricing and a desire to have access to this information.

As noted in the preamble to the proposed rules and earlier in this preamble, the belief that greater price transparency will reduce health care costs by encouraging providers to offer more competitive rates is consistent with the predictions of standard economic theory and a number of empirical studies regarding price transparency in other markets. The Departments agree, however, that the health care market presents unique challenges. The Departments reviewed a study that notes certain special characteristics of the health care market, including that: (1) Diseases and treatments affect each patient differently, making health care difficult to standardize and making price dispersion difficult to monitor; (2) patients cannot always know what they want or need, and physicians effectively must serve as their agents (for example, by recommending specialists and determining whether a patient is admitted to a hospital); and (3) patients are typically in a poor position to choose a hospital because they do not have sufficient information about hospital quality and costs.[244] This study suggests that these special characteristics of the health care market, among other relevant factors, make it difficult to draw conclusions based on empirical evidence gathered from other markets. Nevertheless, the same study concluded that despite these complications, greater price transparency, such as access to posted prices, might lead to more efficient outcomes and lower prices.

Another study evaluated hospital discharge information following the publication of prices.[245] Hospital

[240] Brown Z. Y. ''Equilibrium Effects of Health Care Price Information.'' 101 Review of Economics & Stat. 699 (2019). Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.*

[241] Blase, B. ''Transparent Prices Will Help Consumers and Employers Reduce Health Spending.'' Texas Public Policy Foundation. September 27, 2019. Available at: *https://galen.org/assets/Blase_Transparency_Paper_092719.pdf.*

[242] ''The CAPS Harris Poll.'' Harvard Center for American Political Studies, 45. May 2019. Available at: *https://harvardharrispoll.com/wp-content/uploads/2019/06/HHP_May19_vF.pdf?utm_source=hs_email&utm_medium=email&_hsenc=p2ANqtz--NgSdTYgg GUP4tWyR2IEQ7i8TCg1s3DcHuQyhErIgkX3KFUi3SFgl9OZKm4-JUOOi9tmMQ.*

[243] *Id.* at 46.

[244] Austin, A. D., and Gravelle, J. G. ''Congressional Research Service Report to Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector.'' Congressional Research Service. July 24, 2007. Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf.*

[245] Kim, M. ''The effect of hospital price transparency in health care markets.'' University of

utilization increased for hospitals that priced below the mean market price, while hospital utilization decreased for hospitals that priced above the mean market price.

In a recent study of the New Hampshire price transparency tool, researchers found that health care price transparency could shift care to lower-cost providers and save consumers and payers money.[246] The study specifically focused on X-rays, CT scans, and MRI scans; it determined that the transparency tool reduced the costs of medical imaging procedures by five percent for patients and four percent for issuers; and estimated savings of $7.9 million for patients and $36 million for issuers over a 5-year period.

In another example, in Kentucky, public employees were provided with a price transparency tool that allowed them to shop for health care services and share in any cost-savings realized by seeking lower-cost care.[247] Over a 3-year period, 42 percent of eligible employees used the program to research information about prices and rewards.[248] The study found that 57 percent of those that used the transparency tool chose at least one cost-effective provider, saving state taxpayers $13.2 million and resulting in $1.9 million in cash benefits paid to public employees for seeking lower cost care.[249]

The Departments recognize the transparency efforts in New Hampshire and Kentucky are not necessarily generalizable nationwide and provide only some empirical data to support the overarching goal of these final rules that transparency in health care can lead to savings for consumers and issuers by putting downward pressure on prices. The Departments are of the view that consumers equipped with information about the cost of their medical options prior to receiving care will allow them to be able to make more informed decisions that will put additional downward pressure on health care costs. While the often-unequal relationship between patients and providers can sometimes mean that patients are not always best equipped to determine their care, there are many health care purchasing decisions that could and should take into account a patient's financial concerns. For instance, physician providers may also be able to provide health care transparency information when referring patients to specialists for in- or out-of-network care, such as for elective procedures. The pricing information, combined with the physician's advice, could help health care consumers evaluate options along the cost and quality spectrums and help guide them to high-value options. The Departments are of the view that health care pricing transparency may increase the impact of economic market forces on the health care markets, despite the health care market's unique characteristics. The Departments anticipate that once issuers, plans, and providers are aware that consumers can engage with the markets in an informed manner, they may adjust their costs to potentially be more competitive in their pricing of items and services.

1. Impact Estimates of the Transparency in Coverage Provisions and Accounting Table

The final rules set forth requirements for group health plans and health insurance issuers to disclose to a participant, beneficiary, or enrollee, his or her cost-sharing information for covered items or services from a particular provider or providers. The final rules also include requirements for plans and issuers to disclose in-network rates (including negotiated rates, amounts in underlying fee schedules and derived amounts) for in-network providers, historical allowed amounts and billed charges for covered items and services provided by out-of-network providers, and negotiated rates and historical net prices for prescription drugs through machine-readable files posted on a public internet website. In accordance with OMB Circular A–4, Table 2 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action.

The Departments are unable to quantify all benefits and costs of the final rules. The effects in Table 2 reflect non-quantified impacts and estimated direct monetary costs and transfers resulting from the provisions of the final rules for plans, issuers, beneficiaries, participants, enrollees, and state and the Federal Governments.

TABLE 2—ACCOUNTING TABLE

Intended Outcomes:

- Provides consumers with a tool to determine their estimated out-of-pocket costs, potentially becoming more informed on the cost of their health care, which could result in lower overall costs if consumers choose lower-cost providers or items and services.
- Potential increase in timely payments by consumers of medical bills as a result of knowing their estimated overall costs prior to receiving services and having the ability to budget for expected health care needs.
- Potential profit gains by third-party mobile application developers by selling and exchanging consumer health data and potential benefits to consumers through the development of mobile applications that may be more user-friendly and improve consumer access to cost information, potentially resulting in reductions in out-of-pocket costs.
- Potentially enable consumers shopping for coverage to understand the in-network rates for providers and the negotiated rates and historical net prices for prescription drugs in different group and individual health plans available to them and choose a plan that could minimize their out-of-pocket costs.
- States could potentially use the In-network Rate and Prescription Drugs Files to determine if premium rates are set appropriately.
- Potential reduction in cross-subsidization, which could result in lower prices as prices become more transparent.
- Public posting of in-network rates (including negotiated rates, amounts in underlying fee schedules, and derived amounts), negotiated rates, and historical net prices for prescription drugs could facilitate the review of anti-trust violations and potential collusion.
- Potential for the disclosure of in-network rates to apply pressure on providers to bill less aggressively.
- Strengthening of stakeholders' ability to support consumers.

Benefits:

- Potential societal resource savings (non-quantified efficiency portion of any overall reduction in consumer health care expenditures).
- Potential to reduce the cost of surprise billing to consumers.

Pennsylvania. 2011. Available at: *https://repository.upenn.edu/dissertations/AAI3475926.*

[246] Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 100 Rev. Econ. & Stat. 1. (2018). Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.*

[247] Rhoads, J. ''Right to Shop For Public Employees: How health care incentives are saving money in Kentucky.'' The Dartmouth Institute for Health Policy and Clinical Practice. March 8, 2019. Available at: *https://thefga.org/wp-content/uploads/2019/03/RTS-Kentucky-HealthCareIncentivesSavingMoney-DRAFT8.pdf.*

[248] *Id.*

[249] *Id.*

Costs:	Low estimate (million)	High estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized ($/year)	$4,080.2	$5,472.4	2020	7	2021–2025
	4,047.7	5,392.9	2020	3	2021–2025

Quantitative:

- Cost to plans, issuers and TPAs to plan, develop, and build the required internet-based self-service tool and machine-readable files, to provide in-network rates for in-network providers and out-of-network allowed amounts, and negotiated rates and historical net prices for prescription drugs, maintain appropriate security standards and update and maintain the machine-readable files per the final rules.
- Increase operating costs to plans and issuers as a result of training staff to use the internet-based self-service tool, responding to consumer inquiries, and delivering consumer's cost-sharing information and required notices.
- Cost to plans and issuers to review all the requirements in the final rules.

Non-Quantified:

- Potential cost incurred by plans and issuers that wish to develop a mobile accessible version of their internet-based self-service tool.
- Potential exposure of consumers to identity theft as a result of breaches and theft of PII.
- Potential increase in cyber security costs by plans and issuers to prevent data breaches and potential loss of PII.
- Potential increase in out-of-pocket costs for consumers if providers or prescription drug manufacturers increase prices for items and services or plans and issuers shift those costs to consumers in the form of increased cost sharing other than increased deductibles.
- Potential costs to states to review and enforce provisions of the final rules.
- Potential increase in consumer costs if reductions in cross-subsidization are for uncompensated care, as this could require providers finding a new way to pay for those uncompensated care costs.
- Potential increase in health care costs if consumers confuse cost with quality and value of service.
- Potential costs to inform and educate consumers on the availability and functionality of an internet-based self-service tool.
- Potential consumer confusion related to low health care literacy and the potential complexity of internet-based self-service tools.
- Potential cost to plans and issuers to conduct quality control reviews of the information in the in-network rate, out-of-network allowed amounts, and prescription drug machine-readable files.
- Potential costs to plans, issuers, and TPAs if they are required to renegotiate contracts in order to remove gag clauses in order to meet the requirements of the final rules.
- Potential costs to plans, issuers, and TPAs if they incur use cases per user CPT licensure charges.
- Potential increase in costs to consumers and issuers if providers or prescription drug manufacturers engage in anticompetitive behaviors.
- Potential state and Federal costs associated with any changes in prescription drug prices resulting from the prescription drug machine-readable file release that may impact state Medicaid, CHIP, and Basic Health Plan programs and Federal health care programs.

Transfers:	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Federal Annualized Monetized ($/year)	$425.2	2020	7	2021–2025
	423.0	2020	3	2021–2025
Other Annualized Monetized ($/year)	274	2020	7	2021–2025
	274	2020	3	2021–2025

Quantitative:

- Transfers from the Federal Government to consumers in the form of increased premium tax credits by approximately $1,047 million in 2022, $623 million in 2023, $216 million in 2024, and $218 million in 2025 as a result of estimated premium increases by issuers in the individual market to comply with the final rules.
- Transfer from consumers to issuers in the form of reduced MLR rebate payments in the individual and group markets by approximately $120 million per year by allowing issuers to take credit for ''shared savings'' payments in issuers' MLR calculations.
- Transfers from providers to consumers and issuers of approximately $154 million per year as a result of lower medical costs for issuers and consumers by allowing issuers to share with consumers the savings that result from consumers shopping for care from lower-cost providers.

Non-Quantified:

- Potential transfer from providers to consumers facing collections to reduce the overall amounts owed to providers if they are able to use competitor pricing as a negotiating tool.
- Potential transfer from providers to consumers if there is an overall decrease in health care costs due to providers reducing prices to compete for customers.
- Potential transfer from issuers to consumers if there is an overall decrease in prescription drug costs due to potential reductions in prescription drug prices.
- Potential transfer from consumers to issuers or prescription drug manufacturers if drug manufacturers increase prescription drug prices.
- Potential transfer from consumers to providers if there is an increase in health care costs if providers and services increase their in-network rates to match those of competitors.
- Potential transfer from issuers to consumers if premiums decrease and potential transfer from consumers to issuers if premiums increase.
- Potential transfer from issuers to consumers and the Federal Government in the form of decreased premiums and premium tax credits as a result of issuers adopting provisions encouraging consumers to shop for services from lower-cost providers and sharing the resulting savings with consumers.
- Potential Transfers from the Federal Government to drug manufacturers, PBMs, and retail pharmacies for any change in prescription drug costs, which could impact prices paid by Federal health care programs should prescription drug costs increase.
- Potential Transfers from drug manufacturers, PBMs, and retail pharmacies to the Federal Government to for any change in prescription drug costs, which could impact prices paid by Federal health care programs should prescription drug costs decrease.

Table 2 provides the anticipated benefits and costs (quantitative and non-quantified) to plans and issuers to disclose cost-sharing information as described at 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, 45 CFR 147.211, and at 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, 45 CFR 147.212, and make public in-

network rates, amounts in underlying fee schedules, or derived amounts of in-network providers, out-of-network allowed amounts paid for covered items and services, and negotiated rates and historical net prices for prescription drugs. The following information describes the benefits and costs—qualitative and non-quantified—to plans and issuers separately for these three requirements. Some commenters stated that the Departments attempted analysis of the economic impact of the proposed rules was wholly inadequate and demonstrated that the Departments had not performed the basic fact-gathering and analysis that agencies are expected to undertake before undertaking notice-and-comment rulemaking. These comments stated that the material the Departments presented under section VII, ''Economic Impact Analysis and Paperwork Burden'' was a patchwork of speculation and assumptions without any grounding in empirical data or analysis. The commenters further stated: The Departments listed 10 specific cost elements that they did not attempt to quantify; failed to include any consideration of regulatory familiarization costs; omitted consideration of training costs for both government employees who will be charged with enforcing the regulation and for the staff of regulated issuers and plan sponsors who will be responsible for compliance; and failed to account for the impact of the litigation burden on regulated issuers, plan sponsors, and the public judicial system. Another commenter suggested that the Departments failed to conduct an adequate cost-benefit analysis because they failed to consider and quantify regulatory alternatives, failed to quantify potentially knowable costs, and failed to quantify benefits or offer additional evidence supporting such benefits. Similarly, another commenter stated that the Departments' analysis was lacking in any quantitative assessment of benefits and did not credibly demonstrate that quantification of benefits might be difficult.

The Departments consulted with various stakeholders in an effort to develop the economic analysis associated with the final rules, including the estimated costs. Additionally, the Departments requested comment on the estimates presented in the proposed rules to obtain more information and input with respect to the unquantified costs and benefits. The Departments received a number of comments related to the cost estimates, which are discussed later in the RIA and ICR sections. However, the Departments did not receive any comments providing actionable information as it relates to a number of the unquantifiable aspects of the proposed rules.

As previously discussed in sections II.B.2.C and V.B.1 in this preamble, the Departments received comments related to the lack of estimated costs associated with the renegotiation of provider contracts, litigation expenses, and the removal of gag clauses. However, none of the comments received provided any information that would aid the Departments in estimating such costs. The Departments recognize that there are numerous aspects associated with the final rules that they are unable to estimate due to an overall lack of knowledge and information with regard to the actions that issuers, providers, or TPAs may be required to take to meet the requirements of the final rules. As discussed in sections V.C and D, the Departments have sought to provide estimates to account for the regulatory familiarization costs and other estimates related to the alternatives considered in the development of the final rules. For the final rules, the Departments have updated the regulatory review costs to include familiarization costs for each state DOI (including the District of Columbia), issuers, and TPAs.

2. Requirements for Disclosing Cost-Sharing Information to Participant, Beneficiaries, or Enrollees Under 26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211

Costs

Under 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b) of the final rules group health plans and health insurance issuers must disclose required cost-sharing information in accordance with prescribed method and format requirements upon the request of a participant, beneficiary, or enrollee. The required cost-sharing information includes seven content elements, which are described in paragraph (b)(1) of the regulations and discussed earlier in section II.B.1 in this preamble. The quantitative costs associated with this requirement are detailed in the section VI.A.2—of the ICR later in this preamble.

In addition to the costs described later in the corresponding ICR, the Departments recognize there may be other costs associated with this requirement that are difficult to quantify given the lack of information and data. For example, while the Departments are of the view that the overall effect of the final rules will lower health care costs, the Departments recognize that price transparency may have the opposite effect because in some markets where pricing is very transparent, price ranges can narrow in response to greater transparency, and costs can increase.[250] In section II.B.2.C in this preamble, the Departments addressed comments related to the potential for unintended consequences related to the public disclosures required through the In-network Rate. The Departments note that the current lack of pricing information means that health care consumers are generally not able to include price in their health care purchasing decisions. The Departments are of the view that making pricing information available will begin to ameliorate distortions resulting from consumer decision-making not taking costs sufficiently into account. Additionally, the Departments recognize that states may incur additional costs to enforce the requirements in the final rules.

As described in section VI, the Departments assume most self-insured group health plans will work with a TPA to meet the requirements of the final rules. The Departments estimated costs in the high-range estimate by assuming that all issuers and TPAs (for self-insured group health plans) will need to develop and build their internet-based self-service tool.

As described in section VI.A.1 of the ICR, the Departments assume most self-insured group health plans will work with a TPA to meet the requirements of the final rules. The Departments estimated cost in the high-end estimate by assuming that all issuers and TPAs (for self-insured group health plans) will need to develop and build their internet-based self-service tools from scratch. However, the Departments also provide a low-end estimate by assuming that over 90 percent of plans, issuers, or TPAs currently provide an internet-based self-service tool and will only be required to modify an existing internet-based self-service tool which may already meet some (if not all) the requirements in the final rules.[251] The

[250] Kutscher, B. ''Report: Consumers demand price transparency, but at what cost?'' Modern Healthcare. June 2015. Available at: *https://www.modernhealthcare.com/article/20150623/NEWS/150629957/consumers-demand-price-transparency-but-at-what-cost.*

[251] Sharma, A., Manning, R., and Mozenter, Z. ''Estimating the Burden of the Proposed Transparency in Coverage Rule.'' Bates White Economic Consulting. January 22, 2020. Available at: *https://www.bateswhite.com/media/publication/183_Estimating%20Burden%20of%20Proposed%20TCR.pdf.* In order to determine our estimates in determining the low-

Continued

Departments recognize that some plans, issuers, or TPAs might also voluntarily elect to develop or enhance a mobile application, if one is already available or in some stage of planning and implementation, which will result in additional costs. Additionally, TPAs generally work with multiple self-insured group health plans, and as a result, the costs for each TPA and self-insured group health plan may be lower to the extent they are able to coordinate their efforts and leverage any resulting economies of scale.

Moreover, health care data breach statistics show there has been an upward trend in data breaches over the past 10 years, with 2019 having more reported data breaches than any other year since records first started being published. Between 2009 and 2019 there have been 3,054 health care data breaches involving more than 500 records; resulting in the loss, theft, exposure, or impermissible disclosure of 230,954,151 health care records, equating to more than 69.78 percent of the United States population. Health care data breaches are now being reported at a rate of more than one per day.[252] Based on this information, the Departments recognize the requirements of the final rules provide additional opportunities for health care data breaches. Although privacy and security costs have been imbedded into the development and implementation cost estimates discussed in the section VI.A.1 and further discussed in section II.B.4 of this preamble, the Departments expect that plans and issuers will follow existing applicable state and Federal laws regarding persons who may or must be allowed to access and receive the information. The Departments recognize that some plans and issuers may incur additional expenses to ensure a consumers' PHI and PII are secure and protected. Additionally, as consumers accessing the internet-based self-service tool may be required to input personal data to access the consumer-specific pricing information, consumers may be exposed to increased risk and experience identity theft as a result of breaches and theft of PII. As noted previously in section II.B.4 of this preamble, the Departments are finalizing a provision that reminds plans and issuers of their duty to comply with requirements under other applicable state or Federal laws, including requirements governing the accessibility, privacy, or security of information, or those governing the ability of properly authorized representatives to access participant, beneficiary, or enrollee information held by plans and issuers.

One commenter stated that since multiemployer plans do not directly control the process of negotiations or the resulting information, these plans do not have access to the information necessary to satisfy the final rules and plans could be subject to significant penalties for failure to comply. Another commenter, that surveyed employers who sponsor self-insured ERISA-covered plans, noted that respondents would likely contract with a TPA to comply with the final rules because employers do not have all the necessary data nor the capability to collect that data. Employers indicated that contracting with a TPA for these requirements would come at a significant compliance cost to them. Commenters noted that they rent networks from issuers and contract with those issuers as TPAs to administer plan benefits. It is the issuer that holds the pricing information for medical services, facilities, and providers, not the self-insured employer. Another commenter stated that the burden incurred by plans, issuers, and TPAs would be crippling for smaller TPAs and health plans, and that burden would ultimately be passed along to employers, and, therefore, to consumers. Another commenter expressed concern that all of the data aggregation and collection required under the regulations—along with the need to contract with a third-party developer to create an on-line cost-sharing liability service tool that is capable of providing customized cost-sharing information to a particular participant, beneficiary, or enrollee—may be overly costly to plans. The commenter further suggested that there may also be significant costs associated with data storage.

The Departments appreciate the comments received in response to the proposed rules and recognize that not all plans will be the source of the material information required to meet the requirements of the final rules, and that many plans will ultimately seek out third-party assistance in the development of their internet-based self-service tool and machine-readable files, thus avoiding any potential penalties for noncompliance. As noted in section II.B.5 of this preamble, multiemployer plans may contract with a TPA or other third party (for example, a clearinghouse) to meet the requirements under the final rules. The Departments note that it is possible that obtaining third-party assistance to meet the requirements of the final rules could result in additional costs. The Departments expect, however, that TPA, or other third party, assistance will help alleviate some of the cost concerns expressed by commenters as a result of economies of scale. As noted above, commenters noted that many self-insured ERISA plans rent networks from issuers and contract with issuers as TPAs to administer plan benefits. By leveraging their relationships with their issuer-TPA, self-funded plans may be able to reduce their overall costs by using any tools developed by those issuers. The Departments also recognize that in order to meet the requirements of the final rules, some smaller TPAs and issuers could face disproportionate increases in costs. However, the Departments anticipate that a number of TPAs and issuer-TPAs will seek to coordinate their efforts and take advantage of any resulting economies of scale to reduce their overall costs, and that this approach can be leveraged in order to reduce concerns related to the development of both the internet-based self-service tool as well as the required machine-readable files. The Departments recognize that issuers and TPAs will incur potential costs associated with data storage and providing access to the internet-based self-service tool. These costs can be generally broken down into two sections: Bandwidth pricing and disc space. Bandwidth Pricing accounts for the amount of traffic going to a site, the size of the information that is transferred from the server to the user's browser, and the speed in which that happens. Provided that 99 percent of websites do not exceed 5 gigabytes of bandwidth per month,[253] this means if an issuer's or TPA's self-service tool, hosted on Microsoft's cloud product, would be free or minimal if beyond five gigabytes.[254] Disk Space Pricing accounts for the size of the hard drives necessary to host a website. Assuming that each issuer or TPA would need an estimated 351 gigabytes of storage this would translate to approximately $8 per month. Thus, assuming that each issuer or TPA will not require five gigabytes of bandwidth for their internet-based self-service tool, the Departments are of the

range cost estimate, the Departments estimated that only 90 percent of plans, issuers, and TPAs provided an online tool that would meet the assumptions used in developing the estimated costs.

[252] ''Healthcare Data Breach Statistics.'' HIPAA Journal. Available at: *https://www.hipaajournal.com/healthcare-data-breach-statistics/*.

[253] ''How Much Bandwidth and Disk Space Do I Really Need?'' Hosting Manual. Available at: *https://www.hostingmanual.net/bandwidth-disk-space-need/*.

[254] ''Bandwidth Pricing Details.'' Microsoft Azure. Available at: *https://azure.microsoft.com/en-us/pricing/details/bandwidth/*.

view that the overall costs to store and provide data through the internet-based self-service tool will be minimal. The Departments recognize that the final rules will impose significant costs on plans, issuers, and TPAs, and that some of these costs may be transferred to consumers in the form of higher premiums or changes in the cost-sharing structure of plans.

Intended Outcomes

Informed Consumers. Through increased price transparency, consumers armed with pricing information will have greater control over their own health care spending, which can foster competition among providers, resulting in less disparity in health care prices or an overall reduction in health care prices. Consumers who use the internet-based self-service tool will be able to access their cost-sharing amount paid to date; their progress toward meeting their accumulators, such as deductibles and out-of-pocket limits; their estimated cost-sharing liability for an identified item or service; negotiated rates for in-network providers for covered items and services, and the out-of-network allowed amounts for covered items and services. Additionally, consumers will know how much health care services will cost for a particular treatment-, and, and if applicable, whether coverage of a specific item or service is subject to a prerequisite. As discussed previously in section II.B.1.a of this preamble, section 2713 of PPACA requires group health plans and health insurance issuers to provide certain recommended preventive items and services without cost-sharing. However, if the same items or services are furnished as non-preventive actions or by an out-of-network provider, the participant, beneficiary, or enrollee may be subject to the cost-sharing terms of his or her plan. If a plan or issuer cannot determine whether the request is for a preventive item or service, the plan or issuer must display the non-preventive cost-sharing liability, along with a note that the item or service may not be subject to cost-sharing if it is billed as a preventive service. Pricing information also gives consumers the ability to plan ahead for any known items and services they may require in the near future. The Departments are of the view that access to this information is essential to enable consumers to make informed decisions regarding specific services or treatments, budget appropriately to pay any out-of-pocket expenses, and determine what impact any change in providers, items, or services will have on the cost of a particular service or treatment.

Several consumers stated that they want the opportunity to shop for the best price when seeking out medical care and expressed that this information is critical when deciding whether to proceed with a test or procedure. Other consumers expressed the desire to shop for items and services and stated that shopping for health care would give them more control over their personal health care decisions and spending. Some consumers felt strongly that they should be able to compare prices to find the best deal for non-life-threatening care. Some other consumers also expressed frustration when describing their own experiences of trying and failing to obtain pricing information before receiving a particular service.

The Departments agree that providing the information required in the final rules will provide consumers with tools and information they can use to determine and evaluate the potential costs associated with their particular health care needs, thus providing them the opportunity to obtain the care they need at a cost they find acceptable.

Consumers may become more cost conscious. The Departments are of the view that with increased price transparency consumers may begin to focus more carefully on the costs of services. Currently, consumers may be aware they have a coinsurance of 20 percent for an item or service, but they may be unaware of what dollar amount they will ultimately be responsible for paying. Knowing that dollar amount may motivate consumers to seek lower-cost providers and services or seek needed care they did not obtain because of uncertainty or concerns about the costs. As discussed in sections I.E.3, II.C, and V.B.2–4 in this preamble, there has been recent evidence in New Hampshire and Kentucky that supports the Departments' view that having access to pricing information, along with currently available information on provider quality and incentives to shop for lower prices, can result in consumers choosing providers with lower costs for items and services, thus potentially lowering overall health care costs.[255] The Departments acknowledge that this may only hold true if cost and cost sharing varies between services and providers. Depending on the degree of cost variation between specific items and services, there could be large variations in the degree to which prices change per item or service resulting in wide variations in health care costs and associated out-of-pocket costs.[256] Cost sharing in some alternative contracting models, such as HMOs and Exclusive Provider Organizations (EPO), generally occurs through fixed copayment amounts regardless which provider furnishes a covered item or service and, therefore, the internet-based self-service tool will provide little incentive for consumers to choose less costly providers in this context.

Timely Payment of Medical Bills. The Departments anticipate that consumers with access to the information provided in response to the final rules will be more likely to pay their medical bills on time. A recent Transunion survey found that 79 percent of respondents said they would be more likely to pay their bills in a timely manner if they had price estimates before obtaining care.[257] In addition, a non-profit hospital network found that the more information they shared with patients, the better prepared those patients were for meeting their responsibilities. The hospital network reported that providing price estimates to patients resulted in increased point of service cash collections from $3 million in 2010 to $6 million in 2011.[258] However, the Departments recognize that consumers may not be aware of any potential balance billing charges, where not prohibited by state law, and other potential costs associated with their

[255] Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 100 Rev. of Econ. and Stat. 1. July 16, 2018. Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf*; *see also* Rhoads, J. ''Right to Shop for Public Employees: How health care incentives are saving money in Kentucky.'' The Dartmouth Institute for Health Policy and Clinical Practice. March 8, 2019. Available at: *https://thefga.org/wp-content/uploads/2019/03/RTS-Kentucky-HealthCareIncentivesSavingMoney-DRAFT8.pdf.*

[256] The evidence cited in this RIA yields per-capita annual savings estimates ranging from between $3 and $5 (=$2.8 million + $1.3 million + $7.0 million + $2.3 million two-year savings, across 1.3 million California public employees and their family members, per Boynton and Robinson (2015)), to $6.50 (=$7.9 million + $36 million five-year savings found by Brown (2018), divided across the 1.36 million residents of New Hampshire), to $17 (=$13.2 million three-year savings across 0.26 million beneficiaries, per Rhoads (2019)). If these results were extrapolated to the entire U.S. population, the estimate of rule-induced reductions in annual consumer expenditures could range from $0.98 billion to $5.5 billion, with the median result across the three studies at $2.1 billion. This range has a tendency toward overestimation, in that effects of the Hospital Price Transparency final rule and existing non-Federal transparency programs have not been subtracted off.

[257] Kutscher, B. ''Report: Consumers demand price transparency, but at what cost?'' Modern Healthcare. June 2015. Available at: *https://www.modernhealthcare.com/article/20150623/NEWS/150629957/consumers-demand-price-transparency-but-at-what-cost.*

[258] ''Reimagining Patient Access.'' Insurancenewsnet. December 29, 2015. Available at: *https://insurancenewsnet.com/oarticle/reimagining-patient-access#.*

health care such as facility fees etc. While these consumers will have a better idea of the costs they will incur when obtaining health care, they will likely be unaware of any additional charges they could incur as a result of obtaining care resulting in higher than expected out-of-pocket costs. Additionally, consumers may not fully be aware of their costs due to potential medical complications that might arise during the course of treatment or while obtaining a specific service.

Increased Competition Among Providers. Studies have found that state price transparency regulations have resulted in hospitals decreasing their charges and a decrease in mean price and price variability for queried procedures. One study found the publication of chargemaster data resulted in a decrease in mean price and price variability for queried procedures.[259] However, another study attributed the reduction in charges to the ''reputational costs of perceived overcharging,'' yet also noted that reductions in charges were associated with decreases in discounts leading to no consumer savings.[260] Another issuer-initiated price transparency program, designed to encourage the selection of high-value providers, provided consumers with price differences among MRI facilities.[261] Those patients provided pricing information saw an 18.7 percent reduction in the cost per test and a decrease in the use of hospital-based facilities.[262] The study also found that price variations between hospital and non-hospital facilities were reduced by 30 percent.[263] As discussed in sections I.B in this preamble, the Departments recognize that requiring hospitals to display payer-specific negotiated charges, discounted cash prices, and de-identified minimum and maximum negotiated charges for as many of the 70 CMS selected shoppable services and additional hospital-selected shoppable services for a combined total of at least 300 shoppable services may play a role in decreasing mean prices and price variability.[264] However, the Departments are of the view that the Hospital Price Transparency final rule does not, in itself, result in reduced prices and price variability as the rule does not result in consumers receiving complete price estimates for health care items and services from both hospitals and issuers. Further, the Hospital Price Transparency final rule does not provide price transparency with respect to items and services provided by other health care providers. Therefore, the Departments are of the view that the requirements of the final rules will provide the additional price transparency necessary to empower a more price-conscious and responsible health care consumer and lead to increased competition among providers as consumers will be aware of and have the ability to compare the out-of-pocket cost of a covered item or service prior to receiving an item or service, which could force higher-cost providers to lower their prices in order to compete for the price sensitive consumer.

3. Requirements for Public Disclosure of In-Network Provider Rates for Covered Items and Services, Out-of-Network Allowed Amounts and Prescription Drug Pricing Information Through Machine-Readable Files Under 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212

Costs

Under 26 CFR 54.9815–2715A3(b), 29 CFR 2590.715–2715A3(b), and 45 CFR 147.212(b) of the final rules, group health plans and health insurance issuers are required to make available to the public, on an internet website, three digital files in a machine-readable format. The first file (the In-network Rate File) must include information regarding all applicable rates, which may include negotiated rates, underlying fee schedules, or derived amounts, to the extent they may be used for purposes of determining provider reimbursement or cost-sharing for in-network providers. The Departments note that prescription drug products may be included in the In-network Rate File only to the extent they are included as part of an alternative payment arrangement, such as a bundled payment arrangement. The second file (the Allowed Amount File) must provide data showing the allowed amounts and billed charges with respect to covered items and services, including prescription drugs, furnished by out-of-network providers over a 90-day period beginning 180 days prior to the publication date of the machine-readable file. The third file (the Prescription Drug File) must include information for negotiated rates and historical net prices for prescription drugs, organized by NDC. Plans and issuers are required to make the information available in accordance with certain method and format requirements described at paragraph (b)(2) and update these files monthly as required under paragraph (b)(3). The quantitative costs associated with meeting these requirements are detailed in section VI.2 of the ICR section.

Some commenters stated that the requirement to use billing codes would be very costly and potentially cost-prohibitive. One commenter indicated this is because use of CPT codes, the most commonly used billing codes, requires licensure by the American Medical Association (AMA). According to the commenter, the AMA charges licensing fees based on use cases per user. Another commenter noted that some self-funded plans rent networks and do not have real-time access to network pricing, and there are fees charged to plans to access the negotiated discounts with the provider network the plan has rented. As a result, the commenter suggested that plans will have to pay the network access fees twice—once the information required under the final rules and a second time when the actual claim is received and processed through an intermediary—to meet the requirements of the final rules.

The Departments understand that the use of CPT codes may represent an additional cost for some plans and issuers. Generally, the Departments anticipate that if a plan or issuer currently has the capability or licensure to record CPT codes on EOBs mailed to consumers, the plans or issuers should also be able to use that CPT code to make the public disclosures required through the final rules without, or with minimal, additional costs. The Departments also have concluded that, as plans and issuers would already include licensing costs for using CPT codes in the cost of doing business, they would not incur additional costs to use the CPT codes to populate the machine-readable files. The Departments acknowledge that some plans and issuers could face instances where they could incur additional costs in order to access the required CPT or network information based on the structure of licensing agreements to which they are currently parties. However, due to an overall lack of specific information and knowledge associated with the number of plans and issuers that currently have

[259] Ward, C., and Reeder, T. ''The Evolution and Impact of Hospital Price Transparency in North Carolina.'' North Carolina Medical Journal. Volume 81. Issue 2. April 2020. Available at: *https://www.ncmedicaljournal.com/content/81/2/95.short.*

[260] Christensen, H.B., Floyd, E., and Maffett, M. ''The Only Prescription is Price Transparency: The Effect of Charge-Price-Transparency Regulation on Healthcare Prices.'' Management Science. February 21, 2019. Available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2343367.*

[261] Wu, S.J., et al. ''Price transparency for MRIs increased use of less costly providers and triggered provider competition.'' Health Affairs. August 2014. Available at: *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0168.*

[262] *Id.*

[263] *Id.*

[264] 84 FR 65524 (Nov. 27, 2019).

such licensing agreements, the structure of those agreements, and the alternatives available to those plans and issuers, the Departments are unable to accurately estimate any associated costs that might be incurred under these circumstances.

One commenter stated that for many employer-sponsored health plans, in-network rates usually belong to a network administrator, not the health plan, and, in the event network administrators were to update their contractual agreements to permit plans to receive and share pricing information, it is likely they will charge fees or request financial concessions from plans, which will increase administrative burdens on group health plans.

The Departments understand that requiring release of this pricing information will affect certain commercial arrangements and expectations that prevail in parts of the health care industry today, which could result in certain one-time and ongoing administrative costs. However, the Departments are of the view that making this information available to consumers and the public will serve consumers' long-term interests in facilitating a consumer-oriented, information-driven, more competitive market. Additionally, as discussed previously in section II.C in this preamble, the Departments are finalizing several special rules to streamline the provision of the public disclosures required through the final rules. These special rules were designed to reduce the overall compliance costs of the disclosures required by the final rules and to support smaller issuers and plans in meeting the requirements of the final rules by permitting certain contractual arrangements and the aggregation of allowed amount data in some circumstances.

The Departments also recognize that a certain amount of data storage will be required to post the machine-readable files on a publicly available internet website. Through the efficiencies of cloud computing and data storage, the cost to host large files dramatically decreased in price in the past several years. Popular services such as Simple Storage Service from Amazon Web Services and Standard Storage from the Google Cloud Platform can host files for roughly $0.026 per gigabyte. The Departments' size estimates of roughly 5 gigabytes for each machine-readable file would incur a monthly data storage cost of approximately $0.39 for all of the machine-readable files.

Non-Quantified Costs for Public Disclosure of In-Network Rates. In addition to the costs described in section VI.A.2, the Departments recognize there may be other costs associated with the requirement to make in-network rates publicly available that are difficult to quantify given the current lack of information and data. While the Departments are of the view that the overall effect of the final rules will be to provide greater price transparency and potentially lower health care prices, there are instances in very transparent markets where price ranges can narrow and average costs can increase as a result of price transparency.[265] The Departments also recognize that plans and issuers may experience ongoing additional costs (for example, the cost of quality control reviews) to ensure they comply with the requirements of the final rules. In addition, the Departments are aware that information disclosures allowing competitors to determine the rates their competitors are charging may dampen each competitor's incentive to offer a lower price or result in a higher price equilibrium.[266] While plans and issuers with the highest in-network rates may see a decrease in their in-network rates, as their providers respond to consumer and smaller issuers' concerns regarding paying more for the same item and service, plans and issuers with the lowest in-network rates may see their lower cost providers adjust their rates upward. However, most research suggests that when better price information is available, prices for goods sold to consumers fall. For example, in an advertising-related study, researchers found that the act of advertising the price of a good or service is associated with lower prices.[267]

A potential additional non-quantified cost could be the cost to remove gag clauses from contracts between plans, issuers, and providers. Contracts between plans, issuers, and providers often include a gag clause, which prevents plans and issuers from disclosing in-network rates. The Departments recognize that plans, issuers and providers may incur a one-time expense for their attorneys to review and update their provider contracts to remove any relevant gag clauses. Comments received regarding gag clauses and contract negotiations are further discussed in section VI.A.2 later in this preamble.

Another potential cost concerns the final rules' impact on a plan's or issuer's ability or incentive to establish a robust network of providers. A health insurance provider network is a group of providers that have contracted with a plan or issuer to provide care at a specified price the provider must accept as payment in full. Many times, plans and issuers want consumers to use the providers in their network because these providers have met the plan's or issuer's quality standards and agreed to accept an in-network rate for their services in exchange for the patient volume they will receive by being part of the plan's or issuer's network.[268] Some plans and issuers offer a narrow network: These networks operate with a smaller number of providers, meaning a consumer will have fewer choices when it comes to in-network providers, but often offer lower monthly premiums and out-of-pocket costs.[269] The Departments recognize that making in-network rates public may create a disincentive for plans and issuers to establish a contractual relationship with a provider (including in narrow networks) because providers may be unwilling to give a discount to plans and issuers when that discount will be made public. As addressed further in section VI.C later in this preamble, the requirements of the final rules could result in a reduction in revenue for those smaller plans and issuers that are unable to pay higher rates to providers and may require them to narrow their provider networks, which could affect access to care for some consumers. Due to smaller plans' and issuers' potential inability to pay providers with higher rates, smaller plans and issuers may further narrow their networks to include only providers with lower rates, possibly making it more difficult for smaller plans and issuers to fully comply with network adequacy standards described at 45 CFR 156.230 or other applicable state network adequacy requirements.

Some commenters stated that public disclosure of in-network rates could affect the sustainability and affordability

[265] Kutscher, B. ''Report: Consumers demand price transparency, but at what cost?'' Modern Healthcare. June 2015. Available at: *https://www.modernhealthcare.com/article/20150623/NEWS/150629957/consumers-demand-price-transparency-but-at-what-cost.*

[266] Koslov, T., and Jex, E. ''Price transparency or TMI?'' United States, Federal Trade Commission. Available at: *https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi.*

[267] Austin, D. A, and Gravelle, J. G. ''Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Health Sector.'' Congressional Research Service. June 2007. Available at: *https://fas.org/sgp/crs/secrecy/RL34101.pdf.*

[268] Davis, E. ''Health Insurance Provider Network Overview.'' Verywell Health. August 2019. Available at: *https://www.verywellhealth.com/health-insurance-provider-network-1738750.*

[269] Anderman, T. ''What to Know About Narrow Network Health Insurance Plans.'' Consumer Reports. November 23, 2018. Available at: *https://www.consumerreports.org/health-insurance/what-to-know-about-narrow-network-health-insurance-plans/.*

of QHPs offered through the Exchanges by placing upward pressure on rates and by placing provider participation in networks at risk. One commenter stated that the potential negative effects on QHPs would especially harm unsubsidized consumers and consumers in rural areas where provider consolidation is most common and could impact overall marketplace stability and the risk pool. Furthermore, commenters asserted that increased premiums for QHPs could result in increased Federal spending in the form of higher premium tax credit (PTC) payments, which could substantially increase the Federal deficit over 10 years. One commenter stated that the Departments should not finalize the release of in-network rates until they fully evaluate the impact on affordable plan options on the Exchanges and the effects on Federal spending.

As discussed later in section V.B.5 of this preamble, the Departments estimate premiums for the fully-insured markets will be $471 billion for 2022, including the individual, small group, and large group markets. The Departments estimate that the cost for 2022 represents approximately 2.4 percent of projected commercial insured premiums for the fully-insured market, 1.4 percent in 2023, 0.5 percent in 2024, and 0.5 percent in 2025. Assuming this level of premium increase in the individual market, PTC outlays are estimated to increase by about $1,047 million in 2022, $623 million in 2023, $216 million in 2024, and $218 million in 2025. Given that the 2021 President's Budget estimates that PTC outlays are expected to be $43.8 billion in 2022, $44.8 billion in 2023, $45.875 billion in 2024, and $48.2 billion in 2025,[270] the Departments expect the estimated increase of $1,047 million in 2022, $623 million in 2023, $216 million in 2024, and $218 million in 2025 to have minimal impacts on anticipated enrollment and are not of the view that this increase will result in any widespread negative effects on market stability. Additionally, the Departments have determined that enrollment impacts will be minimal, as estimated premium impacts are relatively small, and rate increases for subsidized enrollees in the individual market will be largely mitigated. Additionally, participants, beneficiaries, and enrollees currently make health insurance coverage decisions based on their particular health and financial situations, and it is not predictable how information provided as a result of the final rules will significantly impact those health insurance coverage decisions. Thus, the Departments do not expect the final rules to significantly increase the selection risk beyond the levels that currently exist. The Departments do acknowledge that the estimated increases in premiums could result in minor harm to unsubsidized consumers as they could be faced with increased premiums that would not be negated by any increases in PTC and this could impact those consumers' decisions related to obtaining health insurance coverage.

The Departments received several comments from issuers, providers, and employers stating that the requirement to publicly disclose in-network rates would threaten the viability of their business models or business models upon which they rely. One commenter stated that the proposal to release in-network rates could affect the viability of individual and small group market health plans sold by small issuers. The commenter further suggested that ''safety net'' health plans (which serve individuals and families that do not have access to other sources of coverage in markets that other issuers find unprofitable) currently may be able to access more favorable contract terms with providers, and these types of arrangements would be at risk if the in-network rate information were required to be made public. The commenter expressed particular concern that exposure of the rates of safety net hospitals may uniquely disadvantage them in negotiations with plans and issuers because they may have to raise rates on certain services to support safety net activities. Similarly, a hospital system stated that publishing in-network rates would negatively impact its ability to contain costs and threaten its current participation in the networks of nearly all area health plans. Another commenter indicated that providers would leave plans' and issuers' networks if plans' and issuers' attempts to achieve more favorable rates using public in-network rate information proved unsuccessful. Another commenter argued that the policy requiring disclosure of in-network rates could also result in the collapse of the network administrator business model, which would result in significantly increased administrative costs for health plans that would need to contract separately with each participating provider.

The Departments understand that requiring the release of this pricing information will upset certain commercial arrangements and expectations that prevail in parts of the health care industry today, which could result in certain one-time and ongoing administrative costs. However, the Departments have concluded that providing increased price transparency and making this information available to the public will serve the public's long-term interests in facilitating a consumer-oriented, information-driven, more competitive market potentially leading to reduced overall health care costs.

Some commenters suggested that, by using publicized in-network rate information, plans and issuers could also coordinate to reduce provider payment levels below market competitive rates, a so-called ''race to the bottom.'' Some of these commenters stated that this ''race to the bottom'' could also potentially hurt access to, and quality of, care. For example, one commenter stated that if provider reimbursement rates were set too low, patient access to care would be negatively impacted because providers will not have the resources to invest in technology, training, and equipment.

One commenter suggested that plans and issuers would likely want to re-negotiate rates once they learn local prices and that dominant issuers could use payer specific in-network rate information to deter and punish hospitals that lower their rates or enter into value-based arrangements with the dominant issuer's competitors.

Several commenters stated that required disclosure of in-network rates could result in an increase in health care prices. Others specifically expressed concerns that making payer-specific in-network rates available would disrupt contract negotiations between providers and health plans and result in providers changing their rates in anticompetitive ways (''race to the top'') and could promote an environment that could support collusion between providers, resulting in increased prices. Other commenters suggested that required disclosures would lead to the consolidation of providers and even greater consolidation in the commercial health insurance industry, and expressed concerns that disclosures could particularly harm small health plans and TPAs who may have been able to get discounted rates by offering health plans in a limited service area.

One commenter noted that other states' transparency systems used several distinguishable features to mitigate the risks of publicizing rates, but noted that, despite these efforts, the data was still used in contract negotiations.

[270] OMB 2021 President's Budget. Available at: *https://www.whitehouse.gov/wp-content/uploads/2020/02/budget_fy21.pdf.*

The Departments recognize that there is the potential for adverse market outcomes as a result of the final rules. As noted previously, the Departments are aware of the potential that plans and issuers could seek to use the public availability of in-network rates or underlying fee schedules in attempts to lower prices in what certain commenters called a ''race to the bottom.'' As noted previously in this section, the Departments recognize the potential for anticompetitive behaviors and increased consolidation that may occur should providers use the in-network rate or fee schedule data to increase their rates or should smaller plans and issuers struggle to comply. The Departments recognize that provider collusion could result in increased prices, and also recognize that this sort of behavior could result in distinct coverage areas or agreements where providers choose not to compete for consumers. As discussed previously in this preamble, the Departments nonetheless have concluded that providing increased price transparency and making this information available to the public will serve the public's long-term interests in facilitating a consumer-oriented, information-driven, more competitive health care market.[271] Should the market become more competitive, as the Departments anticipate, the reduction in prices may provide more options for those providers that function as ''safety-net providers'' to expand their networks or enhance the services they currently provide by organizing and delivering a significant level of health care and other related services to uninsured, Medicaid, and other vulnerable populations. The Departments also reason that the likelihood of price and other forms of collusion will be mitigated to some extent by the actions of state and Federal regulatory and antitrust enforcement authorities and the enforcement of current market laws and regulations. The Departments are of the view that enforcement actions taken to reduce the likelihood of price collusion will further reduce the chances that issuers will seek to reduce the size of their networks.

Although consumer education is not a requirement of the final rules, plans, issuers and TPAs may face additional costs if they chose to inform and educate their consumers about the options available to them, how to use these tools, increase their general health care knowledge. Providing educational opportunities to participants, beneficiaries, or enrollees could encourage those participants, beneficiaries, or enrollees to seek lower cost services, providing plans, issuers and TPAs the potential to realize a return on the investments incurred to comply with the final rules.

Non-Quantified Cost for Public Disclosure of out-of-network allowed amounts. In addition to the costs described in section VI.A.2 and the previous analysis related to the public disclosure of in-network rates, the Departments recognize that there may be other costs associated with the requirement to make historical payments of out-of-network allowed amounts and billed charges publicly available that are difficult to quantify, given the current lack of information and data.

Furthermore, while plans and issuers must de-identify data (such as claim payment information for a single provider) and ensure certain sensitive data are adequately protected, unauthorized disclosures of PHI and PII may increase as a result of manual preparation and manipulation of the required data. The potential disclosures of PHI and PII may require plans, issuers, and TPAs to obtain additional cyber-security insurance that could lead to additional costs.

Non-Quantified Cost for Public Disclosure of Prescription Drug Pricing Information. In addition to the costs described in section VI.A.2 and the previous analysis related to the public disclosure of in-network rates and allowed amounts, the Departments recognize that there are other costs associated with the requirement to make negotiated rates and historical net prices for prescription drugs publicly available that are difficult to quantify, given the current lack of information and data. For example, as a result of the availability of consolidated negotiated rates and historical net prices, drug manufacturers may seek to restructure their rebate and discount programs and could potentially cease providing rebates to plans and issuers, PBMs, or pharmacies, which could then result in less savings being passed on to consumers.

Intended Outcomes

The Departments are of the view that providing greater price transparency by requiring group health plans and health insurance issuers to make information regarding all applicable rates publicly available, which may include negotiated rates, amounts in underlying fee schedules, or derived amounts for in-network provider rates; 90-days of historical allowed amount and billed charges data for out-of-network providers; and prescription drug negotiated rates and historical net prices will ultimately benefit plans and issuers, regulatory authorities, consumers, and the overall health care market.

Group Health Plans and Health Insurance Issuers. Plans and issuers may benefit from these requirements because under the final rules a plan or issuer would have a better understanding of other plans' or issuers' in-network rates. This may allow plans and issuers paying higher rates for the same items or services to negotiate with certain providers to lower their rates, thereby lowering provider reimbursement rates, reducing price variation, and potentially resulting in an overall decrease in health care costs. The Departments acknowledge, however, as noted in the ''costs'' section (V.B.3) earlier in this preamble, that knowledge of other providers' in-network rates could also drive up rates if a provider discovers they are currently being paid less than other providers by a plan or issuer and, therefore, seek to negotiates higher rates.

In addition, the final rules may result in more plans and issuers using a reference pricing structure. Under this structure, participants, beneficiaries, or enrollees who select a provider charging above the reference price (or contribution limit) must pay the entire difference and these differences do not typically count toward that individual's deductible or out-of-pocket limit. Plans and issuers may want to use a reference pricing structure to pass on any potential additional costs associated with what they can identify as higher-cost providers to the participant, beneficiary, or enrollee. The Departments recognize that reference pricing might not impact every consumer. For example, the California Public Employees' Retirement System (CalPERS) provides exceptions from reference pricing when a member lives more than 50 miles from a facility that offers the service below the price limit. It also exempts the patient if the patient's physician gives a clinical justification for using a high-priced facility or hospital setting. Another example is a business with a self-insured group health plan that exempts laboratory tests for patients with a diagnosis of cancer from its reference pricing program. However, reference pricing has generally been shown to result in price reductions, as opposed to mere slowdowns in the rate of price

[271] Gudiksen K.L., Chang, S.M., and King, J.S. ''The Secret of Health Care Prices: Why Transparency Is in the Public Interest.'' California Health Care Foundation. July 2019. Available at: *https://www.chcf.org/wp-content/uploads/2019/06/SecretHealthCarePrices.pdf.*

growth. For example, in the first two years after implementation, reference pricing saved CalPERS $2.8 million for joint replacement surgery, $1.3 million for cataract surgery, $7.0 million for colonoscopy, and $2.3 million for arthroscopy.[272]

Regulatory Authorities. In many states, issuers must obtain prior approval for rate changes from the state's DOI. Regulatory authorities such as state DOIs might benefit from the final rules because knowledge of provider in-network rates and out-of-network allowed amounts paid to out-of-network providers could support determinations of whether premium rates, including requests for premium rate increases, are reasonable and justifiable.

Consumers. Access to the in-network rates between plans and issuers and in-network providers, the amount plans and issuers have paid to out-of-network providers, and prescription drug pricing information will allow consumers to understand the impact of their choice of health insurance coverage option and their choices of providers on the cost of a particular service, item, or treatment. Giving consumers access to this information as part of their health care decision-making process may facilitate a greater degree of control over their own health care costs. Furthermore, having access to publicly available out-of-network allowed amounts will provide consumers who are shopping for health insurance coverage the ability to compare the different rates plans and issuers ultimately pay for items and services, including items and services from providers that might be out-of-network. While the Departments are of the view that consumers will benefit from the final rules, the Departments recognize that utilizing the required information will not be practical or reasonable in an emergency situation. Similarly, some consumers may need assistance in understanding complex terms or other associated mechanisms in order to utilize this information.

The Departments recognize that beneficiaries and enrollees in state and Federal health care programs (including Medicare, Medicaid, CHIP, Basic Health Program and coverage provided by the Department of Defense and Veterans Administration) will be impacted by spillover effects related to any reductions or increase in prices for individual items and services and prescription drugs as a result of the final rules. For example, Medicare Part B has historically reimbursed physicians for physician-administered drugs using a formula that is based off the average sales price (ASP). To the extent the final rules drive changes in prescription drug prices, that will change the Federal reimbursement rates under Medicare Part B and may impact Medicare beneficiaries' out-of-pocket costs for their prescriptions. In addition, by law, Medicaid programs in every state receive the lowest negotiated rate for prescription drugs. To the extent the final rules drive changes in prescription drug prices, this will impact the amount all states, the Federal Government, and some beneficiaries pay for prescription drugs. Similarly, if providers start increasing (or decreasing) their in-network rates, there could also be spillover effects for Medicare Advantage or Medicaid Managed Care Organizations (MCO), particularly for issuers and plans that use the same network for both private plans, Medicare Advantage Plans and Medicaid MCOs. These changes will impact the amount the Federal Government, states, and beneficiaries will need to pay for their Medicare and/or Medicaid.

Overall Health Insurance Market. The price transparency required by the final rules may also induce an uninsured person to obtain health insurance coverage. Depending on premium rates, an uninsured individual might select health insurance coverage after learning the actual dollar difference between the usual and customary rates that he or she pays for items and services and the in-network rates and out-of-network allowed amounts under the terms of a plan or issuer's policy. In addition, the final rules might force providers to lower their rates for certain items and services in order to compete for the price sensitive consumer, plan, or issuer. Although the immediate payment impact would be categorized as a transfer, any accompanying health and longevity improvements would be considered benefits (and any accompanying increases in utilization would, thus, be considered additional costs). As discussed in section V.B in this preamble, a study of New Hampshire's HealthCost initiative found that the availability of pricing information resulted in a five percent reduction in costs for medical imaging procedures. The study further found that patients saved approximately $7.5 million dollars on X-Ray, CT, and MRI scans over the five-year study period (dollars are stated in 2010 dollars).[273]

Some commenters suggested that the biggest impact on health care spending and costs would come from self-insured employers who would now be able to access and use in-network rate data to negotiate lower rates on behalf of plan participants; improve their provider networks; make more informed decisions about plan offerings; help steer enrollees to higher-quality, lower-cost providers; and more meaningfully implement value-based payment designs. Other commenters stated that the proposed rules would help create more efficient and value-based health care systems by encouraging issuers to design innovative benefit designs that push patients toward lower-cost care. Another commenter stated that requiring plans and issuers to share publicly their in-network rates and the allowed amounts paid to out-of-network providers had the potential to increase competition among plans and issuers.

The Departments are of the view that the requirements in the final rules will provide providers, plans, and issuers the ability to provide quality health care services at lower costs to participants, beneficiaries, or enrollees through enhanced provider and payer competition.

4. Medical Loss Ratio (45 CFR 158.221)

''Shared savings'' programs allow issuers to share with enrollees any savings that result from enrollees shopping for, and receiving care from, lower-cost, higher-value providers. In the final rules, HHS is amending 45 CFR 158.221(b) to allow health insurance issuers that elect to offer ''shared savings'' programs to take credit for such ''shared savings'' payments in their MLR calculations. For this impact estimate, HHS is assuming that only relatively large issuers (with at least 28,000 enrollees) that have consistently reported investment costs in health IT on the MLR Annual Reporting Form of at least $10.50 per enrollee, which represents issuers with 70 percent of total reported commercial market health IT investment or issuers that operate in states that currently or may soon support ''shared savings'' plan designs,[274] will initially choose to offer plan designs with a ''shared savings''

[272] Boynton, A., and Robinson, J. ''Appropriate Use of Reference Pricing Can Increase Value.'' Health Affairs Blog. July 7, 2015. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20150707.049155/full/.*

[273] Brown, Z.Y. ''Equilibrium Effects of Health Care Price Information.'' 100 Rev. Econ. & Stat. 1. (2018). Available at: *http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.*

[274] The states that supported ''shared savings'' plan designs at the time the estimate was developed and therefore were included in the estimate are Maine, Massachusetts, New Hampshire, and Utah.

component. HHS assumes that such issuers will share, on average, 50 percent of the savings with enrollees (which will increase the MLR numerator under the final rules), and that issuers whose MLRs were previously below the applicable MLR standards will use their retained portion of the savings to lower enrollees' premiums in future years (which will reduce the MLR denominator). Based on 2017–2019 MLR data, HHS estimates that this will reduce MLR rebate payments from issuers to enrollees by approximately $120 million per year, while facilitating savings that will result from lower medical costs of approximately $154 million per year for issuers and enrollees (some of which will be retained by issuers, shared directly with enrollees, or used by issuers to reduce future premium rates).

5. Summary of Estimated Transfers

The Departments are assuming that because 2021 premium rates are nearly finalized, health insurance issuers will not be able to charge for the expenses incurred to implement the requirements of the final rules in their 2021 rates. Because issuers will not have the opportunity to reflect the 2021 development costs in the 2021 premium rates, some issuers may apply margin to the ongoing expenses as they develop premium rates for 2022 and after. The Departments estimate premiums for the fully-insured markets will be $471 billion for 2022, $494 billion in 2023, $516 billion in 2024, and $539 billion in 2025, which includes the individual, small group, and large group markets.[275] The Departments estimate that the ongoing expense represents approximately 2.4 percent of projected commercial insured premiums for the fully-insured market in 2022, 1.4 percent in 2023, and 0.5 percent in 2024 and 2025 (an average of 1.2 percent per year). Assuming this level of premium increase in the individual market, PTC outlays are estimated to increase by about $1,047 million in 2022, $623 million in 2023, $216 million in 2024, and $218 million in 2025. Given that 2022 PTC outlays are expected to be $44 billion,[276] the Departments expect that the estimated premium impacts will be relatively small, and rate increases for subsidized enrollees in the individual market will largely be mitigated. Therefore, the Departments expect enrollment impacts to be minimal. The Departments note that any impact of the final rules on provider prices has not been estimated as limited evidence has generally shown no predictable impact on provider prices. As a result, the Departments are assuming that the overall impact will be minimal. However, there is a large degree of uncertainty regarding the effect on prices, so actual experience could differ.

The Departments received comments stating that the broader impact to premiums was not considered in the proposed rules. Several commenters stated that increased health care prices could be passed along to consumers, patients, and taxpayers in the form of higher premiums. Some commenters specifically observed that the cost of developing and maintaining the required machine-readable files on a monthly basis would likely be passed on to consumers in the form of higher premiums. Another commenter noted that employers, TPAs, and issuers might incur increased costs relative to the rules regarding potential data breaches, increased liability, and cyber-coverage costs (liability insurance designed to cover financial losses that result from data breaches and other cyber events) that could also impact plan premiums.

Other commenters suggested that use of information in the In-network Rate File could be used by consumers to engage in practices that would lead to adverse selection and potentially higher premiums. One commenter asserted that the proposed rules would allow individuals to enter the insurance pool for specific costly treatments or procedures and then drop coverage or switch coverage at the end of the contract year for a plan with lower premiums, which would result in higher premiums for all consumers because there is no ability for health plans to spread the risk across a reliable and long-term customer base.

By contrast, one commenter observed that premium increases could be mitigated if low-deductible participants, beneficiaries, or enrollees were given information about the cost of the health care they utilize, and that over time price transparency could create lower health care costs.

The Departments recognize that many issuers and TPAs will likely transfer the costs associated with meeting the requirements in the final rules to consumers in the form of increased premiums. However, the Departments do not currently have enough information or evidence to determine the overall effects the final rules will have on premiums and therefore have not estimated how the final rules will impact an individual's premium. The Departments also note that adverse selection risk currently exists in the individual market; individuals already make health care coverage decisions based on their particular health and financial situations. It is not clear how the price information contained in the In-network Rate, Allowed Amount, and Prescription Drug Files will significantly impact an individual's health care coverage decisions. The Departments do not expect the final rules to significantly increase the selection risk beyond the levels that currently exist.

Also, it is questionable how much the final rules will lower health care costs for low deductible participants, beneficiaries, or enrollees because cost-sharing amounts are usually much less than the cost of the services, so that the participants, beneficiaries, or enrollee have no economic incentive to seek lower cost services. Additionally, evidence is limited but generally does not show significant differences in insured participant, beneficiary, or enrollee behavior as a result of price transparency.

C. Regulatory Review Costs

Affected entities will need to understand the requirements of the final rules before they can comply. Group health plans and health insurance issuers are responsible for ensuring compliance with the final rules. However, as assumed elsewhere, it is expected that issuers and TPAs (for self-insured group health plans) will incur this cost and burden for most group health plans, and only the largest self-insured plans may incur this cost and burden directly. Thus, issuers and TPAs (and possibly some of the largest self-insured plans) will be responsible for providing plans with compliant services. The Departments are currently not aware of any specific number of large self-insured plans that will seek to meet the requirements of the final rules without third-party assistance and are thus unable to accurately account for those plans, however, those plans will incur similar costs and burdens as TPAs and issuers in order to develop the required tools and to review and understand the final rules. Therefore, the cost and burden for the regulatory review is estimated to be incurred by the 1,959 issuers and TPAs. The Departments also are of the view that each state DOI, 50 states plus the District of Columbia, will need to review and understand the final rules in order to be able to provide the appropriate level of oversight and enforcement.

[275] 2017 earned premium data was taken from amounts reported for MLR, and trended forward using overall Private Health Insurance trend rates from the NHE projections.

[276] OMB 2021 President's Budget. Available at: *https://www.whitehouse.gov/wp-content/uploads/2020/02/budget_fy21.pdf.*

If regulations impose administrative costs on private entities, such as the time needed to read and interpret the final rules, the Departments should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review and interpret the final rules, the Departments are assuming that the total number of issuers, TPAs, and state DOIs will be required to comply with the final rules.

Nonetheless, the Departments acknowledge that this assumption may understate or overstate the costs of reviewing the final rules. It is possible that not all affected entities will review the final rules in detail, and some entities may seek the assistance of outside counsel to read and interpret them. For these reasons, the Departments are of the view that the number of issuers, TPAs, and DOIs would be a fair estimate of the number of reviewers of the final rules.

Using the wage information from the Bureau of Labor Statistics (BLS) [277] for a Computer and Information Systems Manager (Code 11–3021), a Lawyer (Code 23–1011) and a state Compliance Officer (Code 13–1041).[278] The Departments estimate that the cost for each issuer or TPA to review the final rules will be $285.66 per hour, including overhead and fringe benefits, and each state DOI will incur a cost of approximately $55.58 per hour.[279] Assuming an average reading speed, the Departments estimate that it will take approximately two hours for each staff member to review and interpret the final rules; therefore, the Departments estimate that the cost of reviewing and interpreting the final rules for each issuer and TPA will be approximately $571.32 and $111.16 for each state DOI, including the District of Columbia. Thus, the Departments estimate that the overall cost for the estimated 1,959 issuers and TPAs and each state DOI will be $1,124,885.04 (($571.32 × 1,959 (total number of estimated issuers and TPAs)) + ($111.16 × 51 (total number of DOIs))).

D. Regulatory Alternatives Considered

In developing the policies contained in the final rules, the Departments considered alternatives to the final rules. In the following paragraphs, the Departments discuss the key regulatory alternatives the Departments considered.

1. Limiting Cost-Sharing Disclosures to Certain Covered Items and Services, and Certain Types of Group Health Plans and Health Insurance Issuers

The final rules require group health plans and health insurance issuers to disclose cost-sharing information for any requested covered item or service. The Departments considered limiting the number of items or services for which plans and issuers would be required to provide cost-sharing information to lessen the costs on these entities. However, limiting disclosures to a specified set of items and services reduces the breadth and availability of useful cost estimates to determine anticipated cost-sharing liability and limits the impact of price transparency efforts by reducing the incentives to lower prices and provide higher-quality care. The Departments assumed that plans (or TPAs on their behalf) and issuers, whether for a limited set of covered items and services or for all covered items and services, would be deriving these data from the same data source. Because the data source would be the same, the Departments assumed that any additional costs to produce the information required for all covered items and services, as opposed to a limited set of covered items and services, would be minimal. The Departments are of the view that this limited additional cost is outweighed by the potentially large benefit to consumers of having access to the required pricing information for the full scope of items and services covered by their plan or issuer. For these reasons, in order to allow consumers to estimate their out-of-pocket costs for all services and items covered under their plan or coverage, and to achieve lower health care costs and reduce spending through increased price transparency, the final rules are requiring cost-sharing information be disclosed for all covered items and services. However, in recognition of commenters' concerns regarding the implementation timetable for the internet-based self-service tool, the final rules include a staggered implementation schedule for the disclosure of cost-sharing information through the internet-based self-service tool.

The Departments also considered implementing a more limited approach by imposing requirements only on individual market plans and fully-insured group coverage. However, the Departments are concerned that this limited approach might encourage plans to simply shift costs to sectors of the market where these requirements would not apply and where consumers would have less access to pricing information. The Departments are of the view that all consumers should be able to access the benefits of greater price transparency and that a broader approach will have the greatest likelihood of controlling the cost of health care industry-wide. Indeed, if the requirements of the final rules were limited to only individual market plans, the Departments estimate only 9,716,000 individuals would receive the intended benefits of the final rules. In contrast, under the final rules, a total of 212,314,000 participants, beneficiaries, and enrollees may receive the intended benefits.[280] The Departments acknowledge that limiting applicability of the requirements of the final rules to the individual market would likely reduce the overall cost estimates identified in section V.B.2, but the overall cost estimates per covered life would likely increase. Further, there is a great deal of overlap in issuers that offer coverage in both the individual and group markets. Issuers offering coverage in both markets would be required to comply with the requirements of the final rules even if the Department limited the applicability to only the individual market. Because TPAs provide administrative functionality for self-insured group health insurance coverage, those non-issuer TPA entities would not incur any costs because they do not have any overlap between the individual and group markets. The Departments are of the view that the benefits of providing consumer pricing information to an estimated total 212,314,000 participants, beneficiaries, and enrollees outweigh the increased costs that a subset of plans, issuers, and TPAs, that are not active participants in the individual market, would incur. The Departments have determined that the benefits of the final rules being widely applicable will not only provide access to health care pricing information to a greater number of individuals, but that any developed economies of scale will have a much

[277] Wage information available at *https://www.bls.gov/oes/current/oes_nat.htm.*

[278] Wages obtained for State Government, excluding schools and hospitals at *https://www.bls.gov/oes/current/naics4_999200.htm.*

[279] Adjusted hourly wages are determined by multiplying the mean hourly rate by 100 percent to account for fringe benefits and overhead costs.

[280] ''Health Insurance Coverage in the United States: 2019'' (Appendix A). United States Census Bureau/September 15, 2020. Available at: *https://www2.census.gov/programs-surveys/demo/tables/p60/271/table1.pdf.* The number of covered individuals in the individual market and the total number of covered individuals have been updated from those estimated in the proposed rule. The numbers provided in this final rule are based on more recent data and more accurately reflect the number of covered individuals in the private market (excluding those enrolled in Tricare coverage). The data provided is for 2019, whereas the data presented in the proposed rule was derived from multiple sources for multiple years (2016 and 2019).

greater likelihood of achieving the goal of controlling the cost of health care industry-wide.

As noted in section I.B of this preamble, in the summer and fall of 2018, HHS hosted listening sessions in which attendees stated that existing tools usually use historical claims data, which results in broad, sometimes regional, estimates, rather than accurate and individualized prices. The Departments considered allowing plans and issuers to use rate information from historical claims data to calculate price estimates. The Departments recognize that many plans and issuers use historical claims data to inform and determine cost-sharing estimates, but the Departments are of the view that using pricing information such as negotiated rates will provide for a more accurate and reliable estimate. Providing more accurate estimates of consumer prices will provide more benefit to consumers, allowing them to better estimate their potential out-of-pocket costs and search for items and services they feel are more affordable.

2. Requirement To Make Available Machine-Readable Files of In-Network Rates, Historical Data for Out-of-Network Allowed Amount Payments Made to Out-of-Network Providers, and Prescription Drug Pricing Information on a Public Website

In proposing the requirement that group health plans and health insurance issuers post in-network rates, historical data for out-of-network allowed amount payments made to out-of-network providers, and negotiated rates and historical net prices for each prescription drug on a publicly accessible website, the Departments considered requiring plans and issuers to submit the internet addresses for the machine-readable files to CMS. CMS would then make the information available to the public from CMS's website. A central location could allow the public to access in-network rate information, out-of-network allowed amounts, and prescription drug information for all plans and issuers in one place, potentially reducing confusion and increasing accessibility. Posting in-network rates, out-of-network allowed amounts, and prescription drug information in a central location might also make it easier to post available quality information alongside price information. However, to provide flexibility and reduce costs, the Departments are of the view that plans and issuers should determine where to post the in-network rate, out-of-network allowed amount, and prescription drug information rather than prescribing the location where the information is to be disclosed. Further, requiring plans and issuers to submit internet addresses for their machine-readable files to CMS would result in additional costs to the extent plans and issuers already post this information in a different location.

3. Frequency of Updates to Machine-Readable Files

In developing 26 CFR 54.9815–2715A3(b)(3), 29 CFR 2590.715–2715A3(b)(3), and 45 CFR 147.212(b)(3) of the final rules, the Departments considered requiring more frequent updates (*i.e.,* within 10 calendar days of new rate finalization) to the in-network rates, out-of-network allowed amounts, and prescription drug information. More frequent updates would provide a number of benefits for patients, providers, and the public at large. Specifically, such a process would ensure that the public has access to the most up-to-date rate information so that consumers can make the most meaningful, informed decisions about their health care utilization. Requiring group health plans, health insurance issuers, and TPAs (or other entity acting on a plan or issuers behalf) to update the machine-readable files more frequently would result in increased costs for those affected entities, however. With respect to the In-network Rate File, the Departments estimate that requiring updates within 10 calendar days of rate finalization would result in each plan, issuer, or TPA incurring a burden of 4,428 hours, with an associated equivalent cost of $635,112 in the second year after implementation of the final rules and an annual burden of 1,116 hours, with an associated equivalent cost of $162,828 in subsequent years. Based on recent data the Departments estimate a total 1,959 entities—1,754 issuers [281] and 205 TPAs [282]—will be responsible for implementing the final rules. For all 1,959 issuers and TPAs, the total burden, in the second year of implementation of the final rules, would be 8,674,452 hours, with an associated equivalent cost of $1,244,184,408 and an annual ongoing burden of 2,186,244 hours, with an associated ongoing annual costs of $318,980,052 in subsequent years. As discussed in section VI.A.2, requiring a less frequent 30 calendar day update will reduce the burden, in year two, for each entity to 1,476 hours with an associated equivalent cost of $211,704. The burden and associated costs, in subsequent years, will be reduced to 372 hours, with an associated cost of $54,276. For all 1,959 issuers and TPAs, the total burden, in year two, is reduced to 2,891,484 hours, with and associated equivalent cost of $414,728,136. For subsequent years, the total burden is reduced to 728,748 hours, with an associated equivalent cost of $106,326,684. With respect to the Allowed Amount File, the Departments estimate that requiring updates within 10 calendar days of rate finalization would result in each plan, issuer, or TPA incurring a burden of 1,908 hours, with an associated equivalent cost of $290,628 in the second year and an annual ongoing burden of 468 hours, with an associated equivalent cost of $61,452 in subsequent years. For all 1,959 issuers and TPAs, the total burden, in year two, would be 3,737,772 hours with and associated equivalent cost of $569,340,252. For subsequent years, the total ongoing burden would be 916,812 hours, with an associated equivalent cost of $120,384,468. As further discussed in section VI.A.2, requiring a less frequent update will reduce the year two burden for each issuer and TPA to 636 hours, with an associated equivalent cost of $96,876. For subsequent years, the total ongoing burden will be reduced to 156 hours, with an associated equivalent cost of $20,848. For all 1,959 issuers and TPAs, the total burden for year two is reduced to 1,245,924 hours, with an associated equivalent cost of $189,780,084. For subsequent years, the total ongoing burden will be reduced to 305,604 hours, with an associated equivalent cost of $40,128,156. With respect to the Prescription Drug File, the Departments estimate that requiring updates within 10 calendar days of rate finalization would result in each plan, issuer, or TPA incurring a burden of 2,700 hours, with an associated equivalent cost of $416,664 in the second year and an annual ongoing burden of 1,116 hours, with an associated equivalent cost of $162,828 in subsequent years. For all 1,959 issuers and TPAs, the total burden, in year two, would be 5,289,300 hours with and associated equivalent cost of $816,244,776. For subsequent years, the total ongoing burden would 2,186,244 hours, with an associated equivalent cost of $318,980,052. As discussed in section VI.A.2, requiring a less frequent update will reduce the year two burden for each issuer and TPA to 900 hours, with an associated equivalent cost of $138,888. For subsequent years, the total ongoing burden will be reduced to 372 hours,

[281] 2018 MLR Data Trends.

[282] Non-issuer TPAs based on data derived from the 2016 Benefit Year reinsurance program contributions.

with an associated equivalent cost of $54,276. For all 1,959 issuers and TPAs, the total burden for year two is reduced to 1,763,100 hours, with an associated equivalent cost of $272,081,592. For subsequent years, the total ongoing annual burden will be reduced to 728,748 hours, with an associated equivalent cost of $106,326,684. By requiring monthly updates to the machine-readable files, rather than updates every 10 calendar days, the Departments have chosen to strike a balance between placing a significant burden on issuers (and their service providers) and assuring the availability of accurate information.

4. File Format Requirements

In 26 CFR 54.9815–2715A3(b)(2), 29 CFR 2590.715–2715A3(b)(2), and 45 CFR 147.212(b)(2), the final rules require group health plans and health insurance issuers to post information in three machine-readable files. A machine-readable file is defined as a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost. The final rules require each machine-readable file to use a non-proprietary, open format. The Departments considered requiring issuers and TPAs to post in-network rates, allowed amounts paid for out-of-network services, and prescription drug information using a specific file format, namely JSON. However, the Departments are of the view that being overly prescriptive regarding the file type will impose an unnecessary costs on issuers and TPAs despite the advantages of JSON, namely that JSON files are downloadable and readable for many health care consumers, and the potential for JSON to simplify the ability of price transparency tool developers to access the data. Therefore, the Departments are requiring that issuers and TPAs post the in-network rate, allowed amount, and prescription drug pricing information in three distinct machine-readable files using a non-proprietary, open format. The Departments will provide additional guidance regarding the file format in future technical implementation guidance.

In addition, the Departments considered requiring plans and issuers to provide the specific out-of-network allowed amount methodology needed for consumers to determine out-of-pocket liability for services by providers not considered in-network by the plan or issuer, rather than historical data on paid out-of-network claims. However, the Departments understand providing a formula or methodology for calculating a provider's out-of-network allowed amount does not provide the data users need in an easy-to-use machine-readable format. The Departments determined that providing monthly data files on allowed amounts by plans and issuers over a 90-day period for items and services provided by out-of-network providers will enable users to more readily determine what costs a plan or issuer may pay toward items or services obtained out-of-network. Because a plan or issuer does not have a contract with an out-of-network provider that establishes negotiated rates, the plan or issuer cannot anticipate what that provider's charges will be for any given item or service; therefore, the Departments, as discussed previously in this preamble, are requiring the inclusion of billed charges in the Allowed Amounts File.

Providing data on the billed charge in connection with each unique allowed amount on the out-of-network Allowed Amount File will provide consumer with information related to what their plan or issuer will likely contribute to the costs of items or services obtained from out-of-network providers and the billed charges associated with those item or services. This information will provide the consumer with a reasonably accurate estimate of the amount of additional liability a consumer could be required to pay for a particular item or service received from an out-of-network provider. Out-of-network allowed amount and billed charges data will provide increased price transparency for consumers, and the costs related to producing these data are not considered to be significantly higher than that associated with producing the methodology for determining allowed amounts for payments to out-of-network providers. Given these circumstances, the final rules are requiring that payers provide allowed amount data for out-of-network covered items or services furnished by a particular out-of-network provider during the 90-day time period that begins 180 days prior to the publication date of the Allowed Amount File, and billed charges rather than requiring plans and issuers to report their methodology or formula for calculating the allowed amounts for out-of-network items and services.

5. Requiring Disclosure of Cost-Sharing Information to Participants, Beneficiaries, and Enrollees and Publicly-Posted Machine-Readable Files With In-Network Rates, Out-of-Network Allowed Amounts, and Prescription Drug Pricing Information

The Departments considered whether it would be duplicative to require group health plans and health insurance issuers to disclose cost-sharing information through an internet-based self-service tool or in paper form to participants, beneficiaries, or enrollees so that they may obtain an estimate of their cost-sharing liability for covered items and services and publicly-posted machine-readable files containing data on in-network rates, out-of-network allowed amounts, and prescription drug pricing information. The requirement to disclose cost-sharing information to participants, beneficiaries, or enrollees in the final rules require plans and issuers to provide consumer-specific information on potential cost-sharing liability to enrolled consumers, complete with information about their deductibles, copays, and coinsurance. However, cost-sharing information for these plans and coverage would not be available or applicable to consumers who are uninsured or shopping for plans pre-enrollment. Data disclosed to participants, beneficiaries, or enrollees would also not be available to third parties who are interested in creating internet-based self-service tools to assist both uninsured and insured consumers with shopping for the most affordable items or services. Limiting access to data to a subset of consumers would not promote the transparency goals of the final rules and would reduce the potential for the final rules to drive down health care costs by increasing competition.

As discussed in more detail in section VI.A.1 in this preamble, the Departments have estimated the high-end three-year average annual cost to develop only the internet-based self-service tool, including the initial tool build and maintenance, customer service training, customer assistance, and mailing costs. The Departments estimate the three-year average total burden per issuer, or TPA will be approximately 23,338 hours, with an associated equivalent average annual cost of approximately $3,262,262. For all 1,959 issuers and TPAs, the Departments estimate the total three-year average annual burden will be 45,718,171 hours with an associated equivalent total average annual cost of approximately $6,390,770,952.

Additionally, the Departments estimated that for implementation of the required internet-based self-service tool in conjunction with the out-of-network allowed amount, in-network and prescription drug machine-readable files, the Departments estimate that the annual high-end three-year average annual costs and burden for each issuer or TPA will be approximately 28,958 hours, with an associated equivalent cost of approximately $4,040,142. For all 1,959 issuers and TPAs, the Departments estimate the total three-year average annual burden and cost to be 56,727,751 hours with an associated equivalent total average annual cost of approximately $7,914,635,260.

In contrast, and as discussed in more detail in section VI.A.1, the Departments estimate that the low-end three-year average burden and cost to develop and maintain only the internet-based self-service tool, including the initial tool build and maintenance, customer service training, customer assistance, and mailing costs. The Departments estimate the total three-year average cost and burden per issuer or TPA will be approximately 15,475 hours, with an associated equivalent average annual cost of approximately $2,150,169. For all 1,959 issuers and TPAs, the Departments estimate the total three-year average annual burden to be 30,315,730 hours with an associated equivalent total average annual cost of approximately $4,212,181,157.

Finally, the Departments estimated that for implementation of the required internet-based self-service tool in conjunction with the out-of-network allowed amount, in-network rate, and prescription drug machine-readable files, the Departments estimate that the three-year average annual low-end cost and burden for each issuer or TPA will be approximately 21,095 hours, with an associated equivalent average annual cost of approximately $2,928,048. For all 1,959 issuers and TPAs, the Departments estimate the total three-year average annual low-end burden and cost will be 41,325,310 hours with an associated equivalent total average annual cost of approximately $5,736,045,465. While the Departments recognize that requiring disclosures through all mechanisms will increase the costs for issuers and TPAs required to comply with the final rules, the Departments are of the view that the additional costs associated with greater price transparency are outweighed by the benefits that will accrue to the broader group of consumers (such as the uninsured and individuals shopping for coverage) and other individuals who would benefit directly from the additional information provided through the machine-readable files. Additionally, the Departments are of the view that the final rules have the potential to reduce the cost of surprise billing to consumers. The Departments further believe that the final rules will, with the disclosure of in-network rates, potentially apply pressure on providers to bill less aggressively. Consumer advocacy groups could also use the wide price dispersion of the same CPT level service or NDC level drug by the same providers with different negotiated rates, depending upon issuer or TPA contract, to further place downward pressure on health care costs. In addition, as noted earlier in section II.C.1–2 of this preamble, researchers and third-party developers will also be able to use the data included in the machine-readable files in a way that could create even more benefits to consumers, including those consumers not currently enrolled in a particular plan or coverage. For these reasons, the Departments have concluded that, in addition to requiring plans and issuers to disclose cost-sharing information to participants, beneficiaries, or enrollees through an internet-based self-service tool, requiring plans and issuers to publicly disclose information regarding in-network rates, out-of-network allowed amounts, and prescription drug pricing will further the goals of price transparency and create benefits for all potentially affected stakeholders.

6. Requiring an Internet-Based Self-Service Tool and Machine-Readable Files in Lieu of an API

The Departments considered whether to require group health plans and health insurance issuers to make the information required by the final rules available through a standards-based API, instead of through the proposed internet-based self-service tool and machine-readable files. Access to pricing information through an API could have a number of benefits for consumers, providers, and the public at large. This information could ensure the public has access to the most up-to-date rate information. Providing real-time access to pricing information through a standards-based API could allow third-party innovators to incorporate the information into applications used by consumers or combined with electronic medical records for point-of-care decision-making and referral opportunities by clinicians for their patients. Additionally, being able to access this data through a standards-based API would allow consumers to use the application of their choice to obtain personalized, actionable health care price estimates, rather than being required to use one developed by their plan or issuer (or a service provider), although those consumers may be required to pay for access to those applications.

While there are many benefits to a standards-based API, it is the Departments' view that both an internet-based tool and machine-readable files are the first iterative steps towards developing price transparency standards-based APIs. It is the Departments' view that standards-based API would be a natural next technological step. The Departments also recognize that the majority of issuers have an existing internet-based tool that could be enhanced to meet the disclosure requirements in the final rules. The burden associated with updating existing tools to standardize data attributes is going to be less than building a standards-based API. Looking at the average cost over a 3-year period for the API for all 1,959 issuers and TPAs, the Departments estimate an average annual cost that would significantly exceed the estimated annual cost of implementing the internet-based self-service tool and machine-readable files. The Departments recognize that the development of an API may be streamlined by leveraging existing APIs currently used by plans, issuers, or TPAs for their own applications. Additionally, any requirements for an API would build on the requirements finalized in CMS's Interoperability & Patient Access final rule [283] requiring certain entities, such as Federally-facilitated Exchange QHP issuers and companies that participate in both Medicare and the individual or group market, to provide certain data through a standards-based API. Building on the Interoperability & Patient Access final rule could result in significantly lower costs for issuers and TPAs as it relates to the development and implementation of a standards-based API. Nonetheless, while the Interoperability & Patient Access final rule focuses on the disclosure of information regarding post care and clinical data, the rules finalized here require plans and issuers to provide information related to a participant's, beneficiary's, or enrollee's individual's cost-sharing, allowed amounts for covered items and services from out-of-network providers, and negotiated rates and historical net prices for each prescription drug prior to seeking or obtaining care. The Departments are therefore of the view

[283] 85 FR 25510 (May 1, 2020).

that plans, issuers, and TPAs would incur significant and distinct costs if required to us a standards-based API to comply with the final rules.

Although not estimated here, the Departments expect any associated maintenance costs would also decline in succeeding years as plans, issuers, and TPAs gain additional efficiencies or undertake similar procedures to maintain any currently used internal APIs. Nonetheless, weighing the costs of providing the required information using an internet-based self-service tool and machine-readable files against the potential costs of using a standards-based API, particularly given the timeframes required by the final rules, the Departments are of the view that, at least in the short-term, requiring an internet-based self-service tool and machine-readable files is the more sensible approach.

Even though the Departments are of the view that an internet-based self-service tool and machine-readable files are appropriate in the short-term, as discussed earlier in this preamble, the Departments recognize that a standards-based API format in the long-term may be more beneficial to the public, as it would provide access to the most up-to-date rate information; would allow health care consumers to use the application of their choice to obtain personalized, actionable health care service price estimates; and would allow third-party developers to use the collected data to develop internet-based self-service tools. Therefore, the Departments are considering future rulemaking to further expand access to pricing information through standards-based APIs, including individuals' access to estimates about their own cost-sharing liability and information about in-network rates, historical payment data for out-of-network allowed amounts, and negotiated rates and historical net prices for prescription drugs.

VI. Collection of Information Requirements

The final rules contain ICRs that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 24.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Departments solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of each of the Departments.
- the accuracy of the Departments' 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.

The Departments solicited comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive wage estimates, the Departments generally use data from the BLS to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with ICRs.[284] One commenter noted that the markup rates for labor, fringe benefits, and overhead are underestimated at 100 percent, while the conventional standard is 200 percent to 300 percent. The commenter further stated that if the Departments were to update the burden estimates with the conventional standard for overhead markup, the total of annual quantified costs would increase to over $500 million per year.

The Departments acknowledge that there are various methodologies used to determine and estimate fringe benefits and other overhead costs; however, the commenter did not provide any source recognizing or supporting their assertion that the conventional standard is to use 200 percent to 300 percent increases. The Departments agree that if a higher percentage were used to estimate hourly wages and overhead, then the estimated costs for the final rules could potentially be significantly higher. However, the Departments note that the use of 100 percent is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. The Departments are of the view that doubling the hourly wage to estimate total cost is a reasonably acceptable estimation method.

The Departments recognize that the maturity of technology will vary from organization to organization. An independent study by Bates White Economic Consulting (Bates White), commissioned by one commenter, developed an assessment of the costs of the proposed rules by interviewing a mix of 18 large and small health insurance issuers covering about 78 million lives. They reported various degrees of existing tools' compliance with the requirements of the proposed rules. The Departments reevaluated its initial burden estimates developed for the proposed rules based on feedback from commenters and the Bates Whites study. Because the Departments could not make an estimate for any specific issuer, an independent government cost estimate (IGCE) was conducted for each of the machine-readable files and the internet-based self-service tool to aid the Departments in conducting the burden and cost estimates for the final rules. The goals of an IGCE are to aid the government acquisition process in determining a project's cost estimates based on project requirements or objectives that are typically found in a performance work statement or statement of work. IGCEs are developed by the government without contractor influence and are based on market research. The estimated skill sets required to build both the internet based self-service tool and machine-readable files can be found in TABLE 3 below. The Departments based the IGCE cost estimates on the rule's requirements and each IGCE has baseline assumptions that are built into the final estimate.

The IGCE assumptions for the internet-based self-service tool included things such as research, engineering development, and design and were not based on any existing tools. There was an assumption that product development would be done in the cloud to take advantage of economies of scale or with on-premise infrastructure that allows for the development of ''infrastructure as code.'' The IGCE assumptions for the machine-readable files included that all items and services for a specific plan have a negotiated price, that all price numbers are digitized, that pricing information is stored in many locations (not in a single database), that pricing information is accessible through internal systems, that building the first machine-readable file will facilitate automation for building future machine-readable files, and that there is an ability to run queries against claims data.

Based on comments discussed later sections VI.A.1–2, the Departments have chosen to use the Contract Awarded Labor Category (CALC)[285] database tool, managed by the General Services Administration (GSA), to derive the

[284] May 2018 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at: *https://www.bls.gov/oes/current/oes_stru.htm.*

[285] CALC information and wage rates are available at: *https://calc.gsa.gov/about/.*

hourly rates for the burden and cost estimates in the final rules. The CALC tool was built to assist acquisition professionals with market research and price analysis for labor categories on multiple U.S. GSA & Veterans Administration (VA) contracts. Wages obtained from the CALC database are fully burdened to account for fringe benefits and overhead costs. The Departments chose to use wages derived from the CALC database because, even though the BLS data set is valuable to economists, researchers, and others that would be interested in larger, more macro-trends in parts of the economy, the CALC data set is meant to help market research based on existing government contracts in determining how much a project/product will cost based on the required skill sets needed. The CALC data set also factors in the fully-burdened hourly rates (base pay + benefits) into wages whereas BLS rates do not. CALC occupations and wages provide the Departments with data that aligns more with, and provides more detail related to, the occupations required for the implementation of the requirements in the final rules. As discussed earlier, after consideration and discussion of comments, the Departments chose to further reevaluate the cost and burden estimates. Based on the Departments consultation with internal and external IT professionals and additional research, the Departments have chosen to increase our overall costs and burden estimates to account for our updated understanding of the burdens associated with the final rules and the additional requirements included in the final rules. The Departments further discuss changes to the final cost and burden estimates in the corresponding ICR sections.

While the following estimates for the internet-based self-service tool assume that entities are either iterating on an existing tool or building a brand new tool from the ground up, the Departments are of the view that it is highly likely that third-party developers will take this opportunity to build white-label products that meet the requirements of the final rules and that they will reduce costs through economies of scale by doing so. As such, the Departments' cost estimates may have some tendency towards over-estimation.

Table 3 presents the fully burdened hourly wage and job descriptions used in the Departments' estimates.

TABLE 3—HOURLY WAGES USED IN BURDEN ESTIMATES

CALC occupation title	Mean hourly wage ($/hour)
Project Manager/Team Lead	$153.00
Scrum Master	105.00
Technical Architect/Sr. Developer	149.00
Application Developer, Senior	143.00
Business Analyst	120.00
UX Researcher/Service Designer	154.00
Designer	116.00
DevOps Engineer	181.00
Customer Service Representative	40.00
Web Database/Application Developer IV	152.00
Service Designer/Researcher	114.00

1. ICR Regarding Requirements for Disclosures to Participants, Beneficiaries, or Enrollees (26 CFR 54.9815–2715A2, 29 CFR 2590.715–2715A2, and 45 CFR 147.211)

The Departments add 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b), requiring group health plans and health insurance issuers of individual and group health insurance coverage to disclose, upon request, to a participant, beneficiary, or enrollee, such individual's cost-sharing information for items; negotiated rates and underlying fee schedule rates for in-network providers; and allowed amounts for covered items and services from out-of-network providers. As discussed previously in section II.B.1 of this preamble, in paragraphs 26 CFR 54.9815–2715A2(b)(1)(i), 29 CFR 2590.715–2715A2(b)(1)(i), and 45 CFR 147.211(b)(1)(i) through (vii) the final rules require plans and issuers to make this information available through an internet-based self-service tool on an internet website and, if requested, in paper form or other format agreed upon between the plan, issuer, or TPA and participant, beneficiary, or enrollee.

The final rules require plans and issuers to disclose, upon request, certain information relevant to a determination of a participant's, beneficiary's, or enrollee's cost-sharing liability for a particular health care item or service from a particular provider, to the extent relevant to the individual's cost-sharing liability for the item or service, in accordance with seven content elements: The individual-specific estimated cost-sharing liability; the individual-specific accumulated amounts; the in-network rate; the out-of-network allowed amount for a covered item or service, if applicable; the items and services content list when the information is for items and services subject to a bundled payment arrangement; a notice of prerequisites to coverage (such as prior authorization); and a disclosure notice. However, as discussed earlier in this section II.B.1 of this preamble, in instances where items or services, generally considered preventive, are furnished as non-preventive items or services, the participant, beneficiary, or enrollee may be subject to the cost-sharing terms of his or her plan. If a plan or issuer cannot determine whether the request is for a preventive item or service, the plan or issuer must display the non-preventive cost-sharing liability, along with a note that the item or service may not be subject to cost-sharing if it is billed as a preventive service. The final rules also require the disclosure notice to include several statements, written in plain language, which include disclaimers relevant to the limitations of the cost-sharing information disclosed, including: A statement that out-of-network providers may balance bill participants, beneficiaries, or enrollees, a statement that the actual charges may differ from those for which a cost-sharing liability estimate is given, and a statement that the estimated cost-sharing liability for a covered item is not a guarantee that coverage will be provided for those items and services. In addition, plans and issuers will be permitted to add other disclaimers they determine appropriate so long as such information is not in conflict with the disclosure requirements of the final rules. The Departments have developed model language that plans and issuers will be able to use to satisfy the requirement to provide the notice statements described earlier in section II.B.1 of this preamble.

As discussed in section II.B.1 of this preamble, the final rules require plans and issuers to make available the information described in 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b) of the final rules through an internet-based self-service tool. The information is required to be provided in plain-language through real-time responses. Plans and issuers will be required to allow participants, beneficiaries, or enrollees to search for cost-sharing information for covered items and services by billing code, or by descriptive term, per the user's request, in connection with a specific in-network provider, or for all in-network providers. In addition, the internet-based self-service tool must allow users to input information necessary to determine the out-of-network allowed amount for a covered item or service

provided by an out-of-network provider (such as zip code). The internet-based self-service tool is required to have the capability to refine and reorder results by the geographic proximity of in-network providers, and the estimated amount of cost-sharing liability to the beneficiary, participant, or enrollee.

As discussed in sections II.B.1 and 2 earlier in this preamble, the final rules require plans and issuers to furnish upon request, in paper form, the information required to be disclosed under 26 CFR 54.9815–2715A2(b)(1), 29 CFR 2590.715–2715A2(b)(1), and 45 CFR 147.211(b)(1) of the final rules to a participant, beneficiary, or enrollee. As discussed in sections II.B.1 and 2 in this preamble, a paper disclosure is required to be furnished according to the consumer's filtering and sorting preferences and mailed to the participant, beneficiary, or enrollee within two business days of receiving the request. Plans or issuers may, upon request, provide the required information through other methods, such as over the phone, through face-to-face encounters, by facsimile, or by email.

The Departments assume fully-insured group health plans will rely on issuers to develop and maintain the internet-based self-service tool and provide any requested disclosures in paper form. While the Departments recognize that some self-insured plans might independently develop and maintain the internet-based self-service tool, at this time the Departments assume that self-insured plans will rely on TPAs (including issuers providing administrative services and non-issuer TPAs) to develop the required internet-based self-service tool. The Departments make this assumption because the Departments understand that most self-insured group health plans rely on TPAs for performing most administrative duties, such as enrollment and claims processing. For those self-insured plans that choose to develop their own internet-based self-service tools, the Departments assume that they will incur a similar cost and burden as estimated for issuers and TPAs, as discussed in section VI.A.1 later in this preamble. In addition, 26 CFR 54.9815–2715A2(b)(3), 29 CFR 2590.715–2715A2(b)(3), and 45 CFR 147.211(b)(3) of the final rules provide for a special rule to prevent unnecessary duplication of the disclosures with respect to health insurance coverage, which provides that a plan may satisfy the disclosure requirements if the issuer offering the coverage is required to provide the information pursuant to a written agreement between the plan and issuer. Thus, the Departments have used issuers and TPAs as the unit of analysis for the purposes of estimating required changes to IT infrastructure and administrative costs and burdens. The Departments estimate approximately 1,754 issuers and 205 TPAs will be affected by the final rules.

The Departments acknowledge that the costs described in these ICRs may vary depending on the number of lives covered, the number of providers and items and services for which cost-sharing information must be disclosed, and the fact that some plans and issuers already have robust tools that can be easily adapted to meet the requirements of the final rules. In addition, plans and issuers may be able to license existing cost estimator tools offered by third-party vendors, obviating the need to establish and maintain their own internet-based self-service tools. The Departments assume that any related vendor licensing fees would be dependent upon complexity, volume, and frequency of use, but assume that such fees would be lower than an overall initial build and associated maintenance costs. Nonetheless, for purposes of the estimates in these ICRs, the Departments assume all 1,959 issuers and TPAs will be affected by the final rules. The Departments also developed the following estimates based on the mean average size, by covered lives, of issuers or TPAs. As noted later in this section, the Departments sought comment on the inputs and assumptions that were used to develop these cost and burden estimates, particularly regarding existing efficiencies that would reduce the cost and burden estimates.

High Range Estimate for Internet-Based Self-Service Tool From Start-Up to Operational Functionality

The Departments estimate that the one-time costs and burden each issuer or TPA will incur to complete the one-time technical build; including activities such as planning, assessment, budgeting, contracting, building and systems testing, incorporating any necessary security measures, incorporating disclaimer and model notice language, or development of the model and disclaimer notice materials for those that choose to make alterations. The Departments assume that this one-time cost and burden will be incurred in 2022 to develop and build the internet-based self-service tool and provide information for the 500 required items and services, and additional one-time costs will be incurred in 2023 in order to fully meet the requirements of the final rules. As mentioned earlier in section V.A.2 of this preamble, the Departments acknowledge that a number of issuers and TPAs have previously developed some level of internet-based self-service tool similar to, and containing some functionality related to, the requirements in the final rules. The Departments thus seek to estimate a burden and cost range (high-end and low-end) associated with the final rules for those issuers and TPAs. In order to develop the high-end hourly burden and cost estimates, the Departments assume that all issuers and TPAs will need to develop and build their internet-based self-service tool from start-up to operational functionality. The Departments estimate that for each issuer or TPA it will take a Project Manager/Team Lead 4,160 hours (at $153 per hour), a Scrum Master 4,160 hours (at $105 per hour), a Technical Architect/Sr. Developer 4,160 hours (at $149 per hour), an Application Developer, Senior 4,160 hours (at $143 per hour), a Business Analyst 4,160 hours (at $120 per hour), a UX Researcher/Service Designer 4,160 hours (at $154 per hour), a Designer 4,160 hours (at $116 per hour), a DevOps Engineer 4,160 hours (at $181 per hour), and a Web Database/Application Developer IV 4,160 hours to complete this task. The Departments estimate the total burden per issuer or TPA will be approximately 37,440 hours, with an equivalent cost of approximately $5,295,680. For all 1,959 issuers and TPAs, the total first year one-time total burden is estimated to be 73,344,960 hours, with an equivalent total cost of approximately $10,374,237,120. The Departments' estimates are higher-bound estimates that do not consider potential cost savings that could be realized should issuers and TPAs buy or lease an internet-based self-service tool from a third-party vendor or other issuer. However, the Departments are of the view that issuers or TPAs that choose to buy or rent an internet-based self-service tool from another entity could incur significantly less costs and burdens.

TABLE 4A—TOTAL HIGH-END FIRST YEAR ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR EACH ISSUER OR TPA

CALC occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	4,160	$153.00	$636,480.00
Scrum Master	4,160	105.00	436,800.00
Technical Architect/Sr. Developer	4,160	149.00	619,840.00
Application Developer, Senior	4,160	143.00	594,880.00
Business Analyst	4,160	120.00	499,200.00
UX Researcher/Service Designer	4,160	154.00	640,640.00
Designer	4,160	116.00	482,560.00
DevOps Engineer	4,160	181.00	752,960.00
Web Database/Application Developer IV	4,160	152.00	632,320.00
Total per respondent	37,440	.....	5,295,680.00

TABLE 4B—TOTAL HIGH-END FIRST YEAR ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR ALL ISSUERS AND TPAS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	37,440.0	73,344,960	$10,374,237,120

Several commenters stated that the Departments grossly underestimated the cost burden of implementation on plans and issuers. One commenter stated that surveyed issuers estimated an average cost of $6.2 million to build, develop or modify, implement, test, and launch an internet-based self-service tool. This is 28 times greater than the Departments' proposed estimate for an issuer that needs to build a new tool and 112 times greater than the Departments' estimate for an issuer that has an existing tool. Furthermore, this commenter noted that surveyed issuers estimated average annual maintenance costs of $1.4 million per issuer—over 100 times greater than those anticipated by the Departments. Surveyed issuers also estimated set-up costs that averaged about $5.53 million (ranging from $1,000,000 to $15,000,000) compared to the Departments' proposed estimate of $221,029. This is more than 25 times what the Departments estimated as the cost for a full build of the internet-based self-service tool. Although most of the issuers surveyed had an existing internet-based self-service tool meeting many of the required elements of the final rules, several issuers expressed significant concern about the cost and feasibility of complying with the requirements of the proposed rules. Specifically, the issuers surveyed expressed concerns noting that the requirements may necessitate a complete rebuild of their consumer tool. The surveyed issuers further indicated that the proposed rules would be costlier than implementing real-time claims adjudication, in which the claim for the medical service is adjudicated at the time the service is provided. They stated that they would need to effectively adjudicate the claim before it actually happens—to provide estimates for every conceivable type of medical item or service while integrating this information with various benefits. The surveyed issuers also noted that condensing all of the detail required in the final rules into a user-friendly format for use by enrollees would be a considerable and possibly even infeasible challenge. They further stated that the Departments' assumption that issuers with an existing internet-based self-service tool would face a lower hour burdens and costs to comply with the proposed rules was incorrect.

The Departments have considered the comments submitted in response to the cost and burden estimates related to the internet-based self-service tool. In response, the Departments have adjusted the costs and burden estimates to better reflect and align with the values submitted by commenters. In addition, the Departments have developed the estimates above, and in other ICR sections, using CALC wage rates as discussed in section VI.A of this preamble.

Low Range Estimate for Internet-Based Self-Service Tool Requiring Partial Build

The Departments recognize that a significant number of issuers and TPAs may already have some form of internet-based self-service tool that allows for comparison shopping of different plans and that a large number of issuers and TPAs may currently provide participants, beneficiaries, or enrollees with the ability to obtain some estimated out-of-pocket costs.[286] For those issuers and TPAs that currently have some level of functional internet-based self-service tool that would meet some (or all) of the requirements of the final rules, the Departments recognize that these entities may incur lower burdens and costs overall, as the Departments are of the view that these entities may require an overall lower level of effort and capital expenditure to meet the requirements of the final rules. Thus, the Departments have estimated a low-end burden and cost to comply with the final rules. Assuming that over 90 percent of issuers and TPAs currently provide an internet-based self-service tool and will only be required to make changes to their current system in order to meet the requirements in the final rules, the Departments estimate that 175 issuers and 21 TPAs will be required to develop an internet-based self-service tool from start-up to operational functionality. The Departments also estimate that each of those 196 entities will incur a first-year one-time cost and burden of approximately 37,440 hours, with an

[286] *See* AHIP release dated August 2, 2019. ''AHIP Issues Statement on Proposed Rule Requiring Disclosure of Negotiated Prices.'' America's Health Insurance Providers. August 2, 2019. Available at: *https://www.ahip.org/ahip-issues-statement-on-proposed-rule-requiring-disclosure-of-negotiated-prices/; see also* Higgins, A., Brainard, N., and Veselovskiy, G. ''Characterizing Health Plan Price Estimator Tools: Findings from a National Survey.'' 22 Am. J. Managed Care 126. 2016. Available at: *https://ajmc.s3.amazonaws.com/_media/_pdf/AJMC_02_2016_Higgins%20(final).pdf.*

equivalent cost of approximately $5,295,680 (as discussed previously in this ICR). For those 196 entities, the total first year one-time burden is estimated to be 7,334,496 hours with an equivalent total cost of approximately $1,037,423,712.

TABLE 5A—LOW-RANGE FIRST YEAR ONE-TIME COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR ISSUERS AND TPAS REQUIRING A COMPLETE BUILD

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
196	196	37,440	7,334,496	$1,037,423,712.00

The Departments estimate that those issuers and TPAs that will only be required to make changes to their existing systems will already have operational capabilities that meet approximately 70 percent of the requirements in the final rules and will only incur costs and burdens related to changes needed to fully meet the requirements of the final rules. Based on this assumption, the Departments estimate that 1,579 issuers and 184 TPAs will incur a first-year one-time hour burden of 11,232 hours, with an associated cost of $1,588,704.00 to fully satisfy the initial requirements of the final rules. For all 1,763 issuers and TPAs, the Departments estimates the total first year one-time burden will be 19,803,139 hours, with an equivalent total cost of approximately $2,801,044,022.40. The Departments recognize that issuers and TPAs may currently have some form of internet-based self-service tool that may provide greater functionality that could meet a greater proportion of the requirements in the final rules. In those cases, issuers and TPAs could see lower costs and burdens. The Departments also recognize that there are likely a number of issuers and TPAs that currently provide some form of internet-based self-service tool that would require more development to meet the requirements of the final rules. In those instances, those issuers and TPAs could incur greater costs and burdens. The Departments' estimates are higher-bound estimates that do not consider potential cost savings that could be realized should issuers and TPAs buy or lease an internet-based self-service tool from a third-party vendor or other issuer. However, the Departments are of the view that issuers or TPAs that choose to buy or rent an internet-based self-service tool from another entity could incur significantly less costs and burdens.

TABLE 5B—LOW-END FIRST YEAR ONE-TIME COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR ISSUERS AND TPAS REQUIRING ONLY A PARTIAL BUILD

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,763	1,763	11,232	19,803,139	$2,801,044,022.40

TABLE 5C—TOTAL LOW-END FIRST YEAR ONE-TIME COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR ALL ISSUERS AND TPAS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	13,853	27,137,635	$3,838,467,734.40

In addition to the range of one-time costs and burdens estimated in Tables 4B, 5B, 5C, 6A, and 6B, issuers and TPAs will incur annual costs such as those related to ensuring cost estimation accuracy, providing quality assurance, conducting website maintenance and making updates, and enhancing or updating any needed security measures. The Departments estimate that for each issuer and TPA, it will take a Project Manager/Team Lead 1,040 hours (at $153 per hour), a Scrum Master 1,300 hours (at $105 per hour), an Application Developer, Senior 1,560 hours (at $143 per hour), a Business Analyst (at $120.00 per hour) 520 hours, a Designer (at $116.00 per hour) 1,040 hours, a DevOps Engineer (at $181.00 per hour) 520 hours, a Web Database/Application Developer IV (at $152.00 per hour) 1,560 hours, and a UX Researcher/Service Designer 520 hours (at $154 per hour) to perform these tasks. The total annual burden for each issuer or TPA will be 8,060 hours, with an equivalent cost of approximately $1,113,060. For all 1,959 issuers and TPAs, the total annual maintenance burden is estimated to be 15,789,540 hours, with an equivalent associated total cost of approximately $2,180,484,540.00. The Departments recognize that issuers and TPAs will likely have varying levels of IT capabilities and experience in maintaining and internet-based tool and could incur higher or lower costs and burdens depending on those capabilities. The Departments expect maintenance costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing their internet-based self-service tool.

TABLE 6A—ESTIMATED YEAR TWO IMPLEMENTATION COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR EACH ISSUER OR TPA

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	3,120	$153.00	$477.360.00
Scrum Master	3,120	105.00	327,600.00
Technical Architect/Sr. Developer	3,120	149.00	464,880.00
Application Developer, Senior	4,160	143.00	594,880.00
Business Analyst	2,080	120.00	249,600.00
UX Researcher/Service Designer	2,080	154.00	320,320.00
Designer	1,560	116.00	180,960.00
DevOps Engineer	2,080	181.00	376,480.00
Web Database/Application Developer IV	3,120	152.00	
Total per Respondent	24,440	.....	3,446,320.00

TABLE 6B—ESTIMATED YEAR TWO IMPLEMENATION COST AND HOUR BURDEN FOR INTERNET-BASED SELF-SERVICE TOOL FOR ALL ISSUERS AND TPAS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	24,440.0	47,877,960	$6,611,791,830.97

In addition to the range of one-time costs and burdens estimated in Tables 4B, 5B, 5C, 6A, and 6B, issuers and TPAs will incur annual costs such as those related to ensuring cost estimation accuracy, providing quality assurance, conducting website maintenance and making updates, and enhancing or updating any needed security measures. The Departments estimate that for each issuer and TPA, it will take a Project Manager/Team Lead 1,040 hours (at $153 per hour), a Scrum Master 1,300 hours (at $105 per hour), an Application Developer, Senior 1,560 hours (at $143 per hour), a Business Analyst (at $120.00 per hour) 520 hours, a Designer (at $116.00 per hour) 1,040 hours, a DevOps Engineer (at $181.00 per hour) 520 hours, a Web Database/Application Developer IV (at $152.00 per hour) 1,560 hours, and a UX Researcher/Service Designer 520 hours (at $154 per hour) to perform these tasks. The total annual burden for each issuer or TPA will be 8,060 hours, with an equivalent cost of approximately $1,113,060. For all 1,959 issuers and TPAs, the total annual maintenance burden is estimated to be 15,789,540 hours, with an equivalent associated total cost of approximately $2,180,484,540.00. The Departments recognize that issuers and TPAs will likely have varying levels of IT capabilities and experience in maintaining and internet-based tool and could incur higher or lower costs and burdens depending on those capabilities. The Departments expect maintenance costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing their internet-based self-service tool.

TABLE 7A—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR MAINTENANCE OF INTERNET-BASED SELF-SERVICE TOOL FOR EACH ISSUER OR TPA

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	1,040	$153.00	$159,120.00
Scrum Master	1,300	105.00	136,500.00
Application Developer, Senior	1,560	143.00	223,080.00
Business Analyst	520	120.00	62,400.00
Designer	1,040	116.00	120,640.00
DevOps Engineer	520	181.00	94,120.00
Web Database/Application Developer IV	1,560	152.00	237,120.00
UX Researcher/Service Designer	520	154.00	80,080.00
Total per Respondent	8,060	.....	1,113,060.00

TABLE 7B—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR MAINTENANCE OF INTERNET-BASED SELF-SERVICE TOOL FOR ALL ISSUERS AND TPAS

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	8,060.0	15,789,540	$2,180,484,540.00

As noted previously in this ICR section, commenters stated that the Departments grossly underestimated the cost burden of implementation on plans and issuers. Additionally, commenters stated that the Departments had underestimated the maintenance costs associated with the internet-based self-service tool. Issuers estimated the annual maintenance costs to be on average, about $3.78 million per issuer or TPA (ranging from $375,000 to $10,000,000). As noted previously in this ICR section, based on comments received, the Departments have adjusted the costs and burden estimates to better reflect and align with the values submitted by commenters. The Departments estimate the high-end three-year average total hour burden, for all issuers and TPAs to develop, build, and maintain an internet-based self-service tool will be 45,670,820 hours annually, with an average annual total equivalent cost of $6,388,837,830.

The Departments acknowledge that the costs described earlier in this section may vary depending on the number of covered lives and the number of providers and items and services incorporated into the internet-based self-service tool. Recognizing that many issuers and TPAs currently have some form of internet-based self-service tool in operation that meets some aspects of the requirements of the final rules, the Departments estimate the low-end average three-year annual total burden, for all issuers and TPAs to develop, build, and maintain an internet-based self-service tool will be 30,268,378 hours annually, with an average annual total equivalent cost of $4,210,248,035. The Departments recognize that plans, issuers, and TPAs may be able to license existing internet-based self-service tools offered by vendors, obviating the need to establish, upgrade, and maintain their own internet-based self-service tools, and that vendor licensing fees, dependent upon complexity, volume, and frequency of use, could be lower than the burden and costs estimated here.

TABLE 8—ESTIMATED HIGH-END THREE YEAR AVERAGE ANNUAL HOUR BURDEN AND COSTS FOR ALL ISSUERS AND TPAS TO DEVELOP AND MAINTAIN THE INTERNET-BASED SELF-SERVICE TOOL

Year	Estimated number of health insurance issuers and TPAs	Responses	Burden per respondent (hours)	Total annual burden (hours)	Total estimated labor cost
2022	1,959	1,959	37,440.0	73,344,960	$10,374,237,120
2023	1,959	1,959	24,440.0	47,877,960	6,611,791,830.97
2024	1,959	1,959	8,060.0	15,789,540	2,180,484,540.00
3 year Average	1,959	1,959	23,313	45,670,820	6,388,837,830.32

TABLE 9—ESTIMATED LOW-END THREE YEAR AVERAGE ANNUAL HOUR BURDEN AND COSTS FOR ALL ISSUERS AND TPAS TO DEVELOP AND MAINTAIN THE INTERNET-BASED SELF-SERVICE TOOL

Year	Estimated number of health insurance issuers and TPAs	Responses	Burden per respondent (hours)	Total annual burden (hours)	Total estimated labor cost
2022	1,959	1,959	13,853	27,137,635	$3,838,467,734.40
2023	1,959	1,959	24,440	47,877,960	6,611,791,830.97
2024	1,959	1,959	8,060	15,789,540	2,180,484,540.00
3 year Average	1,959	1,959	15,451	30,268,378	4,210,248,035.12

In addition to the one-time and annual maintenance costs estimated in Table 8 and Table 9, issuers and TPAs will also incur an annual burden and costs associated with customer service representative training, consumer assistance and education, and administrative and distribution costs related to the disclosures required in the final rules. The Departments estimate that, to understand and navigate the internet-based self-service tool and provide the appropriate assistance to consumers, each customer service representative will require approximately two hours (at $40 per hour) of annual consumer assistance training at an associated cost of $80 per hour. The Departments estimate that each issuer and TPA will train, on average, 10 customer service representatives annually, resulting in a total annual burden of 20 hours, with an associated total cost of $800. For all 1,959 issuers and TPAs, the total annual burden is estimated to be 39,180 hours, with an equivalent total annual cost of approximately $1,567,200. The Departments recognize that some issuers or TPAs may require varying levels of training to acquaint their customer service representatives with the functionalities of their internet-based self-service tool depending on the degree of changes required to comply with the final rules, in which case some issuers could incur higher costs and burdens to appropriately train personnel.

TABLE 10A—ESTIMATED ANNUAL COST AND HOUR BURDEN PER ISSUER OR TPA TO TRAIN CUSTOMER SERVICE REPRESENTATIVES TO PROVIDE ASSISTANCE TO CONSUMERS RELATED TO THE INTERNET-BASED SELF-SERVICE TOOL

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Customer Service Representatives	2	$40.00	$80.00
Total per Respondent	2		80.00

TABLE 10B—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS TO TRAIN CUSTOMER SERVICE REPRESENTATIVES TO PROVIDE ASSISTANCE TO CONSUMERS RELATED TO THE INTERNET-BASED SELF-SERVICE TOOL

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	20	39,180	$1,567,200.00

The Departments assume that the greatest proportion of beneficiaries, participants, or enrollees that will request disclosure of cost-sharing information in paper form will do so because they do not have access to the internet. However, the Departments acknowledge that some consumers with access to the internet will contact a plan or issuer for assistance with using the internet-based self-service tool and may request to receive cost-sharing information in paper form.

Recent studies have found that approximately 20 million households do not have an internet subscription.[287] Further, approximately 19 million Americans (6 percent of the population) lack access to fixed broadband services that meet threshold levels.[288] Additionally, a recent Pew Research Center analysis found that 10 percent of U.S. adults do not use the internet, citing the following major factors: difficulty of use, age, cost of internet services, and lack of computer ownership.[289] Additional research indicates that an increasing number, 17 percent, of individuals and households are now considered ''smartphone only'' and that 37 percent of U.S. adults mostly use smartphones to access the internet and that many adults are forgoing the use of traditional broadband services.[290] Further research indicates that younger individuals and households, including approximately 93 percent of households with householders aged 15 to 34, are more likely to have smartphones compared to those aged over 65.[291] The Departments are of the view that the population most likely to use the internet-based self-service tool would generally consist of younger individuals, who are more comfortable using technology and are more likely to have internet access via broadband or smartphone technologies.

The Departments note that there are 212.3 million beneficiaries, participants, or enrollees enrolled in group health plans or with health insurance issuers required to comply with the requirements of the final rules for at least part of the year.[292] On average, it is estimated that each issuer or TPA would annually administer the benefits for 108,379 beneficiaries, participants, or enrollees.

A recent study noted that only one to 12 percent of consumers that have been offered internet-based or mobile application-based price transparency tools use them.[293] Taking that into account, and assuming that six percent of covered individuals lack access to fixed broadband services, the Departments estimate that on average six percent of participants, beneficiaries, or enrollees will seek customer support (a mid-range percentage of individuals that currently use available cost estimator tools) and that an estimated one percent of those participants, beneficiaries, or enrollees will request any pertinent information be disclosed to them in in a non-internet manner—resulting in an estimated 0.06 percent of participants, beneficiaries, or enrollees requesting information. As discussed in section V.D.1 of this preamble, the Departments have adjusted the estimates related to customer service and mailed requests in order to account for more recent data related to the number of participants, beneficiaries, and enrollees. The Departments estimate that each issuer or TPA, on average, will require a customer service representative to interact with a beneficiary, participant, or enrollee approximately 65 times per year on matters related to cost-sharing information disclosures required by the final rules. The Departments estimate that each customer service representative will spend, on average, 15 minutes (at $40 per hour) for each interaction, resulting in a cost of approximately $10 per interaction. The Departments estimate that each issuer or TPA will incur an annual burden of 16 hours, with an associated equivalent cost of approximately $650; resulting in a total annual burden of 31,847 hours, with an associated cost of approximately $1,273,884 for all issuers and TPAs.

The Departments assume that all beneficiaries, participants, or enrollees that contact a customer service representative will request non-internet disclosure of the internet-based self-service tool information. Of these, the Departments estimate that 54 percent of the requested information would be transmitted via email or facsimile at negligible cost to the issuer or TPA and that 46 percent will request the information be provided by mail. The Departments estimate that, on average, each issuer or TPA will send approximately 30 disclosures by mail annually. Based on these assumptions, the Departments estimate that the total number of annual disclosures sent by mail for all issuers and TPAs will be 58,599. The Departments recognize that the numbers of per issuer and TPA mailings may represent a low-end estimate and the number of requests may vary amongst each issuer or TPA depending on the demographics of their beneficiaries, participants, or enrollees. The Departments are of the view that although more individuals will contact customer support for cost information the vast majority of those individuals will likely obtain this information over the phone or have it emailed rather than have it mailed to them.

The Departments assume, on average, the length of the printed disclosure will be approximately nine single-sided pages in length, assuming two pages of

[287] ''2017 American Community Survey Single-Year Estimates.'' United States Census Bureau. September 13, 2018. Available at: *https://www.census.gov/newsroom/press-kits/2018/acs-1year.html*.

[288] ''Eight Broadband Progress Report.'' United States Federal Communications Commission. December 14, 2018. Available at: *https://www.fcc.gov/reports-research/reports/broadband-progress-reports/eighth-broadband-progress-report*. In addition to the estimated 19 million Americans that lack access, they further estimate that ''in areas where broadband is available, approximately 100 million Americans still do not subscribe.''

[289] Anderson, M. et al. ''10% of Americans don't use the internet. Who are they?'' Pew Research Center. April 22, 2019. Available at: *https://www.pewresearch.org/fact-tank/2019/04/22/some-americans-dont-use-the-internet-who-are-they/*.

[290] Anderson, M. ''Mobile Technology and Home Broadband 2019.'' Pew Research Center. June 13, 2019. Available at: *https://www.pewinternet.org/2019/06/13/mobile-technology-and-home-broadband-2019/* (finding that overall 17 percent of Americans are now ''smartphone only'' internet users, up from 8 percent in 2013. They study also shows that 45 percent of non-broadband users cite their smartphones as a reason for not subscribing to high-speed internet).

[291] Ryan, C. ''Computer and internet Use in the United States: 2016.'' American Community Survey Reports: United States Census Bureau. August 2018. Available at: *https://www.census.gov/content/dam/Census/library/publications/2018/acs/ACS-39.pdf*.

[292] *Id.* at 283.

[293] Mehrotra, A., Chernew, M., and Sinaiko, A. ''Health Policy Report: Promises and Reality of Price Transparency.'' April 5, 2018. 14 N. Eng. J. Med. 378. Available at: *https://www.nejm.org/doi/full/10.1056/NEJMhpr1715229*.

information (similar to that provided in an EOB) for three providers (for a total of six pages) and an additional three pages related to the required notice statements, with a printing cost of $0.05 per page. Therefore, including postage costs of $0.55 per mailing, the Departments estimate that each issuer or TPA will incur a material and printing costs of approximately $1.00 ($0.45 printing plus $0.55 postage costs) per mailed request. Based on these assumptions, the Departments estimate that each issuer or TPA will incur an annual printing and mailing cost of approximately $30, resulting in a total annual printing and mailing cost of approximately $58,599 for all issuers and TPAs.

TABLE 11A—ESTIMATED ANNUAL COST AND HOUR BURDEN PER RESPONSE PER ISSUER OR TPA TO ACCEPT AND FULFILL REQUESTS FOR A MAILED DISCLOSURES

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Customer Service Representatives	0.25	$40.00	$10
Total per Respondent	0.25		10

TABLE 11B—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS TO ACCEPT AND FULFILL REQUESTS FOR MAILED DISCLOSURES

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total labor cost of reporting	Printing and materials cost	Total cost
1,959	1132,509	16	31,847	$1,273,884.00	$58,598.66	$1,332,482.66

The Departments solicited comment on the overall estimated costs and burdens related to this collection of information request. The Departments also sought comment on the technical and labor requirements or costs that may be required to meet the requirements of the proposed rules: For example, what costs may be associated with any potential consolidation of information needed for the internet-based self-service tool functionality. The Departments sought comment on the estimated number of issuers and TPAs currently in the group and individual markets and the number of self-insured group health plans that might seek to independently develop an internet-based self-service tool, the percentage of consumers who might use the internet-based self-service tool, and the percentage of consumers who might contact their plan, issuer, or TPA requesting information via a non-internet disclosure method. The Departments sought comment on any other existing efficiencies that could be leveraged to minimize the burden on plans, issuers, and TPAs, as well as how many or what percentage of plans, issuers, and TPAs might leverage such efficiencies. The Departments sought comment on the proposed model notice and any additional information that stakeholders thought should be included, removed, or expanded upon and its overall adaptability.

All comments received with regard the topics above have been noted and addressed in their corresponding ICR sections.

In conjunction with the final rules, CMS is seeking approval for this information collection (OMB control number: 0938–1372 (Transparency in Coverage (CMS–10715)). CMS is requiring the following information collections to include the following burden. DOL and the Department of the Treasury will submit their burden estimates upon approval.

2. ICRs Regarding Requirements for Public Disclosure of In-network Rates, Historical Allowed Amount Data for Covered Items and Services from Out-of-Network Providers and Prescription Drug Pricing Information under 26 CFR 54.9815–2715A3, 29 CFR 2590.715–2715A3, and 45 CFR 147.212.

The Departments are adding 26 CFR 54.9815–2715A3(b), 29 CFR 2590.715–2715A3(b), and 45 CFR 147.212(b) to the final rules requiring group health plans and health insurance issuers to make public in-network rates for covered items and services, out-of-network allowed amounts for covered items or services, and negotiated rates and historical net prices for each prescription drug NDC through three machine-readable files that must conform to guidance issued by the Departments. The list of required data elements that must be included for each file for each covered item or service are discussed in section II.C previously in this preamble and enumerated under paragraph (b)(1)(i) for the In-network Rate File, paragraph (b)(1)(ii) for the Allowed Amount File, and paragraph (b)(1)(iii) for the Prescription Drug File of the final rules. Under paragraphs (b)(2) and (3) of the final rules, the machine-readable files must be posted on a public internet site accessible to any person free of charge and without conditions and must be updated monthly.

For the In-network Rate File, the final rules require the negotiated rates, underlying fee schedules, or derived amounts under a plan or coverage regarding each covered item or service be furnished for in-network providers. As discussed in section II.C earlier in this preamble, the Departments expect plans and issuers to make public the negotiated rate, fee schedule, or derived amount that is used to adjudicate claims for the purpose of reconciling a provider's payment to determine a participant's, beneficiary's, or enrollee's cost-sharing liability. As discussed in the previous ICR section, the Departments assume fully-insured group health plans will rely on issuers and most self-insured group health plans will rely on issuers or TPAs to develop and update the machine-readable files. The Departments recognize that there may be some self-insured plans that wish to individually comply with the final rules and will thus incur a similar burden and cost as described in the following paragraphs.

Many commenters stated the costs associated with the technical build and maintenance of the machine-readable files will be significant, and many commenters strongly suggested that the costs and burden of implementing the files would be significantly higher than those estimated in the proposed rules. Some commenters stated that the final rules would unreasonably burden

issuers with administrative costs and could be especially burdensome for small issuers and self-insured plans. One commenter noted that a significant amount of burden would be placed on out-of-network providers to provide information regarding costs to plans and issuers. Another commenter, a hospital association, stated that the proposed rules would be an administrative burden for hospitals as they would require a massive investment by hospitals to provide data to comply and that these resources would be diverted from patient care support.

The Departments recognize that the requirements in the final rules could result in instances where small issuers and self-insured plans face a disproportionate burden due to their size; however, as noted earlier in this preamble, the Departments expect that small issuers, plans, and TPAs will combine their efforts and seek to take advantage of any resulting economies of scale.

An independent study by Bates White Economic Consulting (Bates White), commissioned by one commenter, developed an assessment of the costs of the proposed rules by interviewing a mix of 18 large and small health insurance issuers covering about 78 million lives; Bates White assessed the average issuer cost to implement the In-network Rate File as $2,139,167 with a range from $85,000 to $10,000,000. Bates White reported that commercial issuers estimated an average cost of $2.1 million per issuer to develop and implement the In-network Rates File. Per the study, issuers view the In-network Rate File as about 20 times costlier to implement than the Departments' proposed estimate. In addition, Bates White assessed the average annual issuer cost to maintain the In-network Rate Files would be $467,000 with a range from $15,000 to $1,000,000. Another commenter noted that commercial issuers estimated annual costs of $600,000 per issuer to maintain the In-network Rate File. Issuers viewed the In-network Rate File as about 13 times costlier to maintain than the Departments' proposed estimate.

In another attempt to quantify this burden, one commenter emphasized that the potential universe of prices that would need to be disclosed on the files is enormous and could be in the hundreds of billions (more than 94,000 codes multiplied by the number of unique practitioners, which in the large issuer's system alone could exceed 2 million).

One commenter noted that the effort to comply would involve an immense amount of data aggregation, de-identification, and application development work, and these tasks would be especially difficult for small issuers and self-insured plans who are more likely to rely on ''rented'' networks. The commenter stated that to comply with the final rules, issuers would need a team with data expertise and knowledge of plan design and medical service billing to aggregate data, build re-pricing engines, and assure accuracy.

Due to the belief that the burden estimate in the proposed rules and related PRA grossly underestimated the burden of implementation on plans and issuers, one commenter suggested the Departments should retract the PRA and work with stakeholders to develop a less burdensome transparency solution. Other commenters stated the burden estimates included in the proposed rules violate the spirit and express provision of the PRA.

The Departments recognize the concerns and issues noted by commenters. As noted in section VI.A in this preamble, the Departments have reviewed comments related to the costs and burdens associated with the requirements of the final rules and devised updated estimates using CALC derived wage rates. The Departments note that the conclusions of the Bates White study referenced earlier in this preamble were based on interviews with issuers in which issuers described the steps they viewed as necessary to establish the required internet-based self-service tool and the machine-readable files, and provided related costs estimates associated with the estimated initial set-up of the internet-based self-service tool and machine-readable files. These estimates, however, did not provide the level of detail necessary for the Departments to assess how those initial cost estimates differ from the Departments' estimates.

The Bates White study also recognized the difficulty associated with assessing issuer estimates reported from issuer study participants. The study recognized that issuers interviewed varied widely in size, had different levels of experience, and had engaged in different levels of analysis of the impacts in the proposed rules. The study further noted the differences in the extent to which issuers evaluated the costs and feasibility of complying with the proposed rules. The study also recognized that issuers interviewed made different assumptions about the degree of support from vendors or trade associations that may have affected issuers' perception of the administrative and operational costs of implementation, and that issuers did not provide details of the varied operational and implementation costs and activities underlying their stated estimates for complying with the proposed rules. Specifically, the study provided no insight regarding the labor categories, wages, or hourly burdens that were considered to produce these cost estimates. Accordingly, the Bates White study did not provide details sufficient to allow those estimates to be compared to the Departments' estimates in the proposed rules.

Given the limited utility of information offered by the Bates White study, the Departments took additional steps to ensure the reasonableness and accuracy of the cost estimates associated with compliance with the final rules. In developing the updated estimates, the Departments took into account the potential aggregation of data and the potential likelihood that the data required to meet the requirements of the final rules would need to be obtained from multiple sources. The Departments recognize that the size and complexity of the machine-readable files will result in data files that are large. However, the Departments do not anticipate that data storage would impose a significant burden for issuers or TPAs due to the relatively inexpensive costs associated with storage methods such as cloud storage.

The Departments estimate a one-time first year burden and cost to issuers and TPAs to make appropriate changes to IT systems and processes, to develop, implement and operate the In-network Rate File in order to meet the requirements of the final rules. The Departments estimate that each health or TPA will require a Project Manager/Team Lead 364 hours (at $153 per hour), a Scrum Master 1,404 hours (at $105 per hour), a Technical Architect/Sr. Developer 2,080 hours (at $149 per hour), an Application Developer, Senior 1,716 hours (at $143 per hour), a Business Analyst 1,404 hours (at $120 per hour), a Service Designer/Researcher 520 hours (at $114 per hour) and a DevOps Engineer 260 hours (at $181 per hour) to complete this task. The total one-time first year burden for each issuer or TPA is estimated to be approximately 7,748 hours, with an equivalent associated cost of approximately $1,033,240. For all 1,959 issuers and TPAs, the Departments estimate the total one-time first year burden will be 15,178,332 hours with an associated cost of approximately $2,024,117,160. The Departments emphasize that these are upper bound estimates that are meant to be sufficient to cover substantial, complex activities

that may be necessary for some plans, issuers, or TPAs to comply with the final rules due to the manner in which their current systems are designed. Such activities may include such significant activities as the design and implementation of databases that will support the production of the In-network Rate Files.

TABLE 12A—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE IN-NETWORK RATE FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	364	$153.00	$55,692.00
Scrum Master	1,404	105.00	147,420.00
Technical Architect/Sr. Developer	2,080	149.00	309,920.00
Application Developer, Senior	1,716	143.00	245,388.00
Business Analyst	1,404	120.00	168,480.00
Service Designer/Researcher	520	114.00	59,280.00
DevOps Engineer	260	181.00	47,060.00
Total per Respondent	7,748		1,033,240.00

TABLE 12B—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE IN-NETWORK RATE FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	7,748	15,178,332	$2,024,117,160.00

In addition to the one-time year one costs estimated in Tables 12A and 12B, issuers or TPAs will incur an additional year two burden and cost to update the In-network Rate File monthly as required in the final rules. The Departments estimate that for each month each issuer or TPA it will require a Project Manager/Team Lead 22 hours (at $153 per hour), a Scrum Master 22 hours (at $105 per hour), a Technical Architect/Sr. Developer 22 hours (at $149 per hour), an Application Developer, Senior 22 hours (at $143 per hour), a Business Analyst 13 hours (at $120 per hour) and a DevOps Engineer 22 hours (at $181 per hour) to make the required updates and needed adjustments to the In-network Rate File. The Departments estimate that each issuer or TPA will incur a monthly year two burden of 123 hours, with an associated monthly cost of approximately $17,642 to adjust and update the In-network Rate File. Each issuer or TPA will need to update the In-network Rate File 12 times during a given year, resulting in a year two burden of 1,476 hours, with an associated equivalent cost of approximately $211,704. The Departments estimate the total year two burden for all 1,959 issuers and TPAs will be 2,891,484 hours, with an associated equivalent cost of approximately $414,728,136. The Departments consider this estimate to be an upper-bound estimate and expect ongoing update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing the In-network Rate File.

TABLE 13A—ESTIMATED MONTHLY YEAR TWO COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE IN-NETWORK RATE FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	22	$153.00	$3,366.00
Scrum Master	22	105.00	2,310.00
Technical Architect/Sr. Developer	22	149.00	3,278.00
Application Developer, Senior	22	143.00	3,146.00
Business Analyst	13	120.00	1,560.00
DevOps Engineer	22	181.00	3,982.00
Total per Respondent	123		17,642.00

TABLE 13B—ESTIMATED YEAR TWO COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE IN-NETWORK RATE FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	1,476	2,891,484	$414,728,136.00

In addition to the one-time year one and monthly year two costs estimated Tables 12A, 12B, 13A, and 13B, in subsequent years, issuers and TPAs will incur an ongoing monthly burden and cost to update and maintain the In-network Rate File on a monthly basis as required by the final rules. The Departments estimate that for each issuer or TPA it will require a Project Manager/Team Lead 9 hours (at $153 per hour) and an Application Developer, Senior 22 hours (at $143 per hour) to make the required updates to the In-network Rate File. The Departments estimate that each issuer or TPA will incur a monthly burden of 31 hours, with an associated cost of approximately $4,523 to update the In-network Rate File. Each issuer or TPA will need to update the In-network Rate File 12 times during a given year, resulting in an ongoing annual hour burden of 372 hours, with an associated equivalent cost of approximately $54,276. The Departments estimate the total annual burden for all 1,959 issuers and TPAs will be 728,748 hours, with an associated equivalent cost of approximately $106,326,684. The Departments consider this estimate to be an upper-bound estimate and expect ongoing update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing the In-network Rate File.

TABLE 14A—ESTIMATED MONTHLY ONGOING COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE IN-NETWORK RATE FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	9	$153.00	$1,377.00
Application Developer, Senior	22	143.00	3,146.00
Total per Respondent	31		4,523.00

TABLE 14B—ESTIMATED ANNUAL ONGOING COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE IN-NETWORK RATE FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	372	728,748	$106,326,684.00

The Departments estimate the total one-time year one burden for all issuers and TPAs will be 15,178,332 hours, with an associated equivalent cost of approximately $2,024,117,160 to develop and build the In-network Rate File in a machine-readable format. In year two, the Departments estimate the burden and costs to update and maintain the In-network Rate file for all issuers and TPAs will be 2,891,484 hours, with an associated equivalent cost of approximately $414,728,136. In subsequent years, the Departments estimate the total annual burden to maintain and update the In-network Rate File will be 728,748 hours, with an annual associated equivalent cost of approximately $106,326,684. The Departments estimate the three-year average annual total burden, for all issuers and TPAs, will be 6,266,188 hours, with an average annual associated equivalent total cost of $848,390,660.

TABLE 15—ESTIMATED THREE YEAR AVERAGE ANNUAL HOUR BURDEN AND COSTS FOR ALL ISSUERS AND TPAS TO DEVELOP AND MAINTAIN THE IN-NETWORK RATE FILE

Year	Estimated number of health insurance issuers and TPAs	Responses	Burden per respondent (hours)	Total annual burden (hours)	Total estimated labor cost
2021	1,959	1,959	7,748	15,178,332	$2,024,117,160.00
2022	1,959	23,508	1,476	2,891,484	414,728,136.00
2023	1,959	23,508	372	728,748	106,326,684.00
3 year Average	1,959	16,325	3,199	6,266,188	848,390,660.00

As mentioned in sections V.B in this preamble, the Departments understand that plans and issuers may include gag clauses in their provider contracting agreements, which prevent disclosure of in-network rates. The Departments sought comment on whether such agreements would need to be renegotiated to remove such clauses, and, if so, sought comment regarding any costs and burden associated with this action.

One commenter stated the Departments have not sufficiently accounted for costs associated with updating legal agreements (with physicians, hospitals, drug manufacturers, and device manufacturers, for example), updating and integrating data from multiple systems, and establishing processes for making updates to files in the ordinary course of business. Another commenter observed the Departments have not adequately accounted for the time, resources, and cost burdens of renegotiating contracts to remove gag clauses or confidentiality clauses, which prevent disclosure of in-network rates. One commenter provided examples of these costs: Printing and paper, mailing, attorney drafting initial amendments and review of non-standard language requests, costs for employees charged with negotiation and administration, and costs paid to vendors.

Due to the potential complexities and time involved in contract negotiations, the Departments recognize that should contracts require renegotiation, all associated parties will face additional costs and burdens. However, the Departments do not have insight into these complexities or knowledge of how these contracts are structured, and they are thus not able to quantify the costs and burdens associated with these tasks. Also, as addressed earlier in this preamble, it is not uncommon for new or modified regulatory requirements or new statutory provisions to alter private contract arrangements. The Departments note that the possibility of new or modified regulatory requirements or new statutory provisions altering such contracts often is contemplated in the contracts themselves; for example, drafters may include contract language indicating that terms may be altered by changes in law or regulation. Such language would obviate the need for updates outsides of the regular contracting schedule and any associated costs and burden.

For the Allowed Amount File, the final rules require plans and issuers to make available a machine-readable file showing the unique out-of-network allowed amounts and billed charges for covered items or services furnished by out-of-network providers during the 90-day time period that begins 180 days before the publication date of the file. As discussed earlier in this preamble, to the extent that a group health plan or health insurance issuer has paid multiple bills for an item or service to a particular out-of-network provider at the same allowed amount, the final rules will only require a plan or issuer to list the allowed amount once. Additionally, if the plan or issuer would only display allowed amounts in connection with 20 or fewer claims for a covered item or service for payment to a provider during any relevant 90-day period, the plan or issuer will not be required to report those unique allowed amounts.

As previously noted, an independent study by Bates White, commissioned by one commenter, assessed the average issuer cost to implement the Allowed Amount File as $1,071,167 with a range from $42,000 to $5,000,000 and estimated the cost to implement the Allowed Amount File as about 9 times costlier to implement than the Departments' proposed estimate. This commenter also argued that the average annual issuer cost to maintain the Allowed Amount File would be $643,000 with a range from $12,000 to $1,500,000. Another commenter argued that the cost to maintain the Allowed Amount File would be about 44 times costlier than the Departments' proposed estimate.

As noted above regarding the In-network Rate File cost and burdens, the Departments have devised updated estimates for the Allowed Amounts File using CALC derived wage rates. In developing the updated estimates, the Departments took into account the potential aggregation of data and the potential likelihood that the data required to meet the requirements of the final rules would need to be obtained from multiple sources.

The Departments estimate a one-time year one burden and cost to issuers and TPAs to make appropriate changes to IT systems and processes, to develop, implement, and operate the Allowed Amount File in order to meet the requirements of the final rules. The Departments estimate that each issuer or TPA will require a Scrum Master 520 hours (at $105 per hour), a Technical Architect/Sr. Developer 780 hours (at $149 per hour), an Application Developer, Senior 2,080 hours (at $143 per hour), a Business Analyst 520 hours (at $120 per hour), and a DevOps Engineer 260 hours (at $181 per hour) to complete this task. The Departments estimate the total one-time first year burden for each issuer or TPA will be approximately 4,160 hours, with an equivalent associated cost of approximately $577,720. For all 1,959 issuers and TPAs, the Departments estimate the total one-time year one burden will be 8,149,440 hours, with an equivalent associated cost of approximately $1,131,753,480.

TABLE 16A—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE ALLOWED AMOUNT FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Scrum Master	520	$105.00	$54,600.00
Technical Architect/Sr. Developer	780	149.00	116,220.00
Application Developer, Senior	2,080	143.00	297,440.00
Business Analyst	520	120.00	62,400.00
DevOps Engineer	260	181.00	47,060.00
Total per Respondent	4,160		577,720.00

TABLE 16B—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE ALLOWED AMOUNT FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	4,160	8,149,440	$1,131,753,480.00

In addition to the one-time year one costs estimated in Tables 16A and 16B, issuers and TPAs will incur additional monthly burdens and costs in year two to update the Allowed Amount File. The Departments estimate that, in year two, each issuer or TPA will require a Scrum Master 9 hours (at $105 per hour), an Application Developer, Senior 22 hours (at $143 per hour), and a DevOps Engineer 22 hour (at $181) to make the required monthly Allowed Amount File updates. The Departments estimate that each issuer or TPA will incur a monthly burden of 53 hours, with an equivalent associated cost of approximately $8,073 to update the Allowed Amount File. The Departments estimate that each issuer or TPA will need to update the Allowed Amount File 12 times during a given year, resulting in a year two annual burden of approximately 636 hours, with an equivalent associated cost of

approximately $96,876. The Departments estimate the total year two burden for all 1,959 issuers and TPAs will be 1,245,924 hours, with an equivalent associated cost of approximately $189,780,084. The Departments consider this estimate to be an upper-bound estimate and expect ongoing Allowed Amount File update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing the Allowed Amount File.

TABLE 17A—ESTIMATED YEAR TWO MONTHLY COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE ALLOWED AMOUNT FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Scrum Master	9	$105.00	$945.00
Application Developer, Senior	22	143.00	3,146.00
DevOps Engineer	22	181.00	3,982.00
Total per Respondent	53	.....	8,073.00

TABLE 17B—ESTIMATED YEAR TWO COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE ALLOWED AMOUNT FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	636	1,245,924	$189,780,084.00

In addition to the one-time year one, monthly and total year two costs estimated in Tables 16A, 16B, 17A and 17B, in subsequent years, issuers and TPAs will incur additional ongoing monthly burdens and costs to update the required Allowed Amount File. The Departments estimate that for each issuer or TPA it will require a Scrum Master 4 hours (at $105 per hour), and an Application Developer, Senior 9 hours (at $143 per hour) to make the required monthly Allowed Amount File updates. The Departments estimate that each issuer or TPA will incur a monthly burden of 13 hours, with an equivalent associated cost of approximately $1,707 to update the Allowed Amount File. The Departments estimate that each issuer or TPA will need to update the Allowed Amount File 12 times during a given year, resulting in an ongoing annual burden of approximately 156 hours, with an equivalent associated cost of approximately $20,484. The Departments estimate the total burden for all 1,959 issuers and TPAs will be 305,604 hours, with an equivalent associated cost of approximately $40,128,156. The Departments consider this estimate to be an upper-bound estimate and expect ongoing Allowed Amount File update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing the Allowed Amount File.

TABLE 18A—ESTIMATED MONTHLY ONGOING COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE ALLOWED AMOUNT FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Scrum Master	4	$105.00	$420.00
Application Developer, Senior	9	143.00	1,287.00
Total per Respondent	13	.....	1,707.00

TABLE 18B—ESTIMATED ANNUAL ONGOING COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE ALLOWED AMOUNT FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	156	305,604	$40,128,156.00

The Departments estimate the one-time year one burden for all issuers and TPAs will be 8,149,440 hours, with an equivalent associated cost of approximately $1,131,753,480 to develop and build the Allowed Amount File to meet the requirements of the final rules. In year two, the Departments estimate the total annual burden of 1,245,924 hours to maintain and update the Allowed Amount File, with an equivalent associated cost of approximately $189,780,084. In subsequent years, the Departments estimate the total annual burden to maintain and update the Allowed Amount File will be 305,604 hours, with an annual equivalent associated cost of approximately $40,128,156. The Departments estimate the three-year average annual total burden for all issuers and TPAs will be 3,233,656 hours, with an average annual total

equivalent associated cost of approximately $453,887,240.

TABLE 19—ESTIMATED THREE YEAR AVERAGE ANNUAL HOUR BURDEN AND COSTS FOR ALL ISSUERS AND TPAS TO DEVELOP AND MAINTAIN THE ALLOWED AMOUNT FILE

Year	Estimated number of issuers and TPAs	Responses	Burden per respondent (hours)	Total annual burden (hours)	Total estimated labor cost
2021	1,959	1,959	4,160	8,149,440	$1,131,753,480.00
2022	1,959	23,508	636	1,245,924	189,780,084.00
2023	1,959	23,508	156	305,604	40,128,156.00
3 year Average	1,959	16,325	1,651	3,233,656	453,887,240.00

The Departments sought comment for this collection of information request related to all aspects of the estimated burdens and costs. Specifically, the Departments sought comments related to any technical or operational difficulties associated with maintaining current and up-to-date provider network information or any out-of-network allowed amounts for covered items and services. The Departments also sought comments related to the technical and labor requirements or costs that may be required to meet the requirements in the final rules; specifically, any factors that could minimize the frequency of updates that issuers or TPAs would be required to make to the Allowed Amount File.

The Departments also solicited comments for this collection of information request related to all aspects of the estimated burdens and costs. Specifically, the Departments sought comments related to any technical or operational difficulties associated with collecting data and maintaining any out-of-network allowed amounts for covered items and services, including, any difficulties associated with the adjudication of paid claims and incorporating covered items or services furnished by a particular out-of-network provider during the 90-day time period that begins 180 days prior to the publication date of the Allowed Amount File. The Departments also sought comments related to the technical and labor requirements or costs that may be required to meet the requirements in the proposed rules: Specifically, any factors that could minimize the burdens and costs associated with updates that issuers or TPAs would be required to make to the Allowed Amount File.

As addressed in section II.C in this preamble, the use of a HIPAA-compliant clearinghouse is permitted, but not required, in order to make the required information public. Plans and issuers are permitted to use HIPAA-compliant clearinghouses to meet the disclosure requirements and the Departments anticipate they may do so if this method is more efficient and cost-effective.

The Departments acknowledge that as many as 95 percent of group health plans and health insurance issuers may already contract with claims clearinghouses that currently collect some or all of the information required to be disclosed under the final rules and might be able to meet the requirements in the final rules easily, potentially obviating the need for the plan, issuer, or TPA to invest in IT system development. The Departments assume that these plans, issuers, and TPAs will still incur burdens and costs, albeit reduced, related to oversight and quality assurance regarding any associated clearinghouse activities. The Departments sought comments on existing efficiencies, such as the use of clearinghouses that could be leveraged by plans, issuers, and TPAs related to the development and updating of the required machine-readable files and how many issuers, TPAs, or self-insured plans may already contract with clearinghouses that collect the information required. Comments received are discussed earlier in the Use of Third Parties to Satisfy Public Disclosure Requirements section of this preamble.

For the Prescription Drug File, the Departments estimate one-time first-year burdens and costs to issuers and TPAs to make appropriate changes to IT systems and processes to develop, implement, and operate the Prescription Drug File in order to meet the requirements in the final rules. The Departments estimate that each issuer or TPA will require a Project Manager/Team Lead 260 hours (at $153 per hour), a Scrum Master 260 hours (at $105 per hour), an Application Developer, Senior 520 hours (at $143 per hour), a Business Analyst 520 hours (at $120 per hour), and a DevOps Engineer 260 hours (at $181 per hour) to complete this task. The total one-time first year burden for each issuer or TPA is estimated to be approximately 1,820 hours, with an equivalent associated cost of approximately $250,900. For all 1,959 issuers and TPAs, the Departments estimate the total one-time first year burden will be 3,565,380 hours, with an associated estimated cost of approximately $491,513,100. The Departments emphasize that these are upper bound estimates that are meant to be sufficient to cover substantial, complex activities that may be necessary for some plans and issuers to comply with the final rules due to the manner in which their current systems are designed. Such activities may include such significant activity as the design and implementation of databases that will support the production of the Prescription Drug File.

TABLE 20A—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE PRESCRIPTION DRUG FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	260	$153.00	$39,780.00
Scrum Master	260	105.00	27,300.00
Application Developer, Senior	520	143.00	74,360.00
Business Analyst	520	120.00	62,400.00

TABLE 20A—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE PRESCRIPTION DRUG FILE—Continued

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
DevOps Engineer	260	181.00	47,060.00
Total per Respondent	1,820		250,900.00

TABLE 20B—ESTIMATED ONE-TIME YEAR ONE COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE PRESCRIPTION DRUG FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	1,959	1,820	3,565,380	$491,513,100.00

In addition to the one-time year one costs estimated in Tables 20A and 20B, issuers and TPAs will incur additional year two burdens and costs to update the required Prescription Drug File monthly. The Departments estimate that for each month, each issuer or TPA will require a Project Manager/Team Lead 22 hours (at $153 per hour), an Application Developer, Senior 22 hours (at $143 per hour), a Business Analyst 9 hours (at $120 per hour) and a DevOps Engineer 22 hours (at $181 per hour) to make the required updates and needed adjustments to the Prescription Drug File. The Departments estimate that each issuer or TPA will incur a monthly, year two, burden of 75 hours, with an associated monthly cost of approximately $11,574 to update the Prescription Drug File. Each issuer or TPA will need to update the Prescription Drug File 12 times during a given year, resulting in a year two burden of 900 hours, with an associated equivalent cost of approximately $138,888. The Departments estimate the total year two burden for all 1,959 issuers and TPAs will be 1,763,100 hours, with an associated equivalent cost of approximately $272,081,592. The Departments consider this estimate to be an upper-bound estimate and expect ongoing update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing the Prescription Drug File.

TABLE 21A—ESTIMATED MONTHLY YEAR TWO COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE PRESCRIPTION DRUG FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Project Manager/Team Lead	22	$153.00	$3,366.00
Application Developer, Senior	22	143.00	3,146.00
Business Analyst	9	120.00	1,080.00
DevOps Engineer	22	181.00	3,982.00
Total per Respondent	75		11,574.00

TABLE 21B—ESTIMATED YEAR TWO COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE PRESCRIPTION DRUG FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	900	1,763,100	$272,081,592.00

In addition to the one-time year one and monthly year two costs estimated in Tables 20A, 20B, 21A and 21B, in subsequent years, issuers and TPAs will incur ongoing monthly burdens and costs to update and maintain the Prescription Drug File on a monthly basis. The Departments estimate that each issuer or TPA will require a Scrum Master 9 hours (at $153 per hour) and an Application Developer, Senior 22 hours (at $143 per hour) to make the required updates to the Prescription Drug File. The Departments estimate that each issuer or TPA will incur a monthly burden of 31 hours, with an associated cost of approximately $4,523, to update the Prescription Drug File. An issuer or TPA will need to update the Prescription Drug File 12 times during a given year, resulting in an ongoing annual burden of 372 hours, with an associated equivalent cost of approximately $54,276. The Departments estimate the total annual burden for all 1,959 issuers and TPAs will be 728,748 hours, with an associated equivalent cost of approximately $106,326,680. The Departments consider this estimate to be an upper-bound estimate and expect ongoing update costs to decline in succeeding years as issuers and TPAs gain efficiencies and experience in updating and managing Prescription Drug File.

TABLE 22A—ESTIMATED MONTHLY ONGOING COST AND HOUR BURDEN PER ISSUER OR TPA FOR THE PRESCRIPTION DRUG FILE

Occupation	Burden hours per respondent	Labor cost per hour	Total cost per respondent
Scrum Master	9	$153.00	$1,377.00
Application Developer, Senior	22	143.00	3,146.00
Total per Respondent	31		4,523.00

TABLE 22B—ESTIMATED ANNUAL ONGOING COST AND HOUR BURDEN FOR ALL ISSUERS AND TPAS FOR THE PRESCRIPTION DRUG FILE

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total cost
1,959	23,508	372	728,748	$106,326,684.00

The Departments estimate the total one-time year one burden for all issuers and TPAs will be 3,565,380 hours, with an associated equivalent cost of approximately $491,513,100 to develop and build the Prescription Drug File in a machine-readable format. In year two, the Departments estimate the burden and costs to update and maintain the Prescription Drug File, on a monthly basis, for all issuers and TPAs to be 1,763,100 hours, with an associated equivalent cost of approximately $272,081,592. In subsequent years, the Departments estimate the total annual burden of 728,748 hours to maintain and update the Prescription Drug File, with an annual associated equivalent cost of approximately $106,326,684. The Departments estimate the three-year average annual total burden, for all issuers and TPAs, will be 2,019,076 hours with an average annual associated equivalent total cost of $289,973,792.

TABLE 23—ESTIMATED THREE YEAR AVERAGE ANNUAL HOUR BURDEN AND COSTS FOR ALL ISSUERS AND TPAS TO DEVELOP AND MAINTAIN THE PRESCRIPTION DRUG FILE

Year	Estimated number of issuers and TPAs	Responses	Burden per respondent (hours)	Total annual burden (hours)	Total estimated labor cost
2021	1,959	1,959	1,820	3,565,380	$491,513,100.00
2022	1,959	23,508	900	1,763,100	272,081,592.00
2023	1,959	23,508	372	728,748	106,326,684.00
3 year Average	1,959	16,325	1,031	2,019,076	289,973,792.00

Due to comments received in response to the proposed rules, the Departments have made changes to the final rules and the ICR sections discussed above. The Departments seek comment regarding the changes associated with these ICR sections. The Departments also seek comment on the use of the CALC database, as discussed in section VI.A, to determine occupational descriptions and hourly wage rates. The Departments seek comment on the revised costs and burdens discussed in section VI.A.1 as they relate to the required internet-based self-service tool. The Departments also seek comment on model language developed by the Departments, as discussed in section II.B.1.g of this preamble, to meet the requirements of the final rule. The Departments also seek comment on the revised costs and burdens, as discussed in section VI.A.2, related to the requirements for the public disclosure of In-network Rate, Allowed Amount, and Prescription Drug Files. Additionally, the Departments seek comment on the data element changes associated with those collection instruments. For the In-network Rate File, the Departments seek comment regarding the data elements added to the collection instrument; specifically, addition of data elements including the TIN, Place of service code, derived amount, underlying fee schedule rates, payment arrangement indicator, the use of base negotiated rates (for certain reimbursement models), and other data elements discussed in section C.1.c of this preamble. The Departments also seek comment on the Allowed Amount File regarding the addition of data elements including the TIN, NPI, and billed charges associated with allowed amounts. The Departments seek comment on all data elements discussed in section C.1.c of this preamble as they relate to the Prescription Drug File, as well as the estimated costs and burdens estimated above.

In association with amendments made to the final rules, CMS is seeking OMB approval for the information collection requirements associated with OMB control number 0938–1372 (CMS–10715—Transparency in Coverage). Comments will be solicited through a 60-day **Federal Register** notice, in accordance with Section 3506(c)(2)(A) of the Paperwork Reduction Act. Data collection requirements associated with the internet-based self-service tool, In-network Rate, Allowed Amount, and Prescription Drug Files will not be effective until OMB approval is sought. The Department of Labor and the Department of the Treasury will submit their burden estimates upon approval.

2. ICRs Regarding Medical Loss Ratio (45 CFR 158.221)

HHS is finalizing its proposal to amend 45 CFR 158.221(b) to allow health insurance issuers offering group or individual health insurance coverage to include in the MLR numerator ''shared savings'' payments made to

enrollees as a result of the enrollee choosing to obtain health care from a lower-cost, higher-value provider. HHS does not anticipate that implementing this provision will require significant changes to the MLR Annual Reporting Form or will significantly change the associated burden. The burden related to this collection is currently approved under OMB Control Number 0938–1164 (Exp. 10/31/2020); Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements (CMS–10418).

3. Summary of Annual Burden Estimates for Requirements

TABLE 24—ESTIMATED THREE YEAR AVERAGE PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB control number	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Mailing cost ($)	Total cost ($)
§§ 54.9815–2715A2(b)(2)(i); 2590.715–2715A2(b)(2)(i); and 147.211(b)(2)(i).	0938–1372*	1,959	1,959	23,313	45,670,820	$6,388,837,830.32	$0	$6,388,837,830.32
§§ 54.9815–2715A2(b)(2)(ii); 2590.715–2715A2(b)(2)(ii); and 147.211(b)(2)(ii).	0938–1372	1,306	84,926	11	21,231	849,256.00	39,065.78	888,321.78
§§ 54.9815–2715A3(b)(i); 2590.715–2715A3(b)(i); and 147.212(b)(1)(i).	0938–1372	1,959	16,325	3,199	6,266,188	848,390,660.00	0	848,390,660.00
§§ 54.9815–2715A3(b)(1)(ii); 2590.715–2715A3(b)(1)(ii); and 147.212(b)(1)(ii).	0938–1372	1,959	16,325	1,651	3,233,656	453,887,240.00	0	453,887,240.00
§§ 54.9815–2715A3(b)(1)(iii); 2590.715–2715A3(b)(1)(iii); and 147.212(b)(1)(iii).	0938–1372	1,959	16,325	1,031	2,019,076	289,973,792.00	0	289,973,792.00
Total			135,860	29,204	57,210,971	7,981,938,778.32	39,065.78	7,981,977,844.10

* High-end three year estimated values are represented in the table and used to determine the overall estimated 3-year average.

For PRA purposes, the Departments are splitting the burden: CMS will account for 50 percent of the associated costs and burdens and the Departments of Labor and the Department of the Treasury will each account for 25 percent of the associated costs and burdens. The burden for CMS will be 28,605,486 hours, with an equivalent associated cost of approximately $3,990,969,389 and a cost burden of $19,533. For the Departments of Labor and the Treasury, each Department will account for a burden of 14,302,743 hours with an equivalent associated cost of approximately $1,995,484,695 and a cost burden of $9,766.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare a final regulatory flexibility analysis to describe the impact of proposed rules on small entities, unless the head of the agency can certify that the rule would not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.''

HHS uses a change in revenues of more than three to five percent as its measure of significant economic impact on a substantial number of small entities.

The final rules require that group health plans and health insurance issuers disclose to a participant, beneficiary, or enrollee such individual's cost-sharing information for covered items or services from a particular provider or providers; to make public in-network rates, including amounts in underlying fee schedules, negotiated rates, and derived amounts for in-network providers; historical allowed amounts paid to out-of-network providers and billed charges for all covered items and services; and negotiated rates and historical net prices for prescription drugs. The Departments are of the view issuers generally exceed the size thresholds for ''small entities'' established by the SBA, so the Departments are not of the view that an initial regulatory flexibility analysis is required for such firms. ERISA-covered plans are often small entities, however. While the Departments are of the view that these plans would rely on the larger issuers or TPAs to comply with the final rules, they would still experience increased costs because the costs of complying with these requirements will likely be passed on to them. However, as discussed in more detail later in this section of this preamble, the Departments are not of the view that the additional costs meet the significant impact requirement. In addition, while the requirements of the final rules do not apply to providers, providers may experience a loss in revenue as a result of the demands of price sensitive consumers and plans, and because smaller issuers may be unwilling to continue paying higher rates than larger issuers for the same items and services. The Departments are of the view that issuers would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $41.5 million or less would be considered small entities under North American Industry Classification System codes. Issuers could possibly be classified under code 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $35 million or less.[294] The Departments are of the view that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report submissions for the 2017 MLR reporting year, approximately 90 out of 500 issuers of health insurance coverage nationwide had total premium revenue of $41.5 million or less. [295] This estimate likely overstates the actual

[294] ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes.'' United States Small Business Administration. Available at: *https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf.*

[295] ''Medical Loss Ratio Data and System Resources.'' CCIIO. Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

number of small health insurance issuers that may be affected, since over 72 percent of these small issuers belong to larger holding groups, and most, if not all, of these small issuers are likely to have non-health lines of business that will result in their revenues exceeding $41.5 million. The Departments are of the view that these same assumptions also apply to the TPAs that would be affected by the final rules. The Departments do not expect any of these 90 potentially small entities to experience a change in rebates under the amendments to the MLR provisions of the final rules in 45 CFR part 158. The Departments acknowledge that it may be likely that a number of small entities might enter into contracts with other entities in order to meet the requirements in the final rules, perhaps allowing for the development of economies of scale. Due to the lack of knowledge regarding what small entities may decide to do in order to meet these requirements and any costs they might incur related to contracts, the Departments sought comment on ways that the final rules will impose additional costs and burdens on small entities and how many would be likely to engage in contracts to meet the requirements.

The Departments received a number of comments related to the potential additional costs, burdens, and other effects the final rules could have on small entities. These comments have been noted and addressed in the RIA and ICR sections titled Regarding Requirements for Public Disclosure of In-network Rates, Historical Allowed Amount Data for Covered Items and Services from Out-of-Network Providers and Prescription Drug Pricing Information; Requirements for Disclosing Cost-sharing information to Participant, Beneficiaries, or Enrollees; and the Applicability Date section of this preamble.

For purposes of the RFA, the DOL continues to consider a small entity to be an employee benefit plan with fewer than 100 participants.[296] Furthermore, while some large employers may have small plans, most small plans are maintained by small employers.

Thus, the Departments are of the view that assessing the impact of the final rules on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business that is based on size standards promulgated by the SBA (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631, *et seq.*). Therefore, EBSA requested comments on the appropriateness of the size standard used in evaluating the impact of the final rules on small entities. Using the DOL definition of small, about 2,160,743 of the approximately 2,327,339 plans are small entities. Using a threshold approach, if the total costs of the final rules are spread evenly across all 1,754 issuers, 205 TPAs, and 2,327,339 ERISA health plans, without considering size, using the three-year average costs, the per-entity costs could be $3,426.77 ($7,981,977,844.10/2,329,298). If those costs are spread evenly across the estimated 212.3 million beneficiaries, participants, or enrollees[297] enrolled in plans or issuers required to comply with the requirements then the average cost per covered individual would be $37.60 ($7,981,977,844.102/212.3 million). Neither the cost per entity nor the cost per covered individual is a significant impact. Further, the costs estimated in section VI in this preamble may be overstated as it is assumed that all of issuers and TPAs will build the internet-based self-service tool and the machine-readable files, compile the appropriate data, and perform the required updates themselves rather than using common third parties such as clearinghouses, as discussed in section II.C in this preamble. If private health insurance transactions are processed through clearinghouses, with at least the fields required in the machine-readable files, there could be an unaccounted for source of savings, as clearinghouses may already process much of the data that issuers and TPAs would be required to collect under the final rules.

In addition, section 1102(b) of the SSA (42 U.S.C. 1302) requires the Departments to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the SSA, the Departments define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds.

As noted and addressed in section II.B.2.C in this preamble, commenters expressed concerns that exposure of in-network rates could have various unintended consequences on the health care industry, group health plans and health insurance issuers, and providers. Also as discussed in the sections VI.A.2, one commenter stated that the proposed rules would create administrative burdens for hospitals as hospitals would be required to make massive investments to provide the data required under the final rules. The Departments note that the final rules do not explicitly apply to hospitals and do not agree that hospitals will require massive investments to comply with the final rules, as opposed to the potential costs they could incur in order to comply with the Hospital Price Transparency final rule. Furthermore, the Departments recognize that while the requirements of the final rules do not apply to providers, including hospitals, some providers may experience a loss in revenue as a result of the demands of price sensitive consumers. The Departments also recognize that while the requirements in the final rules may result in instances where small rural hospitals face additional costs and burdens due to their size and the market dynamics in their areas, the generally reduced competition amongst rural hospitals, due to the overall lower number of hospitals in these areas, will provide them more leverage when negotiating with issuers. Nonetheless, some rural hospitals may see their costs increase if the lack of competition results in these hospitals being unable to negotiate more favorable terms with plans and issuers. This dynamic could result in some small rural hospitals seeing their revenue decrease as reimbursement rates decline and overall costs increase, though rural hospitals could also see reduced costs and burdens if they are able to successfully negotiate more favorable network contracts. Due to a lack of information and overall knowledge, the Departments are not able to confidently estimate the effects the final rules will have on small rural hospitals; however, the Departments are of the view that the final rules will not have a significant impact on the operations of a substantial number of small rural hospitals.

Impact of Regulations on Small Business—Department of the Treasury

Pursuant to section 7805(f) of the Code, the proposed rules that preceded the final rules were submitted to the Chief Counsel for Advocacy of the SBA for comment on their impact on small businesses, and no comments were received.

C. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated

[296] The basis for this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans that cover fewer than 100 participants.

[297] *Id.* at 272.

costs and benefits and take certain actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million.

State, local, or tribal governments may incur costs to enforce some of the requirements of the final rules. The final rules include instructions for disclosures that would affect private sector firms (for example, issuers offering health insurance coverage in the individual and group markets, and TPAs providing administrative services to group health plans). The Departments acknowledge that state governments could incur costs associated with enforcement of sections within the final rules and, although the Departments have not been able to quantify all costs, the Departments expect the combined impact on state, local, and tribal governments to be below the threshold. The costs incurred by the private sector have been previously discussed in Collection of Information Requirements sections.

One commenter contended that due to the requirement to make the machine-readable files publicly available, issuers would also be required to post files with complete negotiated payment amount information, and that these files would be very complex, with thousands of procedure codes and many different plans and networks offered by issuers. The commenter further contended that due to the complexity and size of the files significant state resources would be required to review these files in order to ensure their accuracy, completeness, and timeliness. They contended that without funding states will be challenged in maintaining effective enforcement and urged the Departments to consider providing grants to states to cover the cost of enforcing any final rules.

The Departments recognize that due to size and complexity of the machine-readable files required some states will incur increased burdens and costs to review and ensure compliance with the requirements in the final rules. However, at this time, the Departments do not have available funding to provide grants to assist states in their efforts. The Departments will take it under consideration and evaluate the potential necessity to provide grants to assist states in their efforts should a significant need arise. The Departments expect that a number of states with the requisite authority to enforce the provisions of the final rules may defer enforcement to Federal regulators because of lack of funds.

D. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications. Federal agencies promulgating regulations that have federalism implications must consult with state and local officials and describe the extent of their consultation and the nature of the concerns of state and local officials in this preamble to the regulation.

In the Departments' view, the final rules may have federalism implications, because they would have direct effects on the states, the relationship between national governments and states, and on the distribution of power and responsibilities among various levels of government relating to the disclosure of health insurance coverage information to the public.

Under the final rules, all group health plans and health insurance issuers, including self-insured, non-Federal governmental group health plans as defined in section 2791 of the PHS Act, will be required to develop an internet-based self-service tool to disclose to a participant, beneficiary, or enrollee, the consumer-specific estimated cost-sharing liability for covered items or services from a particular provider and also to provide this information by mail upon request. The final rules also require plans and issuers to disclose provider in-network rates, historical data on out-of-network allowed amounts, and negotiated rates and historical net prices for prescription drugs through digital files in a machine-readable format posted publicly on an internet website. Such Federal standards developed under section 2715A of the PHS Act preempt any related state standards that require pricing information to be disclosed to the participant, beneficiary, or enrollee, or otherwise publicly disclosed, to the extent the state disclosure requirements would provide less information to the consumer or the public than what is required under the final rules.

The Departments are of the view that the final rules may have federalism implications based on the required disclosure of pricing information, as the Departments are aware of at least 28 states that have passed some form of price-transparency legislation, such as all-payer claims databases, consumer-facing price comparison tools, and the right to shop programs.[298] Under these state provisions, state requirements vary broadly in terms of the level of disclosure required.[299] Some states list the price for each individual service, whereas some states list the aggregate costs across providers and over time to measure the price associated with an episode of illness. States also differ in terms of the dissemination of the information. For example, California mandates that uninsured patients receive estimated prices upon request. In contrast, other states use websites or software applications that allow consumers to compare prices across providers. Only seven states have published the pricing information of issuers on consumer-facing public websites.[300] Therefore, the final rules may require a higher level of disclosure by plans and issuers than some state laws.

One commenter asked that the Departments clarify their intentions regarding Federal preemption with respect to state laws that conflict with the final rules. Congress passed PPACA to improve the health insurance markets on a nationwide basis. *King.* v. *Burwell,* 135 S. Ct. 2480, 2496 (2015). Under section 1321(d) of PPACA and section 2724(a) of the PHS Act, nothing in these regulations would preempt state law unless such state law prevents the application of the applicable Federal requirement. Based on this legal context, the Departments intend the implementation of the rules to preempt state law to the extent enforcement of state law would prevent the application of PPACA.[301] To the extent the final rules preempt state law, they do so under well-settled law.

In general, through section 514, ERISA supersedes state laws to the extent that they relate to any covered employee benefit plan, and preserves state laws that regulate insurance, banking, or securities. Furthermore, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act

[298] ''Transparency of Health Costs; State Actions.'' National Conference of State Legislatures. March 2017. Available at: *https://www.ncsl.org/research/health/transparency-and-disclosure-health-costs.aspx.*

[299] Mehrotra, A., Chernew, M., and Sinaiko, A. ''Promise and Reality of Price Transparency.'' 14 N. Engl. J. Med. 378. April 5, 2018. Available at: *https://www.nejm.org/doi/full/10.1056/NEJMhpr1715229.*

[300] Evans, M. ''One State's Effort to Publicize Hospital Prices Brings Mixed Results.'' Wall Street Journal. June 26, 2019. Available at: *https://www.wsj.com/articles/one-states-effort-to-publicize-hospital-prices-brings-mixed-results-11561555562.*

[301] *See* section 1321(d) of PPACA (''Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title.)

(implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the HIPAA requirements (including those of PPACA) are not to be ''construed to supersede any provision of state law which establishes, implements, or continues in effect any standard or requirement solely relating to issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a 'requirement' of a federal standard.'' The conference report accompanying HIPAA indicates that this preemption is intended to be the ''narrowest'' preemption of states laws (See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018). States may therefore continue to apply state law requirements to issuers except to the extent that such requirements prevent the application of PPACA requirements that are the subject of this rulemaking. Accordingly, states have significant latitude to impose requirements on issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the states, the Departments have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of NAIC, and consulting with state insurance officials on an individual basis. The Departments intend to act in a similar fashion in enforcing PPACA, including the provisions of section 2715A of the PHS Act. While developing the final rules, the Departments attempted to balance the states' interests in regulating issuers with Congress' intent to provide an improved level of price transparency to the public in every state. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to the final rules, the Departments certify that the Department of the Treasury, Employee Benefits Security Administration, and the CMS have complied with the requirements of Executive Order 13132 for the final rules in a meaningful and timely manner.

E. Congressional Review Act

The final rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information. Therefore, the final rules have been transmitted to the Congress and the Comptroller General. Pursuant to the Congressional Review Act, the Office of Information and Regulatory Affairs designated the final rules as ''major rules'' as that term is defined in 5 U.S.C. 804(2), because it is likely to result in an annual effect on the economy of $100 million or more. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

F. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise issues, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.

The final rules are considered an Executive Order 13771 regulatory action. The Departments estimate that these rules will generate $3,489.71 million in costs in 2021, $10,761.15 million in 2022, $6,569 million in 2023, and annual costs of approximately $2,330 million thereafter. Discounted at 7 percent relative to year 2016, over a perpetual time horizon the annualized value of these costs is $2,413.54 million. Details on the estimated costs of the final rules can be found in the preceding analyses.

VII. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1135, 1185d, and 1191c; and Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 1311 of PPACA, 2701 through 2763, 2791, 2792, and 2794 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–94), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

Sunita Lough,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: October 28, 2020.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

Signed at Washington DC, this 30th day of October, 2020.

Jeanne Klinefelter Wilson,

Acting Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 8, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 20, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Amendments to the Regulations

For the reasons set forth in this preamble, the Department of the Treasury amends 26 CFR part 54 as set forth below:

PART 54—PENSION EXCISE TAXES

■ **Par. 1.** The authority citation for part 54 is amended by adding an entry for §§ 54.9815–2715A1, 54.9815–2715A2, and 54.9815–2715A3 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

Sections 54.9815–2715A1, 54.9815–2715A2, and 54.9815–2715A3 are also issued under 26 U.S.C. 9833;

* * * * *

■ **Par. 2.** Sections 54.9815–2715A1, 54.9815–2715A2, and 54.9815–2715A3 are added to read as follows:

§ 54.9815–2715A1 Transparency in coverage—definitions.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth definitions for the price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage established in this section and §§ 54.9815–2715A2 and 54.9815–2715A3.

(2) *Definitions.* For purposes of this section and §§ 54.9815–2715A2 and 54.9815–2715A3, the following definitions apply:

(i) *Accumulated amounts* means:

(A) The amount of financial responsibility a participant or beneficiary has incurred at the time a request for cost-sharing information is made, with respect to a deductible or out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these accumulated amounts shall include the financial responsibility a participant or beneficiary has incurred toward meeting his or her individual deductible or out-of-pocket limit, as well as the amount of financial responsibility that all the individuals enrolled under the plan or coverage have incurred, in aggregate, toward meeting the other than self-only deductible or out-of-pocket limit, as applicable. Accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but exclude any expense that does not count toward a deductible or out-of-pocket limit (such as any premium payment, out-of-pocket expense for out-of-network services, or amount for items or services not covered under the group health plan or health insurance coverage); and

(B) To the extent a group health plan or health insurance issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant or beneficiary, has used within that time period).

(ii) *Beneficiary* has the meaning given the term under section 3(8) of the Employee Retirement Income Security Act of 1974 (ERISA).

(iii) *Billed charge* means the total charges for an item or service billed to a group health plan or health insurance issuer by a provider.

(iv) *Billing code* means the code used by a group health plan or health insurance issuer or provider to identify health care items or services for purposes of billing, adjudicating, and paying claims for a covered item or service, including the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG) code, National Drug Code (NDC), or other common payer identifier.

(v) *Bundled payment arrangement* means a payment model under which a provider is paid a single payment for all covered items and services provided to a participant or beneficiary for a specific treatment or procedure.

(vi) *Copayment assistance* means the financial assistance a participant or beneficiary receives from a prescription drug or medical supply manufacturer towards the purchase of a covered item or service.

(vii) *Cost-sharing liability* means the amount a participant or beneficiary is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost-sharing liability generally includes deductibles, coinsurance, and copayments, but does not include premiums, balance billing amounts by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(viii) *Cost-sharing information* means information related to any expenditure required by or on behalf of a participant or beneficiary with respect to health care benefits that are relevant to a determination of the participant's or beneficiary's cost-sharing liability for a particular covered item or service.

(ix) *Covered items or services* means those items or services, including prescription drugs, the costs for which are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(x) *Derived amount* means the price that a group health plan or health insurance issuer assigns to an item or service for the purpose of internal accounting, reconciliation with providers, or submitting data in accordance with the requirements of 45 CFR 153.710(c).

(xi) *Historical net price* means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. The allocation shall be determined by dollar value for non-product specific and product-specific rebates, discounts, chargebacks, fees, and other price concessions to the extent that the total amount of any such price concession is known to the group health plan or health insurance issuer at the time of publication of the historical net price in a machine-readable file in accordance with § 54.9815–2715A3. However, to the extent that the total amount of any non-product specific and product-specific rebates, discounts, chargebacks, fees, or other price concessions is not known to the group health plan or health insurance issuer at the time of file publication, then the plan or issuer shall allocate such rebates, discounts, chargebacks, fees, and other price concessions by using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period, as determined under § 54.9815–2715A3(b)(1)(iii)(D)(*3*).

(xii) *In-network provider* means any provider of any item or service with which a group health plan or health insurance issuer, or a third party for the plan or issuer, has a contract setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary.

(xiii) *Items or services* means all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care.

(xiv) *Machine-readable file* means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost.

(xv) *National Drug Code* means the unique 10- or 11-digit 3-segment number assigned by the Food and Drug Administration, which provides a universal product identifier for drugs in the United States.

(xvi) *Negotiated rate* means the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

(xvii) *Out-of-network allowed amount* means the maximum amount a group health plan or health insurance issuer will pay for a covered item or service furnished by an out-of-network provider.

(xviii) *Out-of-network provider* means a provider of any item or service that does not have a contract under a participant's or beneficiary's group health plan or health insurance coverage to provide items or services.

(xix) *Out-of-pocket limit* means the maximum amount that a participant or beneficiary is required to pay during a coverage period for his or her share of the costs of covered items and services under his or her group health plan or health insurance coverage, including for self-only and other than self-only coverage, as applicable.

(xx) *Plain language* means written and presented in a manner calculated to be understood by the average participant or beneficiary.

(xxi) *Prerequisite* means concurrent review, prior authorization, and step-therapy or fail-first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. The term prerequisite does not include medical necessity determinations generally or other forms of medical management techniques.

(xxii) *Underlying fee schedule rate* means the rate for a covered item or service from a particular in-network provider, or providers that a group health plan or health insurance issuer uses to determine a participant's or beneficiary's cost-sharing liability for the item or service, when that rate is different from the negotiated rate or derived amount.

(b) [Reserved]

§ 54.9815–2715A2 Transparency in coverage—required disclosures to participants and beneficiaries.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage for the timely disclosure of information about costs related to covered items and services under a group plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 54.9815–2715A1 apply.

(b) *Required disclosures to participants and beneficiaries.* At the request of a participant or beneficiary who is enrolled in a group health plan, the plan must provide to the participant or beneficiary the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section.

(1) *Required cost-sharing information.* The information required under this paragraph (b)(1) is the following cost-sharing information, which is accurate at the time the request is made, with respect to a participant's or beneficiary's cost-sharing liability for covered items and services:

(i) An estimate of the participant's or beneficiary's cost-sharing liability for a requested covered item or service furnished by a provider or providers that is calculated based on the information described in paragraphs (b)(1)(ii) through (iv) of this section.

(A) If the request for cost-sharing information relates to items and services that are provided within a bundled payment arrangement, and the bundled payment arrangement includes items or services that have a separate cost-sharing liability, the group health plan or health insurance issuer must provide estimates of the cost-sharing liability for the requested covered item or service, as well as an estimate of the cost-sharing liability for each of the items and services in the bundled payment arrangement that have separate cost-sharing liabilities. While group health plans and health insurance issuers are not required to provide estimates of cost-sharing liability for a bundled payment arrangement where the cost-sharing is imposed separately for each item and service included in the bundled payment arrangement, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant items or services individually, as required in paragraph (b)(1)(v) of this section.

(B) For requested items and services that are recommended preventive services under section 2713 of the Public Health Service Act (PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes. As an alternative, a group health plan or health insurance issuer may allow a participant or beneficiary to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as ''preventive'', ''non-preventive'' or ''diagnostic'' as a means to request the most accurate cost-sharing information.

(ii) Accumulated amounts.

(iii) In-network rate, comprised of the following elements, as applicable to the group health plan's or health insurance issuer's payment model:

(A) Negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service; this rate must be disclosed even if it is not the rate the plan or issuer uses to calculate cost-sharing liability; and

(B) Underlying fee schedule rate, reflected as a dollar amount, for the requested covered item or service, to the extent that it is different from the negotiated rate.

(iv) Out-of-network allowed amount or any other rate that provides a more accurate estimate of an amount a group health plan or health insurance issuer will pay for the requested covered item or service, reflected as a dollar amount, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider; provided, however, that in circumstances in which a plan or issuer reimburses an out-of-network provider a percentage of the billed charge for a covered item or service, the out-of-network allowed amount will be that percentage.

(v) If a participant or beneficiary requests information for an item or service subject to a bundled payment arrangement, a list of the items and services included in the bundled payment arrangement for which cost-sharing information is being disclosed.

(vi) If applicable, notification that coverage of a specific item or service is subject to a prerequisite.

(vii) A notice that includes the following information in plain language:

(A) A statement that out-of-network providers may bill participants or beneficiaries for the difference between a provider's billed charges and the sum of the amount collected from the group health plan or health insurance issuer and from the participant or beneficiary in the form of a copayment or coinsurance amount (the difference referred to as balance billing), and that the cost-sharing information provided pursuant to this paragraph (b)(1) does not account for these potential

additional amounts. This statement is only required if balance billing is permitted under state law;

(B) A statement that the actual charges for a participant's or beneficiary's covered item or service may be different from an estimate of cost-sharing liability provided pursuant to paragraph (b)(1)(i) of this section, depending on the actual items or services the participant or beneficiary receives at the point of care;

(C) A statement that the estimate of cost-sharing liability for a covered item or service is not a guarantee that benefits will be provided for that item or service;

(D) A statement disclosing whether the plan counts copayment assistance and other third-party payments in the calculation of the participant's or beneficiary's deductible and out-of-pocket maximum;

(E) For items and services that are recommended preventive services under section 2713 of the PHS Act, a statement that an in-network item or service may not be subject to cost-sharing if it is billed as a preventive service if the group health plan or health insurance issuer cannot determine whether the request is for a preventive or non-preventive item or service; and

(F) Any additional information, including other disclaimers, that the group health plan or health insurance issuer determines is appropriate, provided the additional information does not conflict with the information required to be provided by this paragraph (b)(1).

(2) *Required methods and formats for disclosing information to participants and beneficiaries.* The methods and formats for the disclosure required under this paragraph (b) are as follows:

(i) *Internet-based self-service tool.* Information provided under this paragraph (b) must be made available in plain language, without subscription or other fee, through a self-service tool on an internet website that provides real-time responses based on cost-sharing information that is accurate at the time of the request. Group health plans and health insurance issuers must ensure that the self-service tool allows users to:

(A) Search for cost-sharing information for a covered item or service provided by a specific in-network provider or by all in-network providers by inputting:

(*1*) A billing code (such as CPT code 87804) or a descriptive term (such as ''rapid flu test''), at the option of the user;

(*2*) The name of the in-network provider, if the user seeks cost-sharing information with respect to a specific in-network provider; and

(*3*) Other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information (such as location of service, facility name, or dosage).

(B) Search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a group health plan or health insurance issuer will pay for a covered item or service provided by out-of-network providers by inputting:

(*1*) A billing code or descriptive term, at the option of the user; and

(*2*) Other factors utilized by the plan or issuer that are relevant for determining the applicable out-of-network allowed amount or other rate (such as the location in which the covered item or service will be sought or provided).

(C) Refine and reorder search results based on geographic proximity of in-network providers, and the amount of the participant's or beneficiary's estimated cost-sharing liability for the covered item or service, to the extent the search for cost-sharing information for covered items or services returns multiple results.

(ii) *Paper method.* Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant or beneficiary. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. The group health plan or health insurance issuer is required to:

(A) Disclose the applicable provider-per-request limit to the participant or beneficiary;

(B) Provide the cost-sharing information in paper form pursuant to the individual's request, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section; and

(C) Mail the cost-sharing information in paper form no later than 2 business days after an individual's request is received.

(D) To the extent participants or beneficiaries request disclosure other than by paper (for example, by phone or email), plans and issuers may provide the disclosure through another means, provided the participant or beneficiary agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method.

(3) *Special rule to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if a health insurance issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(c) *Applicability.* (1) The provisions of this section apply for plan years beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years beginning on or after January 1, 2024.

(2) As provided under § 54.9815–1251, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 54.9815–2711(d)(6) or short-term, limited-duration insurance as defined in § 54.9801–2.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized

representatives to access participant or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 54.9815–2715A3 Transparency in coverage—requirements for public disclosure.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage for the timely disclosure of information about costs related to covered items and services under a group plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 54.9815–2715A1 apply.

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs.* A group health plan or health insurance issuer must make available on an internet website the information required under paragraph (b)(1) of this section in three machine-readable files, in accordance with the method and format requirements described in paragraph (b)(2) of this section, and that are updated as required under paragraph (b)(3) of this section.

(1) *Required information.* Machine-readable files required under this paragraph (b) that are made available to the public by a group health plan or health insurance issuer must include:

(i) An in-network rate machine-readable file that includes the required information under this paragraph (b)(1)(i) for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of this section. The in-network rate machine-readable file must include:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or if no HIOS identifier is available, the Employer Identification Number (EIN);

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) All applicable rates, which may include one or more of the following: negotiated rates, underlying fee schedule rates, or derived amounts. If a group health plan or health insurance issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the group health plan or health insurance issuer uses underlying fee schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount. Applicable rates, including for both individual items and services and items and services in a bundled payment arrangement, must be:

(*1*) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider. If the negotiated rate is subject to change based upon participant or beneficiary-specific characteristics, these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant or beneficiary-specific characteristics;

(*2*) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider;

(*3*) Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and

(*4*) Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

(ii) An out-of-network allowed amount machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) Unique out-of-network allowed amounts and billed charges with respect to covered items or services, furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the machine-readable file (except that a group health plan or health insurance issuer must omit such data in relation to a particular item or service and provider when compliance with this paragraph (b)(1)(ii)(C) would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 20 different claims for payments under a single plan or coverage). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique out-of-network allowed amount must be:

(*1*) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an out-of-network provider; and

(*2*) Associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

(iii) A prescription drug machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-

digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) The NDC and the proprietary and nonproprietary name assigned to the NDC by the Food and Drug Administration (FDA) for each covered item or service that is a prescription drug under each coverage option offered by a plan or issuer;

(C) The negotiated rates which must be:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC; and

(D) Historical net prices that are:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC (except that a group health plan or health insurance issuer must omit such data in relation to a particular NDC and provider when compliance with this paragraph (b)(1)(iii)(D) would require the plan or issuer to report payment of historical net prices calculated using fewer than 20 different claims for payment). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(iii)(D) requires the disclosure of information that would violate any applicable health information privacy law.

(2) *Required method and format for disclosing information to the public.* The machine-readable files described in this paragraph (b) must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services. The machine-readable files must be publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of personally identifiable information to access the file.

(3) *Timing.* A group health plan or health insurance issuer must update the machine-readable files and information required by this paragraph (b) monthly. The group health plan or health insurance issuer must clearly indicate the date that the files were most recently updated.

(4) *Special rules to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(iii) *Aggregation permitted for out-of-network allowed amounts.* Nothing in this section prohibits a group health plan or health insurance issuer from satisfying the disclosure requirement described in paragraph (b)(1)(ii) of this section by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, an issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information, provided the minimum claim threshold described in paragraph (b)(1)(ii)(C) of this section is independently met for each item or service and for each plan or coverage included in an aggregated Allowed Amount File. Under such circumstances, health insurance issuers, service providers, or other parties with which the group health plan or issuer has contracted may aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract. Additionally, nothing in this section prevents the Allowed Amount File from being hosted on a third-party website or prevents a plan administrator or issuer from contracting with a third party to post the file. However, if a plan or issuer chooses not to also host the file separately on its own website, it must provide a link on its own public website to the location where the file is made publicly available.

(c) *Applicability.* (1) The provisions of this section apply for plan years beginning on or after January 1, 2022.

(2) As provided under § 54.9815–1251, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 54.9815–2711(d)(6) or short term limited duration insurance as defined in § 54.9801–2.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that

the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF LABOR

For the reasons set forth in this preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 3. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 4. Sections 2590.715–2715A1, 2590.715–2715A2, and 2590.715–2715A3 are added to read as follows:

§ 2590.715–2715A1 Transparency in coverage—definitions.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth definitions for the price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage established in this section and §§ 2590.715–2715A2 and 2590.715–2715A3.

(2) *Definitions.* For purposes of this section and §§ 2590.715–2715A2 and 2590.715–2715A3, the following definitions apply:

(i) *Accumulated amounts* means:

(A) The amount of financial responsibility a participant or beneficiary has incurred at the time a request for cost-sharing information is made, with respect to a deductible or out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these accumulated amounts shall include the financial responsibility a participant or beneficiary has incurred toward meeting his or her individual deductible or out-of-pocket limit, as well as the amount of financial responsibility that all the individuals enrolled under the plan or coverage have incurred, in aggregate, toward meeting the other than self-only deductible or out-of-pocket limit, as applicable. Accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but exclude any expense that does not count toward a deductible or out-of-pocket limit (such as any premium payment, out-of-pocket expense for out-of-network services, or amount for items or services not covered under the group health plan or health insurance coverage); and

(B) To the extent a group health plan or health insurance issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant or beneficiary, has used within that time period).

(ii) *Billed charge* means the total charges for an item or service billed to a group health plan or health insurance issuer by a provider.

(iii) *Billing code* means the code used by a group health plan or health insurance issuer or provider to identify health care items or services for purposes of billing, adjudicating, and paying claims for a covered item or service, including the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG) code, National Drug Code (NDC), or other common payer identifier.

(iv) *Bundled payment arrangement* means a payment model under which a provider is paid a single payment for all covered items and services provided to a participant or beneficiary for a specific treatment or procedure.

(v) *Copayment assistance* means the financial assistance a participant or beneficiary receives from a prescription drug or medical supply manufacturer towards the purchase of a covered item or service.

(vi) *Cost-sharing liability* means the amount a participant or beneficiary is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost-sharing liability generally includes deductibles, coinsurance, and copayments, but does not include premiums, balance billing amounts by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(vii) *Cost-sharing information* means information related to any expenditure required by or on behalf of a participant or beneficiary with respect to health care benefits that are relevant to a determination of the participant's or beneficiary's cost-sharing liability for a particular covered item or service.

(viii) *Covered items or services* means those items or services, including prescription drugs, the costs for which are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(ix) *Derived amount* means the price that a group health plan or health insurance issuer assigns to an item or service for the purpose of internal accounting, reconciliation with providers, or submitting data in accordance with the requirements of 45 CFR 153.710(c).

(x) *Historical net price* means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. The allocation shall be determined by dollar value for non-product specific and product-specific rebates, discounts, chargebacks, fees, and other price concessions to the extent that the total amount of any such price concession is known to the group health plan or health insurance issuer at the time of publication of the historical net price in a machine-readable file in accordance with § 2590.715–2715A3. However, to the extent that the total amount of any non-product specific and product-specific rebates, discounts, chargebacks, fees, or other price concessions is not known to the group health plan or health insurance issuer at the time of file publication, then the plan or issuer shall allocate such rebates, discounts, chargebacks, fees, and other price concessions by using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period, as determined under § 2590.715–2715A3(b)(1)(iii)(D)(*3*).

(xi) *In-network provider* means any provider of any item or service with which a group health plan or health insurance issuer, or a third party for the plan or issuer, has a contract setting forth the terms and conditions on which

a relevant item or service is provided to a participant or beneficiary.

(xii) *Items or services* means all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care.

(xiii) *Machine-readable file* means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost.

(xiv) *National Drug Code* means the unique 10- or 11-digit 3-segment number assigned by the Food and Drug Administration, which provides a universal product identifier for drugs in the United States.

(xv) *Negotiated rate* means the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

(xvi) *Out-of-network allowed amount* means the maximum amount a group health plan or health insurance issuer will pay for a covered item or service furnished by an out-of-network provider.

(xvii) *Out-of-network provider* means a provider of any item or service that does not have a contract under a participant's or beneficiary's group health plan or health insurance coverage to provide items or services.

(xviii) *Out-of-pocket limit* means the maximum amount that a participant or beneficiary is required to pay during a coverage period for his or her share of the costs of covered items and services under his or her group health plan or health insurance coverage, including for self-only and other than self-only coverage, as applicable.

(xix) *Plain language* means written and presented in a manner calculated to be understood by the average participant or beneficiary.

(xx) *Prerequisite* means concurrent review, prior authorization, and step-therapy or fail-first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. The term prerequisite does not include medical necessity determinations generally or other forms of medical management techniques.

(xxi) *Underlying fee schedule rate* means the rate for a covered item or service from a particular in-network provider, or providers that a group health plan or health insurance issuer uses to determine a participant's or beneficiary's cost-sharing liability for the item or service, when that rate is different from the negotiated rate or derived amount.

(b) [Reserved]

§ 2590.715–2715A2 Transparency in coverage—required disclosures to participants and beneficiaries.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage for the timely disclosure of information about costs related to covered items and services under a group plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 2590.715–2715A1 apply.

(b) *Required disclosures to participants and beneficiaries.* At the request of a participant or beneficiary who is enrolled in a group health plan, the plan must provide to the participant or beneficiary the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section.

(1) *Required cost-sharing information.* The information required under this paragraph (b)(1) is the following cost-sharing information, which is accurate at the time the request is made, with respect to a participant's or beneficiary's cost-sharing liability for covered items and services:

(i) An estimate of the participant's or beneficiary's cost-sharing liability for a requested covered item or service furnished by a provider or providers that is calculated based on the information described in paragraphs (b)(1)(ii) through (iv) of this section.

(A) If the request for cost-sharing information relates to items and services that are provided within a bundled payment arrangement, and the bundled payment arrangement includes items or services that have a separate cost-sharing liability, the group health plan or health insurance issuer must provide estimates of the cost-sharing liability for the requested covered item or service, as well as an estimate of the cost-sharing liability for each of the items and services in the bundled payment arrangement that have separate cost-sharing liabilities. While group health plans and health insurance issuers are not required to provide estimates of cost-sharing liability for a bundled payment arrangement where the cost-sharing is imposed separately for each item and service included in the bundled payment arrangement, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant items or services individually, as required in paragraph (b)(1)(v) of this section.

(B) For requested items and services that are recommended preventive services under section 2713 of the Public Health Service Act (PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes. As an alternative, a group health plan or health insurance issuer may allow a participant or beneficiary to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as ''preventive'', ''non-preventive'' or ''diagnostic'' as a means to request the most accurate cost-sharing information.

(ii) Accumulated amounts.

(iii) In-network rate, comprised of the following elements, as applicable to the group health plan's or health insurance issuer's payment model:

(A) Negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service; this rate must be disclosed even if it is not the rate the plan or issuer uses to calculate cost-sharing liability; and

(B) Underlying fee schedule rate, reflected as a dollar amount, for the requested covered item or service, to the extent that it is different from the negotiated rate.

(iv) Out-of-network allowed amount or any other rate that provides a more accurate estimate of an amount a group health plan or health insurance issuer will pay for the requested covered item or service, reflected as a dollar amount, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider; provided, however, that in circumstances in which a plan or issuer reimburses an out-of-network provider a percentage of the billed charge for a covered item or service, the out-of-network allowed amount will be that percentage.

(v) If a participant or beneficiary requests information for an item or service subject to a bundled payment arrangement, a list of the items and

services included in the bundled payment arrangement for which cost-sharing information is being disclosed.

(vi) If applicable, notification that coverage of a specific item or service is subject to a prerequisite.

(vii) A notice that includes the following information in plain language:

(A) A statement that out-of-network providers may bill participants or beneficiaries for the difference between a provider's billed charges and the sum of the amount collected from the group health plan or health insurance issuer and from the participant or beneficiary in the form of a copayment or coinsurance amount (the difference referred to as balance billing), and that the cost-sharing information provided pursuant to this paragraph (b)(1) does not account for these potential additional amounts. This statement is only required if balance billing is permitted under state law;

(B) A statement that the actual charges for a participant's or beneficiary's covered item or service may be different from an estimate of cost-sharing liability provided pursuant to paragraph (b)(1)(i) of this section, depending on the actual items or services the participant or beneficiary receives at the point of care;

(C) A statement that the estimate of cost-sharing liability for a covered item or service is not a guarantee that benefits will be provided for that item or service;

(D) A statement disclosing whether the plan counts copayment assistance and other third-party payments in the calculation of the participant's or beneficiary's deductible and out-of-pocket maximum;

(E) For items and services that are recommended preventive services under section 2713 of the PHS Act, a statement that an in-network item or service may not be subject to cost-sharing if it is billed as a preventive service if the group health plan or health insurance issuer cannot determine whether the request is for a preventive or non-preventive item or service; and

(F) Any additional information, including other disclaimers, that the group health plan or health insurance issuer determines is appropriate, provided the additional information does not conflict with the information required to be provided by this paragraph (b)(1).

(2) *Required methods and formats for disclosing information to participants and beneficiaries.* The methods and formats for the disclosure required under this paragraph (b) are as follows:

(i) *Internet-based self-service tool.* Information provided under this paragraph (b) must be made available in plain language, without subscription or other fee, through a self-service tool on an internet website that provides real-time responses based on cost-sharing information that is accurate at the time of the request. Group health plans and health insurance issuers must ensure that the self-service tool allows users to:

(A) Search for cost-sharing information for a covered item or service provided by a specific in-network provider or by all in-network providers by inputting:

(*1*) A billing code (such as CPT code 87804) or a descriptive term (such as ''rapid flu test''), at the option of the user;

(*2*) The name of the in-network provider, if the user seeks cost-sharing information with respect to a specific in-network provider; and

(*3*) Other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information (such as location of service, facility name, or dosage).

(B) Search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a group health plan or health insurance issuer will pay for a covered item or service provided by out-of-network providers by inputting:

(*1*) A billing code or descriptive term, at the option of the user; and

(*2*) Other factors utilized by the plan or issuer that are relevant for determining the applicable out-of-network allowed amount or other rate (such as the location in which the covered item or service will be sought or provided).

(C) Refine and reorder search results based on geographic proximity of in-network providers, and the amount of the participant's or beneficiary's estimated cost-sharing liability for the covered item or service, to the extent the search for cost-sharing information for covered items or services returns multiple results.

(ii) *Paper method.* Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant or beneficiary. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. The group health plan or health insurance issuer is required to:

(A) Disclose the applicable provider-per-request limit to the participant or beneficiary;

(B) Provide the cost-sharing information in paper form pursuant to the individual's request, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section; and

(C) Mail the cost-sharing information in paper form no later than 2 business days after an individual's request is received.

(D) To the extent participants or beneficiaries request disclosure other than by paper (for example, by phone or email), plans and issuers may provide the disclosure through another means, provided the participant or beneficiary agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method.

(3) *Special rule to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if a health insurance issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(c) *Applicability.* (1) The provisions of this section apply for plan years beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan

years beginning on or after January 1, 2024.

(2) As provided under § 2590.715–1251, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 2590.715–2711(d)(6) or short term limited duration insurance as defined in § 2590.701–2.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 2590.715–2715A3 Transparency in coverage—requirements for public disclosure.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers offering group health insurance coverage for the timely disclosure of information about costs related to covered items and services under a group plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 2590.715–2715A1 apply.

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs.* A group health plan or health insurance issuer must make available on an internet website the information required under paragraph (b)(1) of this section in three machine-readable files, in accordance with the method and format requirements described in paragraph (b)(2) of this section, and that are updated as required under paragraph (b)(3) of this section.

(1) *Required information.* Machine-readable files required under this paragraph (b) that are made available to the public by a group health plan or health insurance issuer must include:

(i) An in-network rate machine-readable file that includes the required information under this paragraph (b)(1)(i) for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of this section. The in-network rate machine-readable file must include:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or if no HIOS identifier is available, the Employer Identification Number (EIN);

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) All applicable rates, which may include one or more of the following: Negotiated rates, underlying fee schedule rates, or derived amounts. If a group health plan or health insurance issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the group health plan or health insurance issuer uses underlying fee schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount. Applicable rates, including for both individual items and services and items and services in a bundled payment arrangement, must be:

(*1*) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider. If the negotiated rate is subject to change based upon participant or beneficiary-specific characteristics, these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant or beneficiary-specific characteristics;

(*2*) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider;

(*3*) Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and

(*4*) Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

(ii) An out-of-network allowed amount machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) Unique out-of-network allowed amounts and billed charges with respect to covered items or services furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the machine-readable file (except that a group health plan or health insurance issuer must omit such data in relation to a particular item or service and provider when compliance with this paragraph (b)(1)(ii)(C) would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 20 different claims for payments under a single plan or coverage). Consistent with paragraph

(c)(3) of this section, nothing in this paragraph (b)(1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique out-of-network allowed amount must be:

(*1*) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an out-of-network provider; and

(*2*) Associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

(iii) A prescription drug machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) The NDC, and the proprietary and nonproprietary name assigned to the NDC by the Food and Drug Administration (FDA), for each covered item or service under each coverage option offered by a plan or issuer that is a prescription drug;

(C) The negotiated rates which must be:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC; and

(D) Historical net prices that are:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC (except that a group health plan or health insurance issuer must omit such data in relation to a particular NDC and provider when compliance with this paragraph (b)(1)(iii)(D) would require the plan or issuer to report payment of historical net prices calculated using fewer than 20 different claims for payment). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(iii)(D) requires the disclosure of information that would violate any applicable health information privacy law.

(2) *Required method and format for disclosing information to the public.* The machine-readable files described in this paragraph (b) must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services. The machine-readable files must be publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of personally identifiable information to access the file.

(3) *Timing.* A group health plan or health insurance issuer must update the machine-readable files and information required by this paragraph (b) monthly. The group health plan or health insurance issuer must clearly indicate the date that the files were most recently updated.

(4) *Special rules to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(iii) *Aggregation permitted for out-of-network allowed amounts.* Nothing in this section prohibits a group health plan or health insurance issuer from satisfying the disclosure requirement described in paragraph (b)(1)(ii) of this section by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, an issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information, provided the minimum claim threshold described in paragraph (b)(1)(ii)(C) of this section is independently met for each item or service and for each plan or coverage included in an aggregated Allowed Amount File. Under such circumstances, health insurance issuers, service providers, or other parties with which the group health plan or issuer has contracted may aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract. Additionally, nothing in this section prevents the Allowed Amount File from being hosted on a third-party website or prevents a plan administrator or issuer from contracting with a third party to post the file. However, if a plan or issuer chooses not to also host the file separately on its own website, it must provide a link on its own public website to the location where the file is made publicly available.

(c) *Applicability.* (1) The provisions of this section apply for plan years beginning on or after January 1, 2022.

(2) As provided under § 2590.715–1251, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 2590.715–2711(d)(6) or short term limited duration insurance as defined in § 2590.701–2.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph

(b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in this preamble, the Department of Health and Human Services amends 45 CFR parts 147 and 158 as set forth below:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 5. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 6. Sections 147.210, 147.211 and 147.212 are added to read as follows:

§ 147.210 Transparency in coverage—definitions.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth definitions for the price transparency requirements for group health plans and health insurance issuers in the individual and group markets established in this section and §§ 147.211 and 147.212.

(2) *Definitions.* For purposes of this section and §§ 147.211 and 147.212, the following definitions apply:

(i) *Accumulated amounts* means:

(A) The amount of financial responsibility a participant, beneficiary, or enrollee has incurred at the time a request for cost-sharing information is made, with respect to a deductible or out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these accumulated amounts shall include the financial responsibility a participant, beneficiary, or enrollee has incurred toward meeting his or her individual deductible or out-of-pocket limit, as well as the amount of financial responsibility that all the individuals enrolled under the plan or coverage have incurred, in aggregate, toward meeting the other than self-only deductible or out-of-pocket limit, as applicable. Accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but exclude any expense that does not count toward a deductible or out-of-pocket limit (such as any premium payment, out-of-pocket expense for out-of-network services, or amount for items or services not covered under the group health plan or health insurance coverage); and

(B) To the extent a group health plan or health insurance issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant, beneficiary, or enrollee has used within that time period).

(ii) *Billed charge* means the total charges for an item or service billed to a group health plan or health insurance issuer by a provider.

(iii) *Billing code* means the code used by a group health plan or health insurance issuer or provider to identify health care items or services for purposes of billing, adjudicating, and paying claims for a covered item or service, including the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG) code, National Drug Code (NDC), or other common payer identifier.

(iv) *Bundled payment arrangement* means a payment model under which a provider is paid a single payment for all covered items and services provided to a participant, beneficiary, or enrollee for a specific treatment or procedure.

(v) *Copayment assistance* means the financial assistance a participant, beneficiary, or enrollee receives from a prescription drug or medical supply manufacturer towards the purchase of a covered item or service.

(vi) *Cost-sharing liability* means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost-sharing liability generally includes deductibles, coinsurance, and copayments, but does not include premiums, balance billing amounts by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(vii) *Cost-sharing information* means information related to any expenditure required by or on behalf of a participant, beneficiary, or enrollee with respect to health care benefits that are relevant to a determination of the participant's, beneficiary's, or enrollee's cost-sharing liability for a particular covered item or service.

(viii) *Covered items or services* means those items or services, including prescription drugs, the costs for which are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(ix) *Derived amount* means the price that a group health plan or health insurance issuer assigns to an item or service for the purpose of internal accounting, reconciliation with providers or submitting data in accordance with the requirements of § 153.710(c) of this subchapter.

(x) *Enrollee* means an individual who is covered under an individual health insurance policy as defined under section 2791(b)(5) of the Public Health Service (PHS) Act.

(xi) *Historical net price* means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. The allocation shall be determined by dollar value for non-product specific and product-specific rebates, discounts, chargebacks, fees, and other price concessions to the extent that the total amount of any such price concession is known to the group health plan or health insurance issuer at the time of publication of the historical net price in a machine-readable file in accordance with § 147.212. However, to the extent that the total amount of any non-product specific and product-specific rebates, discounts, chargebacks, fees, or other price concessions is not known to the group health plan or health insurance issuer at the time of file publication, then the plan or issuer shall allocate such rebates, discounts, chargebacks, fees, and other price

concessions by using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period, as determined under § 147.212(b)(1)(iii)(D)(*3*).

(xii) *In-network provider* means any provider of any item or service with which a group health plan or health insurance issuer, or a third party for the plan or issuer, has a contract setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee.

(xiii) *Items or services* means all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care.

(xiv) *Machine-readable file* means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost.

(xv) *National Drug Code* means the unique 10- or 11-digit 3-segment number assigned by the Food and Drug Administration, which provides a universal product identifier for drugs in the United States.

(xvi) *Negotiated rate* means the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

(xvii) *Out-of-network allowed amount* means the maximum amount a group health plan or health insurance issuer will pay for a covered item or service furnished by an out-of-network provider.

(xviii) *Out-of-network provider* means a provider of any item or service that does not have a contract under a participant's, beneficiary's, or enrollee's group health plan or health insurance coverage to provide items or services.

(xix) *Out-of-pocket limit* means the maximum amount that a participant, beneficiary, or enrollee is required to pay during a coverage period for his or her share of the costs of covered items and services under his or her group health plan or health insurance coverage, including for self-only and other than self-only coverage, as applicable.

(xx) *Plain language* means written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee.

(xxi) *Prerequisite* means concurrent review, prior authorization, and step-therapy or fail-first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. The term prerequisite does not include medical necessity determinations generally or other forms of medical management techniques.

(xxii) *Underlying fee schedule rate* means the rate for a covered item or service from a particular in-network provider, or providers that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the negotiated rate or derived amount.

(b) [Reserved]

§ 147.211 Transparency in coverage—required disclosures to participants, beneficiaries, or enrollees.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers in the individual and group markets for the timely disclosure of information about costs related to covered items and services under a plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 147.210 apply.

(b) *Required disclosures to participants, beneficiaries, or enrollees.* At the request of a participant, beneficiary, or enrollee who is enrolled in a group health plan or health insurance issuer offering group or individual health insurance coverage, the plan or issuer must provide to the participant, beneficiary, or enrollee the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section.

(1) *Required cost-sharing information.* The information required under this paragraph (b)(1) is the following cost-sharing information, which is accurate at the time the request is made, with respect to a participant's, beneficiary's, or enrollee's cost-sharing liability for covered items and services:

(i) An estimate of the participant's, beneficiary's, or enrollee's cost-sharing liability for a requested covered item or service furnished by a provider or providers, which must reflect any cost-sharing reductions the enrollee would receive, that is calculated based on the information described in paragraphs (b)(1)(ii) through (iv) of this section.

(A) If the request for cost-sharing information relates to items and services that are provided within a bundled payment arrangement, and the bundled payment arrangement includes items or services that have a separate cost-sharing liability, the group health plan or health insurance issuer must provide estimates of the cost-sharing liability for the requested covered item or service, as well as an estimate of the cost-sharing liability for each of the items and services in the bundled payment arrangement that have separate cost-sharing liabilities. While group health plans and health insurance issuers are not required to provide estimates of cost-sharing liability for a bundled payment arrangement where the cost-sharing is imposed separately for each item and service included in the bundled payment arrangement, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant items or services individually, as required in paragraph (b)(1)(v) of this section.

(B) For requested items and services that are recommended preventive services under section 2713 of the Public Health Service Act (PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes. As an alternative, a group health plan or health insurance issuer may allow a participant, beneficiary, or enrollee to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as ''preventive'', ''non-preventive'' or ''diagnostic'' as a means to request the most accurate cost-sharing information.

(ii) Accumulated amounts.

(iii) In-network rate, comprised of the following elements, as applicable to the group health plan's or health insurance issuer's payment model:

(A) Negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service; this rate must be disclosed even if it is not the rate the plan or issuer uses to calculate cost-sharing liability; and

(B) Underlying fee schedule rate, reflected as a dollar amount, for the requested covered item or service, to the

extent that it is different from the negotiated rate.

(iv) Out-of-network allowed amount or any other rate that provides a more accurate estimate of an amount a group health plan or health insurance issuer will pay for the requested covered item or service, reflected as a dollar amount, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider; provided, however, that in circumstances in which a plan or issuer reimburses an out-of-network provider a percentage of the billed charge for a covered item or service, the out-of-network allowed amount will be that percentage.

(v) If a participant, beneficiary, or enrollee requests information for an item or service subject to a bundled payment arrangement, a list of the items and services included in the bundled payment arrangement for which cost-sharing information is being disclosed.

(vi) If applicable, notification that coverage of a specific item or service is subject to a prerequisite.

(vii) A notice that includes the following information in plain language:

(A) A statement that out-of-network providers may bill participants, beneficiaries, or enrollees for the difference between a provider's billed charges and the sum of the amount collected from the group health plan or health insurance issuer and from the participant, beneficiary, or enrollee in the form of a copayment or coinsurance amount (the difference referred to as balance billing), and that the cost-sharing information provided pursuant to this paragraph (b)(1) does not account for these potential additional amounts. This statement is only required if balance billing is permitted under state law;

(B) A statement that the actual charges for a participant's, beneficiary's, or enrollee's covered item or service may be different from an estimate of cost-sharing liability provided pursuant to paragraph (b)(1)(i) of this section, depending on the actual items or services the participant, beneficiary, or enrollee receives at the point of care;

(C) A statement that the estimate of cost-sharing liability for a covered item or service is not a guarantee that benefits will be provided for that item or service;

(D) A statement disclosing whether the plan counts copayment assistance and other third-party payments in the calculation of the participant's, beneficiary's, or enrollee's deductible and out-of-pocket maximum;

(E) For items and services that are recommended preventive services under section 2713 of the PHS Act, a statement that an in-network item or service may not be subject to cost-sharing if it is billed as a preventive service if the group health plan or health insurance issuer cannot determine whether the request is for a preventive or non-preventive item or service; and

(F) Any additional information, including other disclaimers, that the group health plan or health insurance issuer determines is appropriate, provided the additional information does not conflict with the information required to be provided by this paragraph (b)(1).

(2) *Required methods and formats for disclosing information to participants, beneficiaries, or enrollees.* The methods and formats for the disclosure required under this paragraph (b) are as follows:

(i) *Internet-based self-service tool.* Information provided under this paragraph (b) must be made available in plain language, without subscription or other fee, through a self-service tool on an internet website that provides real-time responses based on cost-sharing information that is accurate at the time of the request. Group health plans and health insurance issuers must ensure that the self-service tool allows users to:

(A) Search for cost-sharing information for a covered item or service provided by a specific in-network provider or by all in-network providers by inputting:

(*1*) A billing code (such as CPT code 87804) or a descriptive term (such as ''rapid flu test''), at the option of the user;

(*2*) The name of the in-network provider, if the user seeks cost-sharing information with respect to a specific in-network provider; and

(*3*) Other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information (such as location of service, facility name, or dosage).

(B) Search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a group health plan or health insurance issuer will pay for a covered item or service provided by out-of-network providers by inputting:

(*1*) A billing code or descriptive term, at the option of the user; and

(*2*) Other factors utilized by the plan or issuer that are relevant for determining the applicable out-of-network allowed amount or other rate (such as the location in which the covered item or service will be sought or provided).

(C) Refine and reorder search results based on geographic proximity of in-network providers, and the amount of the participant's, beneficiary's, or enrollee's estimated cost-sharing liability for the covered item or service, to the extent the search for cost-sharing information for covered items or services returns multiple results.

(ii) *Paper method.* Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant, beneficiary, or enrollee. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. The group health plan or health insurance issuer is required to:

(A) Disclose the applicable provider-per-request limit to the participant, beneficiary, or enrollee;

(B) Provide the cost-sharing information in paper form pursuant to the individual's request, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section; and

(C) Mail the cost-sharing information in paper form no later than 2 business days after an individual's request is received.

(D) To the extent participants, beneficiaries, and enrollees request disclosure other than by paper (for example, by phone or email), plans and issuers may provide the disclosure through another means, provided the participant, beneficiary, or enrollee agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method.

(3) *Special rule to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if a health insurance issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(c) *Applicability.* (1) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years (in the individual market, for policy years) beginning on or after January 1, 2024.

(2) As provided under § 147.140, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 147.126(d)(6) or short term limited duration insurance as defined in 45 CFR 144.103.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, beneficiary, or enrollee information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 147.212 Transparency in coverage—requirements for public disclosure.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers in the individual and group markets for the timely disclosure of information about costs related to covered items and services under a plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 147.210 apply.

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs.* A group health plan or health insurance issuer must make available on an internet website the information required under paragraph (b)(1) of this section in three machine-readable files, in accordance with the method and format requirements described in paragraph (b)(2) of this section, and that are updated as required under paragraph (b)(3) of this section.

(1) *Required information.* Machine-readable files required under this paragraph (b) that are made available to the public by a group health plan or health insurance issuer must include:

(i) An in-network rate machine-readable file that includes the required information under this paragraph (b)(1)(i) for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of this section. The in-network rate machine-readable file must include:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or if no HIOS identifier is available, the Employer Identification Number (EIN);

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) All applicable rates, which may include one or more of the following: Negotiated rates, underlying fee schedule rates, or derived amounts. If a group health plan or health insurance issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the group health plan or health insurance issuer uses underlying fee schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount. Applicable rates, including for both individual items and services and items and services in a bundled payment arrangement, must be:

(*1*) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider. If the negotiated rate is subject to change based upon participant, beneficiary, or enrollee-specific characteristics, these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant, beneficiary, or enrollee-specific characteristics;

(*2*) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider;

(*3*) Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and

(*4*) Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

(ii) An out-of-network allowed amount machine-readable file, including:

(A) For each coverage option offered by a group health plan or health

insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) Unique out-of-network allowed amounts and billed charges with respect to covered items or services furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the machine-readable file (except that a group health plan or health insurance issuer must omit such data in relation to a particular item or service and provider when compliance with this paragraph (b)(1)(ii)(C) would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 20 different claims for payments under a single plan or coverage). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique out-of-network allowed amount must be:

(*1*) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an out-of-network provider; and

(*2*) Associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

(iii) A prescription drug machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) The NDC, and the proprietary and nonproprietary name assigned to the NDC by the Food and Drug Administration (FDA), for each covered item or service that is a prescription drug under each coverage option offered by a plan or issuer;

(C) The negotiated rates which must be:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC; and

(D) Historical net prices that are:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC (except that a group health plan or health insurance issuer must omit such data in relation to a particular NDC and provider when compliance with this paragraph (b)(1)(iii)(D) would require the plan or issuer to report payment of historical net prices calculated using fewer than 20 different claims for payment). Consistent with paragraph (b)(3) of this section, nothing in this paragraph (b)(1)(iii)(D) requires the disclosure of information that would violate any applicable health information privacy law.

(2) *Required method and format for disclosing information to the public.* The machine-readable files described in this paragraph (b) must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services. The machine-readable files must be publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of personally identifiable information to access the file.

(3) *Timing.* A group health plan or health insurance issuer must update the machine-readable files and information required by this paragraph (b) monthly. The group health plan or health insurance issuer must clearly indicate the date that the files were most recently updated.

(4) *Special rules to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(iii) *Aggregation permitted for out-of-network allowed amounts.* Nothing in this section prohibits a group health plan or health insurance issuer from satisfying the disclosure requirement described in paragraph (b)(1)(ii) of this section by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, an issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information, provided the minimum claim threshold described in paragraph (b)(1)(ii)(C) of this section is independently met for each item or service and for each plan or coverage included in an aggregated Allowed Amount File. Under such circumstances, health insurance issuers, service providers, or other parties with which the group health plan or issuer has contracted may aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract. Additionally, nothing in this section prevents the Allowed Amount File from being hosted on a third-party website or prevents a plan administrator or issuer from contracting with a third party to post the file. However, if a plan or issuer chooses not to also host the file separately on its own website, it must provide a link on its own public website to the location where the file is made publicly available.

(c) *Applicability.* (1) The provisions of this section apply for plan years (in the

individual market, for policy years) beginning on or after January 1, 2022.

(2) As provided under § 147.140, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 147.126(d)(6) or short term limited duration insurance as defined in § 144.103 of this subchapter.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 7. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg–18.

■ 8. Section 158.221 is amended by adding paragraph (b)(9) to read as follows:

§ 158.221 Formula for calculating an issuer's medical loss ratio.

* * * * *

(b) * * *

(9) Beginning with the 2020 MLR reporting year, an issuer may include in the numerator of the MLR any shared savings payments the issuer has made to an enrollee as a result of the enrollee choosing to obtain health care from a lower-cost, higher-value provider.

* * * * *

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Part V

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 218

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the U.S. Navy Training and Testing Activities in the Northwest Training and Testing (NWTT) Study Area; Final Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 218

[Docket No. 201020–0272]

RIN 0648–BJ30

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the U.S. Navy Training and Testing Activities in the Northwest Training and Testing (NWTT) Study Area

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

ACTION: Final rule; notification of issuance of Letters of Authorization.

SUMMARY: NMFS, upon request from the U.S. Navy (Navy), issues these regulations pursuant to the Marine Mammal Protection Act (MMPA) to govern the taking of marine mammals incidental to the training and testing activities conducted in the Northwest Training and Testing (NWTT) Study Area. The Navy's activities qualify as military readiness activities pursuant to the MMPA, as amended by the National Defense Authorization Act for Fiscal Year 2004 (2004 NDAA). These regulations, which allow for the issuance of Letters of Authorization (LOA) for the incidental take of marine mammals during the described activities and timeframes, prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species and their habitat, and establish requirements pertaining to the monitoring and reporting of such taking.

DATES: Effective from November 9, 2020 to November 8, 2027.

ADDRESSES: A copy of the Navy's application, NMFS' proposed and final rules and subsequent LOAs for the existing regulations, and other supporting documents and documents cited herein may be obtained online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.* In case of problems accessing these documents, please use the contact listed here (see **FOR FURTHER INFORMATION CONTACT**).

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

SUPPLEMENTARY INFORMATION:

Purpose of Regulatory Action

These regulations, issued under the authority of the MMPA (16 U.S.C. 1361 *et seq.*), provide the framework for authorizing the take of marine mammals incidental to the Navy's training and testing activities (which qualify as military readiness activities) from the use of sonar and other transducers, in-water detonations, and potential vessel strikes based on Navy movement in the NWTT Study Area. The NWTT Study Area includes air and water space off the coast of Washington, Oregon, and Northern California; in the Western Behm Canal, Alaska; and portions of waters of the Strait of Juan de Fuca and Puget Sound, including Navy pierside and harbor locations in Puget Sound (see Figure 1–1 of the Navy's rulemaking/LOA application).

NMFS received an application from the Navy requesting seven-year regulations and authorizations to incidentally take individuals of multiple species of marine mammals (''Navy's rulemaking/LOA application'' or ''Navy's application''). Take is anticipated to occur by Level A harassment and Level B harassment as well as a very small number of serious injuries or mortalities incidental to the Navy's training and testing activities.

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs 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, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity, as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I, provide the legal basis for issuing this final rule and the subsequent LOAs. As directed by this legal authority, this final rule contains mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Final Rule

The following is a summary of the major provisions of this final rule regarding the Navy's activities. Major provisions include, but are not limited to:

- The use of defined powerdown and shutdown zones (based on activity);
- Measures to reduce the likelihood of ship strikes;
- Activity limitations in certain areas and times that are biologically important (*e.g.,* for foraging or migration) for marine mammals;
- Implementation of a Notification and Reporting Plan (for dead or live stranded marine mammals); and
- Implementation of a robust monitoring plan to improve our understanding of the environmental effects resulting from the Navy training and testing activities.

Additionally, the rule includes an adaptive management component that allows for timely modification of mitigation or monitoring measures based on new information, when appropriate.

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA 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 issued or, if the taking is limited to harassment, a notice of proposed authorization is provided to the public for review and the opportunity to submit comments.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stocks and will not have an unmitigable adverse impact on the availability of the species or stocks 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 this rule as ''mitigation measures''); and requirements pertaining to the monitoring and reporting of such takings. The MMPA defines ''take'' to mean to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal. The Analysis and Negligible Impact Determination section below discusses the definition of ''negligible impact.''

The NDAA for Fiscal Year 2004 (2004 NDAA) (Pub. L. 108–136) amended section 101(a)(5) of the MMPA to remove the ''small numbers'' and

''specified geographical region'' provisions indicated above and amended the definition of ''harassment'' as applied to a ''military readiness activity.'' The definition of harassment for military readiness activities (Section 3(18)(B) of the MMPA) is (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 such behavioral patterns are abandoned or significantly altered (Level B harassment). In addition, the 2004 NDAA amended the MMPA as it relates to military readiness activities such that the least practicable adverse impact analysis shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

More recently, Section 316 of the NDAA for Fiscal Year 2019 (2019 NDAA) (Pub. L. 115–232), signed on August 13, 2018, amended the MMPA to allow incidental take rules for military readiness activities under section 101(a)(5)(A) to be issued for up to seven years. Prior to this amendment, all incidental take rules under section 101(a)(5)(A) were limited to five years.

Summary and Background of Request

On March 11, 2019, NMFS received an application from the Navy for authorization to take marine mammals by Level A harassment and Level B harassment incidental to training and testing activities (which qualify as military readiness activities) from the use of sonar and other transducers and in-water detonations in the NWTT Study Area over a seven-year period beginning when the 2015—2020 authorization expires. In addition, the Navy requested incidental take authorization by serious injury or mortality for up to three takes of large whales from vessel strikes over the seven-year period. We received revised applications on June 6, 2019 and June 21, 2019, which provided revisions in the take number estimates and vessel strike analysis, and the Navy's rulemaking/LOA application was found to be adequate and complete. On August 6, 2019 (84 FR 38225), we published a notice of receipt (NOR) of application in the **Federal Register**, requesting comments and information related to the Navy's request for 30 days. On October 4, 2019, the Navy submitted an amendment to its application which incorporated new Southern Resident killer whale offshore density information, and on December 19, 2019, the Navy submitted an amendment to its application which incorporated revised testing activity numbers. On June 2, 2020, we published a notice of proposed rulemaking (85 FR 33914) and requested comments and information related to the Navy's request for 45 days. All comments received during the NOR and the proposed rulemaking comment periods were considered in this final rule. Comments received on the proposed rule are addressed in this final rule in the Comments and Responses section.

The following types of training and testing, which are classified as military readiness activities pursuant to the MMPA, as amended by the 2004 NDAA, will be covered under the regulations and LOAs: Anti-submarine warfare (sonar and other transducers, underwater detonations), mine warfare (sonar and other transducers, underwater detonations), surface warfare (underwater detonations), and other testing and training (sonar and other transducers). The activities will not include pile driving/removal or use of air guns.

This would be the third time NMFS has promulgated incidental take regulations pursuant to the MMPA relating to similar military readiness activities in the NWTT Study Area. Specifically, five-year regulations addressing training in the Northwest Training Range Complex were first issued on November 9, 2010 (75 FR 69295; November 10, 2010) and five-year regulations addressing testing in the NUWC Keyport Range Complex were issued on April 11, 2011 (76 FR 20257; April 12, 2011). Regulations addressing both the training and testing activities from the two previous separate rules, Northwest Training and Testing (NWTT), were issued and were effective from November 9, 2015 through November 8, 2020 (80 FR 73555; November 24, 2015). For this third round of rulemaking, the activities the Navy is planning to conduct are largely a continuation of ongoing activities conducted over the past 10 years under the previous rulemakings, with the addition of some new training and testing activities, as well as additional mitigation measures.

The Navy's mission is to organize, train, equip, and maintain combat-ready naval forces capable of winning wars, deterring aggression, and maintaining freedom of the seas. This mission is mandated by Federal law (10 U.S.C. 8062), which requires the readiness of the naval forces of the United States. The Navy executes this responsibility in part by training and testing at sea, often in designated operating areas (OPAREA) and testing and training ranges. The Navy must be able to access and utilize these areas and associated sea space and air space in order to develop and maintain skills for conducting naval operations. The Navy's testing activities ensure naval forces are equipped with well-maintained systems that take advantage of the latest technological advances. The Navy's research and acquisition community conducts military readiness activities that involve testing. The Navy tests ships, aircraft, weapons, combat systems, sensors, and related equipment, and conducts scientific research activities to achieve and maintain military readiness.

The Navy has been conducting training and testing activities in the NWTT Study Area for decades, with some activities dating back to at least the early 1900s. The tempo and types of training and testing activities fluctuate because of the introduction of new technologies, the evolving nature of international events, advances in warfighting doctrine and procedures, and changes in force structure (*e.g.,* organization of ships, submarines, aircraft, weapons, and personnel). Such developments influence the frequency, duration, intensity, and location of required training and testing activities, however the Navy's planned activities for the period of this rule will be largely a continuation of ongoing activities. In addition to ongoing activities, the Navy is planning some new training activities such as torpedo exercise—submarine training and unmanned underwater vehicle training.[1] The Navy is also planning some new testing activities, including: At-sea sonar testing, Mine Countermeasure and Neutralization testing, mine detection and classification testing, kinetic energy weapon testing, propulsion testing, undersea warfare testing, vessel signature evaluation, acoustic and oceanographic research, radar and other system testing, and simulant testing.[2]

[1] Some of the activities included here are new to the 2020 NWTT FSEIS/OEIS, but are not new to the Study Area. TORPEX—SUB activity was previously analyzed in 2010 as part of the Sinking Exercise. The Sinking Exercise is no longer conducted in the NWTT Study Area and the TORPEX—SUB activity is now a separate activity included in the 2020 NWTT FSEIS/OEIS. Unmanned underwater vehicle activity was analyzed in 2010 as a testing activity, but is now being included as a training activity.

[2] Mine detection and classification testing was analyzed in 2010 in the Inland waters, but was not previously analyzed in the Offshore waters. Vessel signature evaluation testing was analyzed in 2010

Continued

The Navy's rulemaking/LOA application reflects the most up-to-date compilation of training and testing activities deemed necessary to accomplish military readiness requirements. The types and numbers of activities included in the rule account for fluctuations in training and testing in order to meet evolving or emergent military readiness requirements. These regulations cover training and testing activities that will occur for a seven-year period following the expiration of the current MMPA authorization for the NWTT Study Area, which expires on November 8, 2020.

Description of the Specified Activity

A detailed description of the specified activity was provided in our **Federal Register** notice of proposed rulemaking (85 FR 33914; June 2, 2020); please see that notice of proposed rulemaking or the Navy's application for more information. Since publication of the proposed rule, the Navy has made some minor changes to its planned activities, all of which are in the form of reductions and thereby have the effect of reducing the impact of the activity. See the discussion of these changes below. In addition, since publication of the proposed rule, additional mitigation measures have been added, which are discussed in detail in the Mitigation Measures section of this rule. The Navy has determined that acoustic and explosive stressors are most likely to result in impacts on marine mammals that could rise to the level of harassment, and NMFS concurs with this determination. Additional detail regarding these activities is provided in Chapter 2 of the 2020 NWTT Final Supplemental Environmental Impact Statement (FSEIS)/Overseas EIS (OEIS) (2020 NWTT FSEIS/OEIS) (*https://www.nwtteis.com*) and in the Navy's rulemaking/LOA application (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities*) and are summarized here.

Dates and Duration

The specified activities can occur at any time during the seven-year period of validity of the regulations, with the exception of the activity types and time periods for which limitations have explicitly been identified (see Mitigation Measures section). The planned number of training and testing activities are described in the Detailed Description of the Specified Activities section (Tables 3 through 4).

Geographical Region

The NWTT Study Area is composed of established maritime operating and warning areas in the eastern North Pacific Ocean region, including areas of the Strait of Juan de Fuca, Puget Sound, and Western Behm Canal in southeastern Alaska. The Study Area includes air and water space within and outside Washington state waters, within Alaska state waters, and outside state waters of Oregon and Northern California (see Figure 1 in the proposed rule). The eastern boundary of the Offshore Area portion of the Study Area is 12 nautical miles (nmi) off the coastline for most of the Study Area, including southern Washington, Oregon, and Northern California. The Offshore Area includes the ocean all the way to the coastline only along that part of the Washington coast that lies beneath the airspace of W–237 and the Olympic Military Operations Area. The Study Area includes four existing range complexes and facilities: The Northwest Training Range Complex, the Keyport Range Complex, Carr Inlet Operations Area, and the Southeast Alaska Acoustic Measurement Facility (Western Behm Canal, Alaska). In addition to these range complexes, the Study Area also includes Navy pierside locations where sonar maintenance and testing occurs as part of overhaul, modernization, maintenance, and repair activities at Naval Base Kitsap, Bremerton; Naval Base Kitsap, Bangor; and Naval Station Everett. Additional detail can be found in Chapter 2 of the Navy's rulemaking/LOA application.

Overview of Training and Primary Mission Areas

The Navy categorizes its at-sea activities into functional warfare areas called primary mission areas. These activities generally fall into the following eight primary mission areas: Air warfare; amphibious warfare; anti-submarine warfare (ASW); electronic warfare; expeditionary warfare; mine warfare (MIW); strike warfare; and surface warfare (SUW). The Navy's planned activities for NWTT generally fall into the following six primary mission areas: Air warfare; anti-submarine warfare; electronic warfare; expeditionary warfare; mine warfare; and surface warfare. Most activities addressed in the NWTT Study Area are categorized under one of these primary mission areas. Activities that do not fall within one of these areas are listed as ''other activities.'' Each warfare community (surface, subsurface, aviation, and expeditionary warfare) may train in some or all of these primary mission areas. The testing community also categorizes most, but not all, of its testing activities under these primary mission areas. A description of the sonar, munitions, targets, systems, and other material used during training and testing activities within these primary mission areas is provided in Appendix A (*Navy Activities Descriptions*) of the 2020 NWTT FSEIS/OEIS.

The Navy describes and analyzes the effects of its activities within the 2020 NWTT FSEIS/OEIS. In its assessment, the Navy concluded that sonar and other transducers and in-water detonations were the stressors most likely to result in impacts on marine mammals that could rise to the level of harassment as defined under the MMPA. Therefore, the Navy's rulemaking/LOA application provides the Navy's assessment of potential effects from these stressors in terms of the various warfare mission areas in which they would be conducted. Those mission areas include the following:

- Anti-submarine warfare (sonar and other transducers, underwater detonations);
- expeditionary warfare;
- mine warfare (sonar and other transducers, underwater detonations);
- surface warfare (underwater detonations); and
- other (sonar and other transducers).

The Navy's training and testing activities in air warfare and electronic warfare do not involve sonar and other transducers, underwater detonations, or any other stressors that could result in harassment, serious injury, or mortality of marine mammals. Therefore, the activities in air warfare and electronic warfare are not discussed further in this rule, but are analyzed fully in the 2020 NWTT FSEIS/OEIS. Additional detail regarding the primary mission areas was provided in our **Federal Register** notice of proposed rulemaking (85 FR 33914; June 2, 2020); please see that notice of proposed rulemaking or the Navy's application for more information.

Overview of Testing Activities Within the NWTT Study Area

The Navy's research and acquisition community engages in a broad spectrum of testing activities in support of the Fleet. These activities include, but are not limited to, basic and applied scientific research and technology development; testing, evaluation, and maintenance of systems (missiles, radar, and sonar) and platforms (surface ships, submarines, and aircraft); and acquisition of systems and platforms.

as a component to other activities, but is included in the list of new activities because it was not previously identified as an independent activity.

The individual commands within the research and acquisition community include Naval Air Systems Command, Naval Sea Systems Command, and Office of Naval Research.

Description of Stressors

The Navy uses a variety of sensors, platforms, weapons, and other devices, including ones used to ensure the safety of Sailors and Marines, to meet its mission. Training and testing with these systems may introduce acoustic (sound) energy or shock waves from explosives into the environment. The following subsections describe the acoustic and explosive stressors for marine mammals and their habitat (including prey species) within the NWTT Study Area. Because of the complexity of analyzing sound propagation in the ocean environment, the Navy relied on acoustic models in its environmental analyses and rulemaking/LOA application that considered sound source characteristics and varying ocean conditions across the NWTT Study Area. Stressor/resource interactions that were determined to have de minimis or no impacts (*e.g.,* vessel noise, aircraft noise, weapons noise, and explosions in air) were not carried forward for analysis in the Navy's rulemaking/LOA application. No Major Training Exercises (MTEs) or Sinking Exercise (SINKEX) events are planned in the NWTT Study Area. NMFS reviewed the Navy's analysis and conclusions on de minimis sources and finds them complete and supportable.

Acoustic stressors include acoustic signals emitted into the water for a specific purpose, such as sonar, other transducers (devices that convert energy from one form to another—in this case, into sound waves), as well as incidental sources of broadband sound produced as a byproduct of vessel movement, aircraft transits, and use of weapons or other deployed objects. Explosives also produce broadband sound but are characterized separately from other acoustic sources due to their unique hazardous characteristics. Characteristics of each of these sound sources are described in the following sections.

In order to better organize and facilitate the analysis of approximately 300 sources of underwater sound used for training and testing by the Navy, including sonar and other transducers and explosives, a series of source classifications, or source bins, were developed. The source classification bins do not include the broadband sounds produced incidental to vessel and aircraft transits and weapons firing. Noise produced from vessel, aircraft, and weapons firing activities are not carried forward because those activities were found to have de minimis or no impacts, as stated above.

The use of source classification bins provides the following benefits:

- Provides the ability for new sensors or munitions to be covered under existing authorizations, as long as those sources fall within the parameters of a ''bin;''
- Improves efficiency of source utilization data collection and reporting requirements anticipated under the MMPA authorizations;
- Ensures a conservative approach to all impact estimates, as all sources within a given class are modeled as the most impactful source (highest source level, longest duty cycle, or largest net explosive weight) within that bin;
- Allows analyses to be conducted in a more efficient manner, without any compromise of analytical results; and
- Provides a framework to support the reallocation of source usage (hours/explosives) between different source bins, as long as the total numbers of takes remain within the overall analyzed and authorized limits. This flexibility is required to support evolving Navy training and testing requirements, which are linked to real world events.

Sonar and Other Transducers

Active sonar and other transducers emit non-impulsive sound waves into the water to detect objects, navigate safely, and communicate. Passive sonars differ from active sound sources in that they do not emit acoustic signals; rather, they only receive acoustic information about the environment, or listen. In this rule, the terms sonar and other transducers will be used to indicate active sound sources unless otherwise specified.

The Navy employs a variety of sonars and other transducers to obtain and transmit information about the undersea environment. Some examples are mid-frequency hull-mounted sonars used to find and track enemy submarines; high-frequency small object detection sonars used to detect mines; high-frequency underwater modems used to transfer data over short ranges; and extremely high-frequency (greater than 200 kilohertz (kHz)) Doppler sonars used for navigation, like those used on commercial and private vessels. The characteristics of these sonars and other transducers, such as source level, beam width, directivity, and frequency, depend on the purpose of the source. Higher frequencies can carry more information or provide more information about objects off which they reflect, but attenuate more rapidly. Lower frequencies attenuate less rapidly, so they may detect objects over a longer distance, but with less detail.

Additional detail regarding sound sources and platforms and categories of acoustic stressors was provided in our **Federal Register** notice of proposed rulemaking (85 FR 33914; June 2, 2020); please see that notice of proposed rulemaking or the Navy's application for more information.

Sonars and other transducers are grouped into classes that share an attribute, such as frequency range or purpose of use. As detailed below, classes are further sorted by bins based on the frequency or bandwidth; source level; and, when warranted, the application in which the source would be used. Unless stated otherwise, a reference distance of 1 meter (m) is used for sonar and other transducers.

- Frequency of the non-impulsive acoustic source:
  - Low-frequency sources operate below 1 kHz;
  - Mid-frequency sources operate at and above 1 kHz, up to and including 10 kHz;
  - High-frequency sources operate above 10 kHz, up to and including 100 kHz;
  - Very-high-frequency sources operate above 100 kHz but below 200 kHz;
- Sound pressure level of the non-impulsive source;
  - Greater than 160 decibels (dB) re 1 micro Pascal (μPa), but less than 180 dB re: 1 μPa;
  - Equal to 180 dB re: 1 μPa and up to 200 dB re: 1 μPa;
  - Greater than 200 dB re: 1 μPa;
- Application in which the source would be used:
  - Sources with similar functions that have similar characteristics, such as pulse length (duration of each pulse), beam pattern, and duty cycle.

The bins used for classifying active sonars and transducers that are quantitatively analyzed in the NWTT Study Area are shown in Table 1 below. While general parameters or source characteristics are shown in the table, actual source parameters are classified.

TABLE 1—SONAR AND OTHER TRANSDUCERS QUANTITATIVELY ANALYZED IN THE NWTT STUDY AREA

Source class category	Bin	Description
Low-Frequency (LF): Sources that produce signals less than 1 kHz.	LF4	LF sources equal to 180 dB and up to 200 dB.
	LF5	LF sources less than 180 dB.
Mid-Frequency (MF): Tactical and non-tactical sources that produce signals between 1 and 10 kHz.	MF1	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–53C and AN/SQS–60).
	MF1K	Kingfisher mode associated with MF1 sonars.
	MF2	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–56).
	MF3	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).
	MF4	Helicopter-deployed dipping sonars (*e.g.,* AN/AQS–22).
	MF5	Active acoustic sonobuoys (*e.g.,* DICASS).
	MF6	Underwater sound signal devices (*e.g.,* MK 84 SUS).
	MF9	Sources (equal to 180 dB and up to 200 dB) not otherwise binned.
	MF10	Active sources (greater than 160 dB, but less than 180 dB) not otherwise binned.
	MF11	Hull-mounted surface ship sonars with an active duty cycle greater than 80 percent.
	MF12	Towed array surface ship sonars with an active duty cycle greater than 80 percent.
High-Frequency (HF): Tactical and non-tactical sources that produce signals between 10 and 100 kHz.	HF1	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).
	HF3	Other hull-mounted submarine sonars (classified).
	HF4	Mine detection, classification, and neutralization sonar (*e.g.,* AN/SQS–20).
	HF5	Active sources (greater than 200 dB) not otherwise binned.
	HF6	Sources (equal to 180 dB and up to 200 dB) not otherwise binned.
	HF8	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–61).
	HF9	Weapon-emulating sonar source.
Very High-Frequency (VHF): Tactical and non-tactical sources that produce signals greater than 100 kHz but less than 200 kHz.	VHF1	Active sources greater than 200 dB.
	VHF2	Active sources with a source level less than 200 dB.
Anti-Submarine Warfare (ASW): Tactical sources (*e.g.,* active sonobuoys and acoustic countermeasures systems) used during ASW training and testing activities.	ASW1	MF systems operating above 200 dB.
	ASW2	MF Multistatic Active Coherent sonobuoy (*e.g.,* AN/SSQ–125).
	ASW3	MF towed active acoustic countermeasure systems (*e.g.,* AN/SLQ–25).
	ASW4	MF expendable active acoustic device countermeasures (*e.g.,* MK 3).
	ASW5 [1]	MF sonobuoys with high duty cycles.
Torpedoes (TORP): Active acoustic signals produced by torpedoes.	TORP1	Lightweight torpedo (*e.g.,* MK 46, MK 54, or Anti-Torpedo Torpedo).
	TORP2	Heavyweight torpedo (*e.g.,* MK 48).
	TORP3	Heavyweight torpedo (*e.g.,* MK 48).
Looking Sonar (FLS): Forward or upward looking object avoidance sonars used for ship navigation and safety.	FLS2	HF sources with short pulse lengths, narrow beam widths, and focused beam patterns.
Acoustic Modems (M): Sources used to transmit data	M3	MF acoustic modems (greater than 190 dB).
Synthetic Aperture Sonars (SAS): Sonars used to form high-resolution images of the seafloor.	SAS2	HF SAS systems.
Broadband Sound Sources (BB): Sonar systems with large frequency spectra, used for various purposes.	BB1	MF to HF mine countermeasure sonar.
	BB2	HF to VHF mine countermeasure sonar.

[1] Formerly ASW2 in the 2015–2020 (Phase II) rulemaking.

Explosives

This section describes the characteristics of explosions during naval training and testing. The activities analyzed in the Navy's rulemaking/LOA application that use explosives are described in additional detail in Appendix A (*Training and Testing Activities Descriptions*) of the 2020 NWTT FSEIS/OEIS. Explanations of the terminology and metrics used when describing explosives in the Navy's rule making/LOA application are also in Appendix H (*Acoustic and Explosive Concepts*) of the 2020 NWTT FSEIS/OEIS.

The near-instantaneous rise from ambient to an extremely high peak pressure is what makes an explosive shock wave potentially damaging. Farther from an explosive, the peak pressures decay and the explosive waves propagate as an impulsive, broadband sound. Several parameters influence the effect of an explosive: The weight of the explosive in the warhead, the type of explosive material, the boundaries and characteristics of the propagation medium, and, in water, the detonation depth and the depth of the receiver (*i.e.,* marine mammal). The net explosive weight, which is the explosive power of a charge expressed as the equivalent weight of trinitrotoluene (TNT), accounts for the first two parameters. The effects of these factors are explained in Appendix D (*Acoustic and Explosive Concepts*) of the 2020 NWTT FSEIS/OEIS. The activities analyzed in the Navy's rulemaking/LOA application and this final rule that use explosives are described in further detail in Appendix A (*Navy Activities Descriptions*) of the 2020 NWTT FSEIS/OEIS. Explanations of the terminology and metrics used when describing explosives are provided in Appendix D (*Acoustic and Explosive Concepts*) of the 2020 NWTT FSEIS/OEIS.

Explosive detonations during training and testing activities are associated with high-explosive munitions, including,

but not limited to, bombs, missiles, naval gun shells, torpedoes, mines, demolition charges, and explosive sonobuoys. Explosive detonations during training and testing involving the use of high-explosive munitions (including bombs, missiles, and naval gun shells) could occur in the air or near the water's surface. Explosive detonations associated with torpedoes and explosive sonobuoys would occur in the water column; mines and demolition charges could be detonated in the water column or on the ocean bottom. Most detonations will occur in waters greater than 200 ft in depth, and greater than 50 nmi from shore, with the exception of Mine Countermeasure and Neutralization testing planned in the Offshore Area, and existing mine warfare training areas in Inland Waters (*i.e.,* Crescent Harbor and Hood Canal Explosive Ordnance Disposal Training Ranges). Mine countermeasure and neutralization testing is a new planned testing activity that would occur closer to shore than other in-water explosive activities analyzed in the 2015 NWTT Final EIS/OEIS for the Offshore Area of the NWTT Study Area. This activity would occur in waters 3 nmi or greater from shore in the Quinault Range Site (outside the Olympic Coast National Marine Sanctuary), or 12 nmi or greater from shore elsewhere in the Offshore Area, and will not occur off the coast of California. Since publication of the proposed rule, the Navy has agreed that it will conduct explosive Mine Countermeasure and Neutralization testing in daylight hours only, and in Beaufort Sea state number 3 conditions or less. Two of the three events would involve the use of explosives, and would typically occur in water depths shallower than 1,000 ft. The two multi-day events (1–10 days per event) would include up to 36 E4 explosives (>2.5–5 lb net explosive weight) and 5 E7 explosives (>20–60 lb net explosive weight). Use of E7 explosives would occur greater than 6 nmi from shore. Since publication of the proposed rule, the Navy has agreed that, within 20 nmi from shore in the Marine Species Coastal Mitigation Area, the Navy will conduct no more than one Mine Countermeasure and Neutralization testing event annually, not to exceed the use of 20 E4 and 3 E7 explosives, from October 1 through June 30. Additionally, within 20 nmi from shore in the Marine Species Coastal Mitigation Area, the Navy will not exceed 60 E4 and 9 E7 explosives over seven years, from October 1 through June 30. Finally, to the maximum extent practical, the Navy will conduct explosive Mine Countermeasure and Neutralization Testing from July 1 through September 30 when operating within 20 nmi from shore in the Marine Species Coastal Mitigation Area. In order to better organize and facilitate the analysis of explosives used by the Navy during training and testing that could detonate in water or at the water surface, explosive classification bins were developed. The use of explosive classification bins provides the same benefits as described for acoustic source classification bins discussed above and in Section 1.4.1 (Acoustic Stressors) of the Navy's rulemaking/LOA application.

Explosives detonated in water are binned by net explosive weight. The bins of explosives in the NWTT Study Area are shown in Table 2 below.

TABLE 2—EXPLOSIVES ANALYZED IN THE NWTT STUDY AREA

Bin	Net explosive weight (lb)	Example explosive source
E1	0.1–0.25	Medium-caliber projectiles.
E2	>0.25–0.5	Medium-caliber projectiles.
E3	>0.5–2.5	Explosive Ordnance Disposal Mine Neutralization.
E4	>2.5–5	Mine Countermeasure and Neutralization.
E5	>5–10	Large-caliber projectile.
E7	>20–60	Mine Countermeasure and Neutralization.
E8	>60–100	Lightweight torpedo.
E10	>250–500	1,000 lb bomb.
E11	>500–650	Heavyweight torpedo.

Propagation of explosive pressure waves in water is highly dependent on environmental characteristics such as bathymetry, bottom type, water depth, temperature, and salinity, which affect how the pressure waves are reflected, refracted, or scattered; the potential for reverberation; and interference due to multi-path propagation. In addition, absorption greatly affects the distance over which higher-frequency components of explosive broadband noise can propagate. Appendix D (*Acoustic and Explosive Concepts*) of the 2020 NWTT FSEIS/OEIS explains the characteristics of explosive detonations and how the above factors affect the propagation of explosive energy in the water.

Marine mammals could be exposed to fragments from underwater explosions associated with the specified activities. When explosive ordnance *(e.g.,* bomb or missile) detonates, fragments of the weapon are thrown at high-velocity from the detonation point, which can injure or kill marine mammals if they are struck. These fragments may be of variable size and are ejected at supersonic speed from the detonation. The casing fragments will be ejected at velocities much greater than debris from any target due to the proximity of the casing to the explosive material. Risk of fragment injury reduces exponentially with distance as the fragment density is reduced. Fragments underwater tend to be larger than fragments produced by in-air explosions (Swisdak and Montaro, 1992). Underwater, the friction of the water would quickly slow these fragments to a point where they no longer pose a threat. Opposingly, the blast wave from an explosive detonation moves efficiently through the seawater. Because the ranges to mortality and injury due to exposure to the blast wave are likely to far exceed the zone where fragments could injure or kill an animal, the thresholds and associated ranges for assessing the likelihood of mortality and injury from a blast, which are also used to inform mitigation zones, are assumed to encompass risk due to fragmentation.

Other Stressor—Vessel Strike

Vessel strikes are not specific to any particular training or testing activity, but rather a potential, limited, sporadic, and incidental result of Navy vessel movement within the NWTT Study Area. Navy vessels transit at speeds that are optimal for fuel conservation or to meet training and testing requirements. Should a vessel strike occur, it would likely result in incidental take from

serious injury and/or mortality and, accordingly, for the purposes of the analysis we assume that any authorized ship strike would result in serious injury or mortality. Information on Navy vessel movement is provided in the *Vessel Movement* section of this rule. Additional detail on vessel strike was provided in our **Federal Register** notice of proposed rulemaking (85 FR 33914; June 2, 2020); please see that notice of proposed rulemaking or the Navy's application for more information.

Detailed Description of Specified Activities

Planned Training and Testing Activities

The Navy's Operational Commands and various System Commands have identified activity levels that are needed in the NWTT Study Area to ensure naval forces have sufficient training, maintenance, and new technology to meet Navy missions in the Northwest. Training prepares Navy personnel to be proficient in safely operating and maintaining equipment, weapons, and systems to conduct assigned missions. Navy research develops new science and technology followed by concept testing relevant to future Navy needs.

The training and testing activities that the Navy plans to conduct in the NWTT Study Area are summarized in Table 3 (training) and Table 4 (testing). The tables are organized according to primary mission areas and include the activity name, associated stressor(s), description of the activity, sound source bin, the locations of those activities in the NWTT Study Area, and the number of activities. For further information regarding the primary platform used (*e.g.,* ship or aircraft type) see Appendix A (*Training and Testing Activities Descriptions*) of the 2020 NWTT FSEIS/OEIS.

This section indicates the number of activities that could occur each year and then the maximum total that could occur over seven years. When a range of annual activities is provided, the maximum number is analyzed. The maximum number of activities may occur during some years, but not others, as several activities—Torpedo Exercise-Submarine Training, Tracking Exercise-Helicopter Training, Civilian Port Defense- Homeland Security Anti-Terrorism/Force Protection Training, Bomb Exercise Training, and Missile Exercise Training—do not occur every year, and other activities may occur every year, but less frequently than the maximum annual total. However, to conduct a conservative analysis, NMFS analyzed the maximum times these activities could occur over one year and seven years, with the assumption that this number of activities would be representative of the annual and seven-year activity totals.

TABLE 3—TRAINING ACTIVITIES ANALYZED FOR THE SEVEN-YEAR PERIOD IN THE NWTT STUDY AREA

Stressor category	Activity	Description	Typical duration of event	Source bin	Location	Annual number of events	7-Year number of events
Anti-Submarine Warfare							
Acoustic; Explosive	Torpedo Exercise—Submarine (TORPEX—Sub).	Submarine crews search for, track, and detect submarines. Event would include one MK–48 torpedo used during this event.	8 hours	TORP2	Offshore Area >12 nmi from land.	0–2	5
Acoustic	Tracking Exercise –Helicopter (TRACKEX—Helo).	Helicopter crews search for, track, and detect submarines.	2–4 hours	MF4, MF5	Offshore Area >12 nmi from land.	0–2	5
Acoustic	Tracking Exercise—Maritime Patrol Aircraft (TRACKEX—MPA).	Maritime patrol aircraft crews search for, track, and detect submarines.	2–8 hours	ASW2, ASW5, MF5, TORP1.	Offshore Area >12 nmi from land.	373	2,611
Acoustic	Tracking Exercise –Ship (TRACKEX—Ship).	Surface ship crews search for, track, and detect submarines.	2–4 hours	ASW3, MF1, MF11.	Offshore Area	62	434
Acoustic	Tracking Exercise—Submarine (TRACKEX—Sub).	Submarine crews search for, track, and detect submarines.	8 hours	HF1, MF3	Offshore Area	75–100	595
Mine Warfare							
Acoustic	Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises.	Maritime security personnel train to protect civilian ports and harbors against enemy efforts to interfere with access to those ports.	Multiple days.	HF4, SAS2	Inland Waters	0–1	5
Explosive	Mine Neutralization—Explosive Ordnance Disposal (EOD).	Personnel disable threat mines using explosive charges.	Up to 4 hours.	E3	Crescent Harbor EOD Training Range, Hood Canal EOD Training Range.	[1] 6	[1] 42
Surface Warfare							
Explosive	Bombing Exercise (Air-to-Surface)(BOMBEX [A–S]).	Fixed-wing aircrews deliver bombs against surface targets.	1 hour	E10	Offshore Area (W–237) > 50 nmi from land.	0–2 (counts only the explosive events)	5
Explosive	Gunnery Exercise (Surface-to-Surface)—Ship (GUNEX [S–S]—Ship).	Surface ship crews fire large- and medium-caliber guns at surface targets.	Up to 3 hours.	E1, E2, E5	Offshore Area > 50 nmi from land.	[1] 34 (counts only the explosive events)	[1] 238
Explosive	Missile Exercise (Air-to-Surface)(MISSILEX [A–S]).	Fixed-wing aircrews simulate firing precision-guided missiles, using captive air training missiles (CATMs) against surface targets. Some activities include firing a missile with a high-explosive (HE) warhead.	2 hours	E10	Offshore Area (W–237) >50 nmi from land.	0–2	5
Other Training							
Acoustic	Submarine Sonar Maintenance.	Maintenance of submarine sonar and other system checks are conducted pierside or at sea.	Up to 1 hour.	LF5, MF3, HF1.	NBK Bangor, NBK Bremerton, and Offshore Area >12 nmi from land.	26	182
Acoustic	Surface Ship Sonar Maintenance.	Maintenance of surface ship sonar and other system checks are conducted pierside or at sea.	Up to 4 hours.	MF1	NBK Bremerton, NS Everett, and Offshore Area >12 nmi from land.	25	175

TABLE 3—TRAINING ACTIVITIES ANALYZED FOR THE SEVEN-YEAR PERIOD IN THE NWTT STUDY AREA—Continued

Stressor category	Activity	Description	Typical duration of event	Source bin	Location	Annual number of events	7-Year number of events
Acoustic	Unmanned Underwater Vehicle Training.	Unmanned underwater vehicle certification involves training with unmanned platforms to ensure submarine crew proficiency. Tactical development involves training with various payloads for multiple purposes to ensure that the systems can be employed effectively in an operational environment..	Up to 24 hours.	FLS2, M3	Inland Waters, Offshore Area.	60	420

[1] These activities have been reduced since publication of the proposed rule.

TABLE 4—TESTING ACTIVITIES ANALYZED FOR THE SEVEN-YEAR PERIOD IN THE NWTT STUDY AREA

Stressor category	Activity	Description	Typical duration	Source bin	Location	Annual number of events	7-Year number of events
Naval Sea Systems Command Testing Activities Anti-Submarine Warfare							
Acoustic	Anti-Submarine Warfare Testing.	Ships and their supporting platforms (rotary-wing aircraft and unmanned aerial systems) detect, localize, and prosecute submarines.	4–8 hours of active sonar use.	ASW1, ASW2, ASW3, ASW5, MF1K, MF4, MF5, MF10, MF11, MF12, TORP1.	Offshore Area	44	308
Acoustic	At-Sea Sonar Testing	At-sea testing to ensure systems are fully functional in an open ocean environment..	From 4 hours to 11 days.	ASW3, HF1, HF5, M3, MF3,.	Offshore Area	4	28
				ASW3, HF5, TORP1.	Inland Waters (DBRC)	4–6	34
Acoustic	Countermeasure Testing.	Countermeasure testing involves the testing of systems that will detect, localize, and track incoming weapons, including marine vessel targets. Countermeasures may be systems to obscure the vessel's location or systems to rapidly detect, track, and counter incoming threats. Testing includes surface ship torpedo defense systems and marine vessel stopping payloads.	From 4 hours to 6 days.	ASW3, ASW4, HF8, MF1, TORP2.	Offshore Area (QRS)	14	98
				ASW3, ASW4.	Inland Waters (DBRC, Keyport Range Site).	29	203
				ASW4	Western Behm Canal, AK.	1	5
Acoustic	Pierside-Sonar Testing	Pierside testing to ensure systems are fully functional in a controlled pierside environment prior to at-sea test activities.	Up to 3 weeks.	ASW3, HF3, MF1, MF2, MF3, MF9, MF10, MF12.	Inland Waters (NS Everett, NBK Bangor, NBK Bremerton).	88–99	635
Acoustic	Submarine Sonar Testing/Maintenance.	Pierside, moored, and underway testing of submarine systems occurs periodically following major maintenance periods and for routine maintenance.	Up to 3 weeks.	HF6, MF9	Western Behm Canal, AK.	1–2	10
Acoustic; Explosive	Torpedo (Explosive) Testing.	Air, surface, or submarine crews employ explosive and non-explosive torpedoes against artificial targets.	1–2 hours during daylight only.	E8, E11, ASW3, HF1, HF6, MF1, MF3, MF4, MF5, MF6, TORP1, TORP2.	Offshore Area> 50 nmi from land.	4	28
Acoustic	Torpedo (Non-explosive) Testing.	Air, surface, or submarine crews employ non-explosive torpedoes against targets, submarines, or surface vessels..	Up to 2 weeks.	ASW3, ASW4, HF1, HF5, HF6, MF1, MF3, MF4, MF5, MF6, MF9, MF10, TORP1, TORP2.	Offshore Area	22	154
				HF6, LF4, TORP1, TORP2, TORP3.	Inland Waters (DBRC)	61	427

TABLE 4—TESTING ACTIVITIES ANALYZED FOR THE SEVEN-YEAR PERIOD IN THE NWTT STUDY AREA—Continued

Stressor category	Activity	Description	Typical duration	Source bin	Location	Annual number of events	7-Year number of events
Mine Warfare							
Acoustic; Explosive	Mine Countermeasure and Neutralization Testing.	Air, surface, and subsurface vessels neutralize threat mines and mine-like objects..	1–10 days	E4, E7, HF4.	Offshore Area	[1] 2	[1] 6
				HF4	Inland Waters	3	13
Acoustic	Mine Detection and Classification Testing.	Air, surface, and subsurface vessels and systems detect and classify mines and mine-like objects. Vessels also assess their potential susceptibility to mines and mine-like objects..	Up to 24 days.	BB1, BB2, LF4.	Offshore Area (QRS)	1	7
				BB1, BB2, HF4, LF4.	Inland Waters (DBRC, Keyport Range Site).	42	294
Unmanned Systems							
Acoustic	Unmanned Underwater Vehicle Testing.	Testing involves the production or upgrade of unmanned underwater vehicles. This may include testing of mission capabilities (*e.g.,* mine detection), evaluating the basic functions of individual platforms, or conducting complex events with multiple vehicles..	Typically 1–2 days, up to multiple months.	FLS2, HF5, TORP1, VHF1.	Offshore Area (QRS)	38–39	269
				DS3, FLS2, HF5, HF9, M3, SAS2, VHF1, TORP1.	Inland Waters (DBRC, Keyport Range Site, Carr Inlet).	371–379	2,615
Vessel Evaluation							
Acoustic	Undersea Warfare Testing.	Ships demonstrate capability of countermeasure systems and underwater surveillance, weapons engagement, and communications systems. This tests ships' ability to detect, track, and engage undersea targets..	Up to 10 days.	ASW3, ASW4, HF4, MF1, MF4, MF5, MF6, MF9, TORP1, TORP2.	Offshore Area	1–12	27
Other Testing							
Acoustic	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships, aircraft, and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems..	Up to 14 days.	LF4, MF9	Offshore Area (QRS)	1	7
					Inland Waters (DBRC, Keyport Range Site).	3	21
Acoustic	Acoustic Component Testing.	Various surface vessels, moored equipment, and materials are tested to evaluate performance in the marine environment.	1 day to multiple months.	HF3, HF6, LF5, MF9.	Western Behm Canal, AK.	13–18	99
Acoustic	Cold Water Support	Fleet training for divers in a cold water environment, and other diver training related to Navy divers supporting range/test site operations and maintenance..	8 hours	HF6	Inland Waters (Keyport Range Site, DBRC, Carr Inlet).	4	28
					Western Behm Canal, AK.	1	7
Acoustic	Post-Refit Sea Trial	Following periodic maintenance periods or repairs, sea trials are conducted to evaluate submarine propulsion, sonar systems, and other mechanical tests..	8 hours	HF9, M3, MF10.	Inland Waters (DBRC)	30	210
Acoustic	Semi-Stationary Equipment Testing.	Semi-stationary equipment (*e.g.,* hydrophones) is deployed to determine functionality..	From 10 minutes to multiple days.	HF6, HF9, LF4, MF9, VHF2.	Inland Waters (DBRC, Keyport Range Site).	120	840
				HF6, HF9	Western Behm Canal, AK.	2–3	12
Naval Air Systems Command Testing Activities Anti-Submarine Warfare							
Acoustic; Explosive	Tracking Test—Maritime Patrol Aircraft.	The test evaluates the sensors and systems used by maritime patrol aircraft to detect and track submarines and to ensure that aircraft systems used to deploy the tracking systems perform to specifications and meet operational requirements..	4–8 flight hours.	E1, E3, ASW2, ASW5, MF5, MF6.	Offshore Area	8	56

[1] In the proposed rule, NMFS analyzed three events annually, and 15 events over the seven-year period; however, only two of the three annual events include sonar and/or explosives. The third annual event does not have acoustic components, and therefore, is not included here in the final rule. Additionally, the seven-year number of events has been reduced since publication of the proposed rule.

Summary of Acoustic and Explosive Sources Analyzed for Training and Testing

Tables 5 through 8 show the acoustic and explosive source classes, bins, and quantities used in either hours or counts associated with the Navy's training and testing activities over a seven-year period in the NWTT Study Area that were analyzed in the Navy's rulemaking/LOA application and by NMFS through the rulemaking process. Table 5 describes the acoustic source classes (*i.e.,* low-frequency (LF), mid-frequency (MF), and high-frequency (HF)) that could occur over seven years under the planned training activities. Acoustic source bin use in the proposed activities will vary annually. The seven-year totals for the planned training activities take into account that annual variability.

TABLE 5—ACOUSTIC SOURCE CLASSES ANALYZED AND USAGE FOR SEVEN-YEAR PERIOD FOR TRAINING ACTIVITIES IN THE NWTT STUDY AREA

Source class category	Bin	Description	Unit [1]	Annual	7-year total
Low-Frequency (LF): Sources that produce signals less than 1 kHz.	LF5	LF sources less than 180 dB	H	1	5
Mid-Frequency (MF): Tactical and non-tactical sources that produce signals between 1 and 10 kHz.	MF1	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–53C and AN/SQS–61).	H	164	1,148
	MF3	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).	H	70	490
	MF4	Helicopter-deployed dipping sonars (*e.g.,* AN/AQS–22 and AN/AQS–13).	H	0–1	1
	MF5	Active acoustic sonobuoys (*e.g.,* DICASS)	C	918–926	6,443
	MF11	Hull-mounted surface ship sonars with an active duty cycle greater than 80%.	H	16	112
High-Frequency (HF): Tactical and non-tactical sources that produce signals between 10 and 100 kHz.	HF1	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).	H	48	336
	HF4	Mine detection, classification, and neutralization sonar (*e.g.,* AN/SQS–20).	H	0–65	269
Anti-Submarine Warfare (ASW): Tactical sources (*e.g.,* active sonobuoys and acoustic countermeasures systems) used during ASW training and testing activities.	ASW2	MF Multistatic Active Coherent sonobuoy (*e.g.,* AN/SSQ–125).	C	350	2,450
	ASW3	MF towed active acoustic countermeasure systems (*e.g.,* AN/SLQ–25).	H	86	602
	ASW5	MF sonobuoys with high duty cycles	H	50	350
Torpedoes (TORP): Source classes associated with the active acoustic signals produced by torpedoes.	TORP1	Lightweight torpedo (*e.g.,* MK 46, MK 54, or Anti-Torpedo Torpedo).	C	16	112
	TORP2	Heavyweight torpedo (*e.g.,* MK 48)	C	0–2	5
Forward Looking Sonar (FLS): Forward or upward looking object avoidance sonars used for ship navigation and safety.	FLS2	HF sources with short pulse lengths, narrow beam widths, and focused beam patterns.	H	240	1,680
Acoustic Modems (M): Systems used to transmit data through the water.	M3	MF acoustic modems (greater than 190 dB)	H	30	210
Synthetic Aperture Sonars (SAS): Sonars in which active acoustic signals are post-processed to form high-resolution images of the seafloor.	SAS2	HF SAS systems	H	0–561	2,353

[1] H = hours; C = count.

Table 6 describes the acoustic source classes and numbers that could occur over seven years under the planned testing activities. Acoustic source bin use in the planned activities would vary annually. The seven-year totals for the planned testing activities take into account that annual variability.

TABLE 6—ACOUSTIC SOURCE CLASSES ANALYZED AND USAGE FOR SEVEN-YEAR PERIOD FOR TESTING ACTIVITIES IN THE NWTT STUDY AREA

Source class category	Bin	Description	Unit [1]	Annual	7-year total
Low-Frequency (LF): Sources that produce signals less than 1 kHz.	LF4	LF sources equal to 180 dB and up to 200 dB	H	177	1,239
	LF5	LF sources less than 180 dB	H	0–18	23
Mid-Frequency (MF): Tactical and non-tactical sources that produce signals between 1 and 10 kHz.	MF1	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–53C and AN/SQS–61).	H	20–169	398
	MF1K	Kingfisher mode associated with MF1 sonars	H	48	336
	MF2	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–56).	H	32	224
	MF3	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).	H	34–36	239
	MF4	Helicopter-deployed dipping sonars (*e.g.,* AN/AQS–22 and AN/AQS–13).	H	41–50	298
	MF5	Active acoustic sonobuoys (*e.g.,* DICASS)	C	300–673	2,782
	MF6	Active underwater sound signal devices (*e.g.,* MK 84 SUS).	C	60–232	744
	MF9	Active sources (equal to 180 dB and up to 200 dB) not otherwise binned.	H	644–959	5,086
	MF10	Active sources (greater than 160 dB, but less than 180 dB) not otherwise binned.	H	886	6,197

TABLE 6—ACOUSTIC SOURCE CLASSES ANALYZED AND USAGE FOR SEVEN-YEAR PERIOD FOR TESTING ACTIVITIES IN THE NWTT STUDY AREA—Continued

Source class category	Bin	Description	Unit [1]	Annual	7-year total
	MF11	Hull-mounted surface ship sonars with an active duty cycle greater than 80 percent.	H	48	336
	MF12	Towed array surface ship sonars with an active duty cycle greater than 80 percent.	H	100	700
High-Frequency (HF): Tactical and non-tactical sources that produce signals between 10 and 100 kHz.	HF1	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).	H	10	68
	HF3	Other hull-mounted submarine sonars (classified).	H	1–19	30
	HF4	Mine detection, classification, and neutralization sonar (*e.g.,* AN/SQS–20).	H	1,860–1,868	11,235
	HF5	Active sources (greater than 200 dB) not otherwise binned.	H	352–400	2,608
	HF6	Active sources (equal to 180 dB and up to 200 dB) not otherwise binned.	H	1,705–1,865	12,377
	HF8	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–61).	H	24	168
	HF9	Weapon emulating sonar source	H	257	1,772
Very High-Frequency (VHF): Tactical and non-tactical sources that produce signals greater than 100 kHz but less than 200 kHz.	VHF1	Very high frequency sources greater than 200 dB.	H	320	2,240
	VHF2	Active sources with a frequency greater than 100 kHz, up to 200 kHz with a source level less than 200 dB.	H	135	945
Anti-Submarine Warfare (ASW): Tactical sources (*e.g.,* active sonobuoys and acoustic countermeasures systems) used during ASW training and testing activities.	ASW1	MF systems operating above 200 dB	H	80	560
	ASW2	MF systems operating above 200 dB	C	240	1,680
	ASW3	MF towed active acoustic countermeasure systems (*e.g.,* AN/SLQ–25).	H	487–1,015	4,091
	ASW4	MF expendable active acoustic device countermeasures (*e.g.,* MK 3).	C	1,349–1,389	9,442
	ASW5	MF sonobuoys with high duty cycles	H	80	560
Torpedoes (TORP): Source classes associated with the active acoustic signals produced by torpedoes.	TORP1	Lightweight torpedo (*e.g.,* MK 46, MK 54, or Anti-Torpedo Torpedo).	C	298–360	2,258
	TORP2	Heavyweight torpedo (*e.g.,* MK 48)	C	332–372	2,324
	TORP3	Heavyweight torpedo test (*e.g.,* MK 48)	C	6	42
Forward Looking Sonar (FLS): Forward or upward looking object avoidance sonars used for ship navigation and safety.	FLS2	HF sources with short pulse lengths, narrow beam widths, and focused beam patterns.	H	24	168
Acoustic Modems (M): Systems used to transmit data through the water.	M3	MF acoustic modems (greater than 190 dB)	H	1,088	7,616
Synthetic Aperture Sonars (SAS): Sonars in which active acoustic signals are post-processed to form high-resolution images of the seafloor.	SAS2	HF SAS systems	H	1,312	9,184
Broadband Sound Sources (BB): Sonar systems with large frequency spectra, used for various purposes.	BB1	MF to HF mine countermeasure sonar	H	48	336
	BB2	HF to VHF mine countermeasure sonar	H	48	336

[1] H = hours; C = count.

Table 7 describes the number of in-water explosives that could be used in any year under the planned training activities. Under the planned activities, bin use will vary annually, and the seven-year totals for the planned training activities take into account that annual variability.

TABLE 7—EXPLOSIVE SOURCE CLASS BINS ANALYZED AND NUMBER OF DETONATIONS USED FOR SEVEN-YEAR PERIOD FOR TRAINING ACTIVITIES IN THE NWTT STUDY AREA

Bin	Net explosive weight [1] (lb) [2]	Example explosive source	Annual [3]	7-year total
E1	0.1–0.25	Medium-caliber projectiles	60–120	672
E2	>0.25–0.5	Medium-caliber projectiles	65–130	728
E3	>0.5–2.5	Explosive Ordnance Disposal Mine Neutralization	6	42
E5	>5–10	Large-caliber projectile	56–112	628

TABLE 7—EXPLOSIVE SOURCE CLASS BINS ANALYZED AND NUMBER OF DETONATIONS USED FOR SEVEN-YEAR PERIOD FOR TRAINING ACTIVITIES IN THE NWTT STUDY AREA—Continued

Bin	Net explosive weight [1] (lb) [2]	Example explosive source	Annual [3]	7-year total
E10	>250–500	1,000 lb bomb	0–4	9

[1] Net explosive weight refers to the equivalent amount of TNT. The actual weight of a munition may be larger due to other components.
[2] lb = pound(s).
[3] Annual Nominal—Max. Two values indicate a range from Nominal to Max annual totals.

Table 8 describes the number of in-water explosives that could be used in any year under the planned testing activities. Under the planned activities, bin use will vary annually, and the seven-year totals for the planned testing activities take into account that annual variability.

TABLE 8—EXPLOSIVE SOURCE CLASS BINS ANALYZED AND NUMBER OF DETONATIONS USED FOR SEVEN-YEAR PERIOD FOR TESTING ACTIVITIES IN THE NWTT STUDY AREA

Bin	Net explosive weight [1] (lb) [2]	Example explosive source	Annual [3]	7-year total
E1	0.1–0.25	SUS buoy	8	56
E3	>0.5–2.5	Explosive sonobuoy	72	504
E4	>2.5–5	Mine Countermeasure and Neutralization	36	108
E7	>20–60	Mine Countermeasure and Neutralization	5	15
E8	>60–100	Lightweight torpedo	4	28
E11	>500–650	Heavyweight torpedo	4	28

[1] Net explosive weight refers to the equivalent amount of TNT. The actual weight of a munition may be larger due to other components.
[2] lb = pound(s).
[3] Annual Nominal—Max.

Vessel Movement

Vessels used as part of the planned activities include ships, submarines, unmanned vessels, and boats ranging in size from small, 22 ft rigid hull inflatable boats to aircraft carriers with lengths up to 1,092 ft. Large ships greater than 60 ft generally operate at speeds in the range of 10–15 kn for fuel conservation. Submarines generally operate at speeds in the range of 8–13 kn in transits and less than those speeds for certain tactical maneuvers. Small craft (for purposes of this discussion—less than 60 ft in length) have much more variable speeds (dependent on the mission). While these speeds are representative of most events, some vessels need to temporarily operate outside of these parameters. For example, to produce the required relative wind speed over the flight deck, an aircraft carrier engaged in flight operations must adjust its speed through the water accordingly. Conversely, there are other instances, such as launch and recovery of a small rigid hull inflatable boat; vessel boarding, search, and seizure training events; or retrieval of a target when vessels will be dead in the water or moving slowly ahead to maintain steerage.

The number of military vessels used in the NWTT Study Area varies based on military training and testing requirements, deployment schedules, annual budgets, and other unpredictable factors. Many training and testing activities involve the use of vessels. These activities could be widely dispersed throughout the NWTT Study Area, but will be typically conducted near naval ports, piers, and range areas. Training and testing activities involving vessel movements occur intermittently and are variable in duration, ranging from a few hours to up to two weeks. There is no seasonal differentiation in military vessel use. Large vessel movement primarily occurs with the majority of the traffic flowing between the installations and the Operating Areas (OPAREAS). Smaller support craft would be more concentrated in the coastal waters in the areas of naval installations, ports, and ranges. The number of activities that include the use of vessels for training events is lower (approximately 10 percent) than the number for testing activities. Testing can occur jointly with a training event, in which case that testing activity could be conducted from a training vessel.

Additionally, a variety of smaller craft will be operated within the NWTT Study Area. Small craft types, sizes, and speeds vary. During training and testing, speeds generally range from 10–14 kn; however, vessels can and will, on occasion, operate within the entire spectrum of their specific operational capabilities. In all cases, the vessels/craft will be operated in a safe manner consistent with the local conditions.

Standard Operating Procedures

For training and testing to be effective, personnel must be able to safely use their sensors and weapon systems as they are intended to be used in military missions and combat operations and to their optimum capabilities. While standard operating procedures are designed for the safety of personnel and equipment and to ensure the success of training and testing activities, their implementation often yields benefits on environmental, socioeconomic, public health and safety, and cultural resources.

Because standard operating procedures are essential to safety and mission success, the Navy considers them to be part of the planned specified activities, and they have been included in the environmental analysis in the 2020 NWTT FSEIS/OEIS. Additional details on standard operating procedures were provided in our **Federal Register** notice of proposed rulemaking (85 FR 33914; June 2, 2020); please see that notice of proposed rulemaking or the Navy's application for more information.

Comments and Responses

We published the proposed rule in the **Federal Register** on June 2, 2020 (85 FR 33914), with a 45-day comment period. With that proposed rule, we requested public input on our analyses, our preliminary findings, and the

proposed regulations, and requested that interested persons submit relevant information and comments. During the 45-day comment period, we received 9,047 comments. Of this total, one submission was from the Marine Mammal Commission, two submissions were from tribes or coalitions of tribes, three submissions were from state agencies or officials, and the remaining comments were from organizations or individuals acting in an official capacity (*e.g.,* non-governmental organizations (NGOs)) and private citizens. We received some submissions that expressed general opposition toward the Navy's proposed training and testing activities and requested that NMFS not issue the regulations and LOAs, but provided no specific comments or information. These general comments have been noted, but because they did not include information pertinent to NMFS' decision, they are not addressed further.

NMFS has reviewed and considered all public comments received on the proposed rule and issuance of the LOAs. General comments that did not provide information pertinent to NMFS' decisions have been noted, but are not addressed further. All substantive comments and our responses are described below. We provide no response to specific comments that addressed species or statutes not relevant to the rulemaking under section 101(a)(5)(A) of the MMPA (*e.g.,* comments related to sea turtles). We organize our comment responses by major categories.

Impact Analysis and Thresholds

Comment 1: A commenter stated that the criteria that the Navy has produced to estimate temporary and permanent threshold shift in marine mammals, and that NMFS applied in the proposed rule, are erroneous and non-conservative. According to the commenter, Wright (2015) has identified several statistical and numerical faults in the Navy's approach, such as pseudo-replication, use of means rather than onset (as with the treatment of blast trauma), and inconsistent treatment of data, that tend to bias the criteria towards an underestimation of effects. The commenter stated that similar and additional issues were raised by a dozen scientists during the public comment period on the draft criteria held by NMFS. The commenter asserts that the issue is NMFS' broad extrapolation from a small number of individual animals, mostly bottlenose dolphins, without taking account of what Racca *et al.* (2015b) have succinctly characterized as a ''non-linear accumulation of uncertainty.'' The commenter asserts that the auditory impact criteria should be revised. Another commenter noted that NMFS has not considered that repeated exposure to noise that can cause TTS can lead to PTS, or that TTS increases the likelihood of vessel strike.

Response: The ''Navy criteria'' that the commenter references for estimating were developed in coordination with NMFS and ultimately finalized, following three peer reviews and three public comment periods, as NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing-Underwater Acoustic Thresholds for Onset of Permanent and Temporary Threshold Shifts (Acoustic Technical Guidance). NMFS disagrees with the commenter's criticism about inconsistent treatment of data and any suggestion that the use of the Acoustic Technical Guidance provides erroneous results. The Acoustic Technical Guidance represents the best available science and provides thresholds and weighting functions that allow us to predict when marine mammals are likely to incur permanent threshold shift (PTS). All public comments on the Acoustic Technical Guidance, including those referenced by the commenter here, were addressed in full in the **Federal Register** notice announcing the finalization of the Acoustic Technical Guidance. We refer the reader to *https://www.federalregister.gov/documents/2016/08/04/2016-18462/technical-guidance-for-assessing-the-effects-of-anthropogenic-sound-on-marine-mammal* for full responses to those previously raised comments.

As described in the Estimated Take of Marine Mammals section, when the acoustic thresholds, the Navy model, and other inputs into the take calculation are considered, the authorized incidental takes represent the maximum number of instances in which marine mammals are reasonably expected to be taken, which is appropriate under the statute and there is no need or requirement for NMFS to authorize a larger number.

Multiple studies from humans, terrestrial mammals, and marine mammals have demonstrated less temporary threshold shift (TTS) from intermittent exposures compared to continuous exposures with the same total energy because hearing is known to experience some recovery in between noise exposures, which means that the effects of intermittent noise sources such as tactical sonars are likely overestimated. Marine mammal TTS data have also shown that, for two exposures with equal energy, the longer duration exposure tends to produce a larger amount of TTS. Most marine mammal TTS data have been obtained using exposure durations of tens of seconds up to an hour, much longer than the durations of many tactical sources (much less the continuous time that a marine mammal in the field would be exposed consecutively to those levels), further suggesting that the use of these TTS data are likely to overestimate the effects of sonars with shorter duration signals.

Regarding the suggestion of pseudoreplication and erroneous models, since marine mammal hearing and noise-induced hearing loss data are limited, both in the number of species and in the number of individuals available, attempts to minimize pseudoreplication would further reduce these already limited data sets. Specifically, with marine mammal behaviorally derived temporary threshold shift studies, behaviorally derived data are only available for two mid-frequency cetacean species (bottlenose dolphin, beluga) and two phocid (in-water) pinniped species (harbor seal and northern elephant seal), with otariid (in-water) pinnipeds and high-frequency cetaceans only having behaviorally-derived data from one species each. Arguments from Wright (2015) regarding pseudoreplication within the TTS data are therefore largely irrelevant in a practical sense because there are so few data. Multiple data points were not included for the same individual at a single frequency. If multiple data existed at one frequency, the lowest TTS onset was always used. There is only a single frequency where TTS onset data exist for two individuals of the same species: 3 kHz for bottlenose dolphins. Their TTS (unweighted) onset values were 193 and 194 dB re 1 μPa2s. Thus, NMFS believes that the current approach makes the best use of the given data. Appropriate means of reducing pseudoreplication may be considered in the future, if more data become available. Many other comments from Wright (2015) and the comments from Racca *et al.* (2015b) appear to be erroneously based on the idea that the shapes of the auditory weighting functions and TTS/PTS exposure thresholds are directly related to the audiograms; *i.e.,* that changes to the composite audiograms would directly influence the TTS/PTS exposure functions (*e.g.,* Wright (2015) describes weighting functions as ''effectively the mirror image of an audiogram'' (p. 2) and states, ''The underlying goal was to estimate how much a sound level needs to be above

hearing threshold to induce TTS.'' (p. 3)). Both statements are incorrect and suggest a fundamental misunderstanding of the criteria/threshold derivation. This would require a constant (frequency-independent) relationship between hearing threshold and TTS onset that is not reflected in the actual marine mammal TTS data. Attempts to create a ''cautionary'' outcome by artificially lowering the composite audiogram thresholds would not necessarily result in lower TTS/PTS exposure levels, since the exposure functions are to a large extent based on applying mathematical functions to fit the existing TTS data.

Please refer to the response to Comment 9 for additional information regarding the use of ''means rather than onset'' in the analysis of blast trauma.

Regarding the comment about repeated exposures to TTS leading to PTS, NMFS is aware of studies by Kujawa and Liberman (2009) and Lin *et al.* (2011), which found that despite completely reversible TS that leave cochlear sensory cells intact, large (but temporary) TS could cause synaptic level changes and delayed cochlear nerve degeneration in mice and guinea pigs. However, the large TS (*i.e.,* maximum 40 decibel dB) that led to the synaptic changes shown in these studies are in the range of the large shifts used by Southall *et al.* (2007) and in NMFS Acoustic Technical Guidance (2018) to define PTS onset (*i.e.,* 40 dB). There is no evidence indicating that smaller levels of TTS would lead to similar changes or the long-term implications of irreversible neural degeneration and NMFS has included several conservative assumptions in its protocol for examining marine mammal hearing loss data *(e.g.,* using a 6 dB threshold shift to represent TTS onset, not directly accounting for exposures that did not result in threshold shifts, assuming there is no recovery with the 24-h baseline accumulation period or between intermittent exposures). Moreover, as described in the final rule, TTS incurred as a result of exposures to Navy NWTT activities is expected to be of a smaller degree and, further, no individual is expected to incur repeated exposures of TTS in a manner that could accrue to PTS. Nonetheless, NMFS acknowledges the complexity of sound exposure on the nervous system, and will re-examine this issue as more data become available. Separately, the commenter provides no credible evidence to support the speculative assertion that TTS increases the likelihood of vessel strike of marine mammals.

Comment 2: A commenter recommended that NMFS clarify whether and how the Navy incorporated uncertainty in its density estimates for its animat modeling specific to NWTT and if uncertainty was not incorporated, re-estimate the numbers of marine mammal takes based on the uncertainty inherent in the density estimates provided in Department of the Navy (2019) or the underlying references (Jefferson *et al.,* 2017, Smultea *et al.,* 2017, NMFS SARs, *etc.*).

Response: Uncertainty was incorporated into the density estimates used for modeling and estimating take for NMFS' rule. Where available, a coefficient of variation (CV) was used to represent uncertainty in the species-specific density estimates. The CV was incorporated into the acoustic effects model by randomly varying the number of animats distributed for each scenario within the range described by the CV. If a measure of uncertainty was not available, then the number of animats distributed in the model remained the same for each modeled scenario. Multiple iterations of each modeled scenario were run until the results converged with minimal variation, meaning that even without incorporating a CV into the animat distribution, uncertainty in the exposure results were minimized.

The commenter is referred to the technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing* (U.S. Department of the Navy, 2018) for clarification on the consideration of uncertainty in density estimates. Specifically, see Section 4.2 (Marine Species Distribution Builder) of the technical report where details are provided on how statistical uncertainty surrounding density estimates was incorporated into the modeling for the NWTT Study Area, as has been done for all other recent NMFS and Navy analyses of training and testing at sea. To the commenter's more specific question, as with the 2018/2020 Hawaii-Southern California Training and Testing (HSTT) final rules and 2020 Mariana Islands Training and Testing (MITT) final rule, a lognormal distribution was used in the density regression model. Uncertainty was incorporated into the take estimation through the density estimates and it is not necessary to re-estimate the take numbers for marine mammals.

Comment 3: A commenter recommended that NMFS specify in the preamble to the final rule whether the data regarding behavioral audiograms (Branstetter *et al.,* 2017, Kastelein *et al.,* 2017b) and TTS (Kastelein *et al.,* 2017a and c, Popov *et al.,* 2017, Kastelein *et al.,* 2018a and 2019b, c, and d) support the continued use of the current weighting functions and PTS and TTS thresholds.

Response: NMFS has carefully considered the references that the commenter cites and the new data included in those articles are consistent with the thresholds and weighting functions included in the current version of the Acoustic Technical Guidance (NMFS, 2018). Furthermore, the recent peer-reviewed updated marine mammal noise exposure criteria by Southall *et al.* (2019a) provide identical PTS and TTS thresholds and weighting functions to those provided in NMFS' Acoustic Technical Guidance. NMFS will continue to review and evaluate new relevant data as it becomes available and consider the impacts of those studies on the Acoustic Technical Guidance to determine what revisions/updates may be appropriate.

Comment 4: A commenter stated that the Navy, and in turn NMFS, has not provided adequate justification for ignoring the possibility that single underwater detonations can cause a behavioral response. The commenter recommends that NMFS estimate and ultimately authorize behavior takes of marine mammals during all explosive activities, including those that involve single detonations. In a similar comment, another commenter stated that the literature on responses to explosions does not distinguish between single and multiple detonations, and asserts that it is arbitrary for NMFS, in estimating takes and assessing impacts, to assume that only multiple rounds of in-water detonations can cause Level B harassment takes by behavioral disturbance.

Response: NMFS does not ignore the possibility that single underwater detonations can cause a behavioral response. The current take estimate framework allows for the consideration of animals exhibiting behavioral disturbance during single explosions as they are counted as ''taken by Level B harassment'' if they are exposed above the TTS threshold, which is only 5 dB higher than the behavioral harassment threshold. We acknowledge in our analysis that individuals exposed above the TTS threshold may also be harassed by behavioral disruption and those potential impacts are considered in the negligible impact determination. Neither NMFS nor the Navy are aware of evidence to support the assertion that animals will have significant behavioral responses (*i.e.,* those that would rise to the level of a take) to temporally and

spatially isolated explosions at received levels below the TTS threshold. However, if any such responses were to occur, they would be expected to be few and to result from exposure to the somewhat higher received levels bounded by the TTS thresholds and would, thereby, be accounted for in the take estimates. The derivation of the explosive injury criteria is provided in the 2017 technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III).*

Comment 5: A commenter stated that the behavioral response functions (BRFs) rely on captive animal studies and the risk functions do not incorporate a number of relevant studies on wild marine mammals (specifically referencing a passive acoustic study on blue whales). The commenter states that some were included in the only published quantitative synthesis of behavioral response data, Gomez *et al.* (2016), while others appeared after that synthesis was published, and after the Navy produced its BRFs two years ago. The commenter asserts that exclusion of those studies fails to meet regulatory requirements (citing to National Environmental Policy Act (NEPA) regulations) that base evaluation of impacts on research methods generally accepted in the scientific community and that the result is arbitrary.

The commenter asserts that it is not clear from the proposed rule, the 2020 NWTT DSEIS/OEIS, or the Navy's associated technical report on acoustic ''criteria and thresholds'' exactly how each of the studies considered relevant were applied in the analysis, or how the functions were fitted to the data, but the available evidence on behavioral response raises concerns that—notwithstanding the agencies' claims to the contrary—the functions are not conservative for some species. For this reason and others, the commenter requests that NMFS make additional technical information available, including expert elicitation and peer review (if any), so that the public can fully comment pursuant to the Administrative Procedure Act (APA).

Response: We refer the commenter to the Criteria and Thresholds for the U.S. Navy Acoustic and Explosive Effects Analysis (Phase III) Technical Report (U.S. Department of the Navy, 2017) for details on how the Navy accounted for the differences in captive and wild animals in the development of the behavioral response risk functions, which NMFS has evaluated and deemed appropriate to incorporate into the analysis in the rule. The appendices to this report detail the specific data points used to generate the BRFs. Data points come from published data that is readily available and cited within the technical report.

The Navy used the best available science in the analysis, which has been reviewed by external scientists and approved by NMFS. The Navy considered all data available at the time for the development of updated criteria and thresholds, and limiting the data to the small number of field studies would not provide enough data with which to develop the new risk functions. In addition, the Navy accounted for the fact that captive animals may be less sensitive, and the scale at which a moderate-to-severe response was considered to have occurred is different for captive animals than for wild animals, as the Navy understands those responses will be different. The new risk functions were developed in 2016, before several recent papers were published or the data were available. The Navy and NMFS continue to evaluate the information as new science is made available. The criteria have been rigorously vetted within the Navy community, among scientists during expert elicitation, and then reviewed by the public before being applied. It is unreasonable to revise and update the criteria and risk functions every time a new paper is published. NMFS concurs with the Navy's evaluation and conclusion that there is no new information that necessitates changing the acoustic thresholds at this time.

These new papers provide additional information, and the Navy is considering them for updates to the criteria in the future, when the next round of updated criteria will be developed. Regarding consideration of research findings involving a passive acoustic study on blue whale vocalizations and behavior, the Navy considered multiple recent references, including but not limited to: Paniagua-Mendoza, 2017; Lesage, 2017; DeRuiter, 2017; Mate, 2016; Lomac-MacNair, 2016; Friedlaender, 2016; and Mate, 2015. Thus far, no new information has been published or otherwise conveyed that would fundamentally change the assessment of impacts or conclusions of this rule. To be included in the BRF, data sets needed to relate known or estimable received levels to observations of individual or group behavior. Melcon *et al.* (2012) does not relate observations of individual/group behavior to known or estimable received levels at that individual/group. In Melcon *et al.* (2012), received levels at the HARP buoy averaged over many hours are related to probabilities of D-calls, but the received level at the blue whale individuals/group are unknown.

Comment 6: Commenters recommended that NMFS refrain from using cut-off distances in conjunction with the Bayesian BRFs and re-estimate the numbers of marine mammal takes based solely on the Bayesian BRFs, as the use of cut-off distances could be perceived as an attempt to reduce the numbers of takes. One commenter suggested that the actual cut-off distances used by the Navy appear to be unsubstantiated and questioned several of the choices made in the development of the cutoff distances (although alternate recommendations were not included).

Response: The consideration of proximity (cut-off distances) was part of the criteria developed in consultation between the Navy and NMFS, and is appropriate based on the best available science which shows that marine mammal responses to sound vary based on both sound level and distance. Therefore these cut-off distances were applied within the Navy's acoustic effects model. The derivation of the BRFs and associated cut-off distances is provided in the 2017 technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III).* To account for non-applicable contextual factors, all available data on marine mammal reactions to actual Navy activities and other sound sources (or other large scale activities such as seismic surveys when information on proximity to sonar sources was not available for a given species group) were reviewed to find the farthest distance to which significant behavioral reactions were observed. For use as distance cut-offs to be used in conjunction with the BRFs, these distances were rounded up to the nearest 5 or 10 km interval, and for moderate to large scale activities using multiple or louder sonar sources, these distances were greatly increased—doubled in most cases. The Navy's BRFs applied within these distances provide technically sound methods reflective of the best available science to estimate the impact and potential take for the actions analyzed within the 2020 NWTT FSEIS/OEIS and included in this rule. NMFS has independently assessed the thresholds used by the Navy to identify Level B harassment by behavioral disturbance (referred to as ''behavioral harassment thresholds'' throughout the rest of the rule) and finds that they appropriately apply the best available science and it is not necessary to recalculate take estimates.

The commenters also specifically expressed concern that distance ''cut-

offs'' alleviate some of the exposures that would otherwise have been counted if the received level alone were considered. It is unclear why the commenters find this inherently inappropriate, as this is what the data show. There are multiple studies illustrating that in situations where one would expect behavioral disturbance of a certain degree because of the received levels at which previous responses were observed, it has not occurred when the distance from the source was larger than the distance of the first observed response.

Comment 7: A commenter stated that dipping sonar, like hull-mounted sonar, appears to be a significant predictor of deep-dive rates in beaked whales, with the dive rate falling significantly (*e.g.,* to 35 percent of that individual's control rate) during sonar exposure, and likewise appears associated with habitat abandonment. According to the commenter, the data sources used to produce the Navy's BRFs concern hull-mounted sonar, an R/V-deployed sonar playback, or an in-pool source. According to the commenter, the generic BRF for beaked whales used in the rule does not incorporate their heightened response to these sources, although such a response would be presumed to shift its risk function ''leftward.'' Nor do the response functions for other species account for this difference, although unpredictability is known to exacerbate stress response in a diversity of mammalian species and should conservatively be assumed, in this case, to lead to a heightened response in marine mammal species other than beaked whales.

Response: The best available science was used to develop the BRFs. The current beaked whale BRF acknowledges and incorporates the increased sensitivity observed in beaked whales during both behavioral response studies and during actual Navy training events, as well as the fact that dipping sonar can have greater effects than some other sources with the same source level. Specifically, the distance cut-off for beaked whales is 50 km, larger than any other group. Moreover, although dipping sonar has a significantly lower source level than hull-mounted sonar, it is included in the category of sources with larger distance cut-offs, specifically in acknowledgement of its unpredictability and association with observed effects. This means that ''takes'' are reflected at lower received levels that would have been excluded because of the distance for other source types. An article referenced by the commenter (Associating patterns in movement and diving behavior with sonar use during military training exercises: A case study using satellite tag data from Cuvier's beaked whales at the Southern California Anti-submarine Warfare Range (Falcone *et al.,* 2017)) was not available at the time the BRFs were developed. However, NMFS and the Navy have reviewed the article and concur that neither this article nor any other new information that has been published or otherwise conveyed since the BRFs were developed changes the assessment of impacts or conclusions in the 2020 NWTT FSEIS/OEIS or in this rulemaking. Additionally, the current beaked whale BRF covers the responses observed in this study since the beaked whale risk function is more sensitive than the other risk functions at lower received levels. The researchers involved with the study continue to further refine their analytical approach and integrate additional statistical parameters for future reporting. Nonetheless, the new information and data presented in the article were thoroughly reviewed by NMFS and the Navy and will be quantitatively incorporated into future BRFs, as appropriate, when and if other new data that would meaningfully change the functions would necessitate their revision. Furthermore, ongoing beaked whale monitoring at the same site where the dipping sonar tests were conducted has not documented habitat abandonment by beaked whales. Passive acoustic detections of beaked whales have not significantly changed over ten years of monitoring (DiMarzio *et al.,* 2018, updated in 2020). From visual surveys in the same area since 2006, there have been repeated sightings of the same individual beaked whales, beaked whale mother-calf pairs, and beaked whale mother-calf pairs with mothers on their second calf (Schorr *et al.,* 2018, 2020). Satellite tracking studies of beaked whales documented high site fidelity to this area (Schorr *et al.,* 2018, updated in 2020).

Comment 8: A commenter recommends that NMFS: (1) Explain why, if the constants and exponents for onset mortality and onset slight lung injury thresholds for the current phase of incidental take rulemaking for the Navy (Phase III) have been amended to account for lung compression with depth, they result in lower rather than higher absolute thresholds when animals occur at depths greater than 8 m and (2) specify what additional assumptions were made to explain this counterintuitive result.

Response: The derivation of the explosive injury equations, including any assumptions, is provided in the 2017 technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III).* Specifically, the equations were modified for the current rulemaking period (Phase III) to fully incorporate the injury model in Goertner (1982), specifically to include lung compression with depth. NMFS independently reviewed and concurred with this approach.

The impulse mortality/injury equations are depth dependent, with thresholds increasing with depth due to increasing hydrostatic pressure in the model for both the previous 2015–2020 phase of rulemaking (Phase II) and Phase III. The underlying experimental data used in Phase II and Phase III remain the same, and two aspects of the Phase III revisions explain the relationships the commenter **Notes:**

(1) The numeric coefficients in the equations are computed by inserting the Richmond *et al.* (1973) experimental data into the model equations. Because the Phase III model equation accounts for lung compression, the plugging of experimental exposure values into a different model results in different coefficients. The numeric coefficients are slightly larger in Phase III versus Phase II, resulting in a slightly greater threshold near the surface.

(2) The rate of increase for the Phase II thresholds with depth is greater than the rate of increase for Phase III thresholds with depth because the Phase III equations take into account the corresponding reduction in lung size with depth (making an animal more vulnerable to injury per the Goertner model), as the commenter notes.

Comment 9: A commenter recommended that NMFS use onset mortality, onset slight lung injury, and onset gastrointestinal (GI) tract injury thresholds rather than the 50-percent thresholds to estimate both the numbers of marine mammal takes and the respective ranges to effect. If NMFS does not implement the recommendation, the commenter further recommends that NMFS (1) specify why it is inconsistently basing its explosive thresholds for Level A harassment on onset of PTS and Level B harassment on onset of TTS and onset behavioral response, while the explosive thresholds for mortality and Level A harassment are based on the 50-percent criteria for mortality, slight lung injury, and GI tract injury, (2) provide scientific justification supporting the assumption that slight lung and GI tract injuries are less severe than PTS and thus the 50-percent rather than onset criteria are more appropriate for estimating Level A harassment for those types of injuries,

and (3) justify why the number of estimated mortalities should be predicated on at least 50 percent rather than 1 percent of the animals dying.

Another commenter also stated that they do not understand why the Navy and NMFS use the 50 percent average for the explosive impact analysis while using onset for purposes of assessing the effectiveness of the Navy's mitigation zones. This commenter also stated that this approach is not consistent with the probability standards set forth in the MMPA. The MMPA incorporates a standard of ''significant potential'' into its definition of ''injury'' for military readiness activities; this standard plainly differs from the higher ''likelihood'' standard that applies to behavioral disruption. And while the probability standard for mortality is not specifically defined in the Act, Congress expressly amended the MMPA in 1994 to incorporate a ''potential'' standard in the wake of the Ninth Circuit decision in *U.S.* v. *Hiyashi,* 22 F.3d 859 (9th Cir. 1993). If NMFS is to satisfy the plain language of the MMPA, and provide a more conservative estimate of harm, it cannot base its mortality and injury estimates on the mean.

Response: First, we note an error in one of the commenters' assertions. The BRFs used in the behavioral harassment thresholds are not based on the onset of any behavioral response. They are based on responses at or above a severity at which we believe ''take'' occurs, therefore the BRFs do not predict onset behavioral response. Also, the ''onset'' of TTS is not when there is any measurable TTS (*i.e.,* 0.5, 1 dB); we've defined the onset of TTS as where there is a consistently measurable amount of TTS, which has been defined as 6 dB of TTS. Additionally, the weighting function components of the TTS thresholds are based on the average of all of the data points. Since the PTS threshold is derived from an offset of the TTS threshold, this same averaging concept holds true for PTS criteria.

For explosives, the type of data available are different than those available for hearing impairment, and this difference supports the use of different prediction methods. Nonetheless, as appropriate and similar to take estimation methods for PTS, NMFS and the Navy have used a combination of exposure thresholds and consideration of mitigation to inform the take estimates. The Navy used the range to 1 percent risk of onset mortality and onset injury (also referred to as ''onset'' in the 2020 NWTT FSEIS/OEIS) to inform the development of mitigation zones for explosives. Ranges to effect based on 1 percent risk criteria to onset injury and onset mortality were examined to ensure that explosive mitigation zones would encompass the range to any potential mortality or non-auditory injury, affording actual protection against these effects. In all cases, the mitigation zones for explosives extend beyond the range to 1 percent risk of onset non-auditory injury, even for a small animal (representative mass = 5 kg). Given the implementation and expected effectiveness of this mitigation, the application of the indicated threshold is appropriate for the purposes of estimating take. Using the 1 percent onset non-auditory injury risk criteria to estimate take would result in an over-estimate of take, and would not afford extra protection to any animal. Specifically, calculating take based on marine mammal density within the area that an animal might be exposed above the 1 percent risk to onset injury and onset mortality criteria would over-predict effects because many of those exposures will not happen because of the effective mitigation. The Navy, in coordination with NMFS, has determined that the 50 percent incidence of onset injury and onset mortality occurrence is a reasonable representation of a potential effect and appropriate for take estimation, given the mitigation requirements at the 1 percent onset injury and onset mortality threshold, and the area ensonified above this threshold would capture the appropriate reduced number of likely injuries.

While the approaches for evaluating non-auditory injury and mortality are based on different types of data and analyses than the evaluation of PTS and behavioral disturbance, and are not identical, NMFS disagrees with the commenter's assertion that the approaches are inconsistent, as both approaches consider a combination of thresholds and mitigation (where applicable) to inform take estimates. For the same reasons, it is not necessary for NMFS to ''provide scientific justification supporting the assumption that slight lung and GI tract injuries are less severe than PTS,'' as that assumption is not part of NMFS' rationale for the methods used. NMFS has explained in detail its justification for the number of estimated mortalities, which is based on both the 50 percent threshold and the mitigation applied at the one percent threshold. Further, we note that many years of Navy monitoring following explosive exercises has not detected evidence that any injury or mortality has resulted from Navy explosive exercises with the exception of one incident with dolphins in California, after which mitigation was adjusted to better account for explosives with delayed detonations (*i.e.,* zones for events with time-delayed firing were enlarged).

Further, for these reasons, the methods used for estimating mortality and non-auditory injury are appropriate for estimating take, including determining the ''significant potential'' for non-auditory injury consistent with the statutory definition of Level A harassment for military readiness activities, within the limits of the best available science. Using the one percent threshold would be inappropriate and result in an overestimation of effects, whereas given the mitigation applied within this larger area, the 50 percent threshold results an appropriate mechanism for estimating the significant potential for non-auditory injury.

Comment 10: A commenter had concerns regarding the various areas, abundance estimates, and correction factors that the Navy used for pinnipeds. The commenter referenced information in the context of both what the Navy used and what the commenter argued they should have used and summarized the discussion with several recommendations.

Broadly, the commenter stated that since NMFS used the draft 2019 Stock Assessment Reports (SARs) or the most recently finalized SAR for the abundance estimates in its negligible impact determination analyses (Tables 9 and 52–57 in the **Federal Register** notice), it also must use the most recent abundance estimates to inform the associated densities and resulting take estimates as those abundance estimates represent the best available science.

The commenter noted that the abundance estimate for northern fur seals was based on pup count data from 2014 and did not include the more recent data from Bogoslof Island in 2015 and from St. Paul and St. George in 2016. For northern fur seals, the commenter recommended that NMFS revise the density based on the abundance estimate that includes data from Bogoslof Island in 2015 and from St. Paul and St. George in 2016.

The commenter noted that the abundance estimate for Guadalupe fur seals was based on pup count data from 2008 and 2010 and did not include the more recent survey data from 2013–2015 and associated correction factors. For Guadalupe fur seals, the commenter recommended that NMFS revise the density based on abundance data from 2013–2015 at both Isla Guadalupe and Isla San Benito.

The commenter stated that the abundance estimate for Steller sea lions was based on pup and non-pup count and trend data from 2015 and did not incorporate the more recent trend data from 2017. The commenter also noted that the Navy applied non-pup growth rates to the non-pup and pup abundance estimates rather than applying the non-pup growth rates to the non-pup abundances and the pup growth rates to the pup abundances. For Steller sea lions, the commenter recommended that NMFS revise the density based on adjusting the 2015 pup and non-pup data using the trend data from 2017, applying the non-pup growth rate to the non-pup counts and the pup growth rates to the pup counts.

For Guadalupe fur seal, Steller sea lion, California sea lions, harbor seals, and elephant seals, the commenter recommended that NMFS revise the densities based on applying the relevant growth rates up to at least 2020.

For harbor seals in the Strait of Juan de Fuca and the San Juan Islands, the commenter recommended that NMFS revise the densities based on assuming that 46 percent of the animals would be in the water at a given time from Huber *et al.* (2001).

Based on the recommendations above, the commenter recommended that NMFS re-estimate the numbers of takes accordingly in the final rule.

Response: The Navy provided NMFS clarification regarding the referenced concerns about areas, abundance estimates, and correction factors that were used for pinnipeds. We first note that take estimation is not an exact science. There are many inputs that go into an estimate of marine mammal exposure, and the data upon which those inputs are based come with varying levels of uncertainty and precision. Also, differences in life histories, behaviors, and distributions of stocks can support different decisions regarding methods in different situations. Further, there may be more than one acceptable method to estimate take in a particular situation. Accordingly, while the applicant bears the responsibility of providing by species or stock the estimated number and type of takes (see 50 CFR 216.104(a)(6)) and NMFS always ensures that an applicant's methods are technically supportable and reflect the best available science, NMFS does not prescribe any one method for estimating take (or calculating some of the specific take estimate components that the commenter is concerned about). NMFS reviewed the areas, abundances, and correction factors used by the Navy to estimate take and concurs that they are appropriate. While some of the suggestions the commenter makes could provide alternate valid ways to conduct the analyses, these modifications are not required in order to have equally valid and supportable analyses. In addition, we note that (1) some of the specific recommendations that the commenter makes are largely minor in nature within the context of our analysis (*e.g.,* ''46 not 37 percent'') and (2) even where the recommendation is somewhat larger in scale, given the ranges of the majority of these stocks, the size of the stocks, and the number and nature of pinniped takes, recalculating the estimated take for any of these pinniped stocks using the commenter's recommended changes would not change NMFS' assessment of impacts on the rates of recruitment or survival of any of these stocks, or the negligible impact determinations. Below, we address the commenter's issues in more detail and, while we do not explicitly note it in every section, NMFS has reviewed the Navy's analysis and choices in relation to these comments and concurs that they are technically sound and reflect the best available science.

Northern fur seal—The Navy analyzed unpublished tagging data provided by subject matter experts at NMFS' Alaska Fisheries Science Center (AKFSC). The Navy also did not integrate the 2015 data from Bogoslof Island suggested by the commenter based on advice from subject matter experts at the AKFSC, due to a volcanic eruption at the rookery on Bogoslof Island where a portion of the counts are made, which in the opinion of the AKFSC experts skewed the 2015 data. Therefore, the Navy found that incorporating this data would not reflect the best available science. NMFS concurs with this assessment, and therefore, has not included this information in the take estimation in this final rule. Regarding the recommendation for NMFS to revise the density based on the abundance estimate from St. Paul and St. George in 2016, to complete the modeling on schedule, the density data available at that time from the final 2016 SAR (Muto *et al.,* 2017) were used. Note that the latest pup counts reported in the final 2019 SAR (Muto *et al.,* 2020) using the more recent data from Bogoslof Island in 2015 and St. Paul and St. George in 2016 result in a lower pup count than the one used in the density calculation, which suggests that the estimates used for this final rule are likely conservative.

Guadalupe fur seal—The Navy Marine Species Density Database (NMSDD) technical report describes density estimates that were used in the Navy's acoustics effects model. To complete the modeling on schedule, the density data available at that time from the final 2016 SAR (Carretta *et al.,* 2017) were used. The initial abundance estimate of 20,000 fur seals was based on surveys between 2008 and 2010 as the commenter points out, but to account for a likely increasing population trend, the Navy applied a growth rate of 7.64 percent per year to estimate an abundance for the year 2017. That resulted in an abundance of 33,485 fur seals (a 67 percent increase over the reported abundance of 20,000). The final 2019 SAR (Carretta *et al.,* 2020) reported comparable abundance estimates based on the later surveys, some of which were from sources published in 2018, and an estimated growth rate of 5.9 percent, less than the growth rate applied by the Navy. The Navy's abundance estimate for the year 2017 is consistent with the latest abundance estimates.

Steller sea lion—As stated above, the NMSDD technical report describes density estimates that were used in the Navy's acoustics effects model. To complete the modeling on schedule, the density data available at that time from the final 2016 SAR (Muto *et al.,* 2017) were used. Steller sea lion densities were calculated independently for regional populations in Washington, Oregon, California, and southeast Alaska, consistent with the stock assessment reports. No trend data were (or are currently) estimated for pups in Washington, therefore, the non-pup growth rate of 8.77 percent per year was used for the entire population. In addition, the baseline abundance for Washington sea lions was increased over the abundance from the stock assessment report based on data reported in Wiles (2015) before the growth rate was applied to project a 2017 abundance. For sea lions in Oregon, California, and southeast Alaska the non-pup growth rate was used, because the number of non-pups in each population was substantially greater than the number of pups. Using separate growth rates for pups and non-pups in all three regions results in less than a 1 percent increase in the projected 2017 abundance. The associated change in the density is minimal and would not change the results of NMFS' or the Navy's analysis of acoustic impacts on Steller sea lions.

Harbor seal—Density estimates for harbor seal in the Strait of Juan de Fuca and San Juan Islands were based on sighting data provided by the Washington Department of Fish and Game (Jeffries, 2017). In the context of analyzing that data, a 37 percent in-

water correction factor was applied to the abundance estimate, which is specific to southern Puget Sound. Huber *et al.* (2001) noted that a 46 percent in-water correction factor would have been more appropriate given that the survey location was in the Strait. However, there were specific haulout factors for other areas within the Study Area that gave lower estimates throughout the Inland Waters. Subject matter experts from the Alaska Fisheries Science Center and the Northwest Fisheries Science Center concurred with the Navy's use of 37 percent as being most representative.

Regarding revising the densities based on applying the relevant growth rates up to at least 2020, the density estimates are based on sighting numbers from surveys over many years to encompass variation and are not future predictions. It would not be appropriate to base densities on growth rates. The densities do not incorporate abundances or estimates of growth rate since the abundances for population and their population trend (reduction or growth) are not directly applicable to the density within a given area. Subject matter experts at the NMFS Alaska Fisheries Science Center advised in 2015 and again in 2019 that growth/decline rates provided in the SARs should not be used to project future population numbers for use in the Navy's analysis where abundance have been integrated into the analysis. NMFS concurs with this assessment and has not applied the growth rates in the take estimation in this final rule.

Additionally, the Navy's purpose in applying an annual growth rate to estimate pinniped abundances in 2017 was to account for stock assessment report abundances that were based on surveys conducted several years prior to 2017. The intent was to update an older abundance estimate to the time of the Navy's analysis, not to predict abundances several years into the future. Projecting abundances from the past to the present (2017) allowed adjustments. For example, the growth rate for Guadalupe fur seal reported in the 2016 SAR (Carretta *et al.,* 2017) was 10.3 percent; however, as the commenter pointed out, that rate is based on survey data from 2008–2010. Subsequently, the 2015–2016 unusual mortality event (UME) occurred and the growth rate needed to be revised, which the Navy did. Projections extending into the future would not have allowed these types of corrections.

Please see Comment 18 for additional information about the harbor seal abundance estimates included in this final rule.

Comment 11: A commenter stated that a majority of the data that the Navy reviews and uses to determine species population density and breeding grounds is admittedly old and is not the most accurate representation of the species population or their geographic location. In its requirements for an authorization, the MMPA clearly states that requesters must include ''the species and numbers of marine mammals likely to be found within the activity area'' in order to demonstrate the requesting party's understanding of their activity impact on the animals and habitat. Normally, this sort of data requires up-to-date assessment reports, statistics, and accurate data that accurately portray the information that is necessary to require an authorization under the MMPA. However, the commenter stated that the Navy is violating the MMPA by providing outdated data from 2012 and 2014 to account for current patterns of marine activities in 2020–2027, even though they are conducting training exercises in the same Northwest waters where they are hoping to continue practicing for another seven years.

The commenter suggested that the Navy should instead provide accurate up-to-date surveys of the activity areas as well as data for a long-term projection for at least 30 years of activity in the area if it continues to expect to apply for the same authorization over and over again.

Response: The *U.S. Navy Marine Species Density Database Phase III for the Northwest Training and Testing Study Area Final Technical Report* includes an in-depth description of the process used to derive density estimates for marine mammal species occurring in the NWTT Study Area, and to provide a summary of species-specific and area-specific density estimates incorporated into the Marine Species Density Database. NMFS concurs that as described in the report, the process the Navy uses ensures that the density estimates reflect the best available data. Given the extensive and comprehensive process, it is not possible (or necessary) to update the density estimates or information about marine mammal breeding grounds each time a new paper is published, nor does the commenter provide additional data or publications that should have been incorporated into the density estimates or identify new information related to breeding grounds. However, the Navy will continue to incorporate, and NMFS will continue to consider, additional data for the next phase of Navy training and testing activities (Phase IV). Through the use of the Navy's methodology and the data inputs used, which were coordinated with NMFS, NMFS has ensured that this final rule incorporates the best available information related to marine mammal density and breeding areas in this final rule.

The commenter suggested that the Navy should provide accurate, up-to-date surveys of the activity areas, as well as data for a long-term projection for at least 30 years of activity in the NWTT Study Area. As discussed in the Monitoring section of this final rule, the Navy funds numerous marine mammal monitoring efforts, and this data is incorporated into the density and abundance estimates as appropriate. For example, this final rule incorporates new data regarding harbor seal abundance in NWTT inland waters from Navy-funded surveys (see the Analysis and Negligible Impact Determination section of this final rule). It is unclear what the commenter means by suggesting that the Navy provide a long-term projection for at least 30 years of activity in the area; however, NMFS notes that the current authorization is limited to seven years. NMFS will conduct a new analysis on the potential effects to marine mammals assuming the Navy seeks an authorization for training and testing activities beyond 2027 in the NWTT Study Area, and will ensure that the best available science, including new data as available, is included in that analysis.

Comment 12: A commenter recommended that NMFS require the Navy to provide the method(s) by which species-specific cetacean densities were calculated for Western Behm Canal and cite the primary literature from which those data originated in the report (Department of the Navy (2019)). The commenter states that that level of information should be provided in all technical reports that underpin the Navy's density databases for future Phase III and IV DSEISs, DEISs, and proposed rules.

Response: There were two primary sources of density data used to establish cetacean density estimates for Behm Canal: (1) The marine mammal occurrence/density report prepared in support of Navy activities at the Southeast Alaska Acoustic Measurement Facility (U.S. Department of the Navy, 2010) and (2) Density estimates derived by the National Marine Mammal Laboratory, Alaska Fisheries Science Center based on systematic surveys conducted in Southeast Alaska (*e.g.,* Dahlheim *et al.,* 2015). These sources were cited as appropriate in the species-specific sections of Department of the Navy (2020); methods by which species-

specific density estimates were calculated are also described in Department of the Navy (2020). Multiple sources were used to establish pinniped density estimates for Behm Canal. All are cited as appropriate and methods described within the species-specific sections of Department of the Navy, 2020 (U.S. Navy Marine Species Density Database Phase III for the Northwest Training and Testing Study Area: Technical report. Naval Facilities Engineering Command Pacific, Pearl Harbor, Hawaii. 258 pages).

Comment 13: A commenter stated that the delineation of Biologically Important Areas by NMFS, the updates made by the Navy to its predictive habitat models, and evidence of additional important habitat areas within the NWTT Study Area provide the opportunity for the agencies to improve upon their current approach to the development of alternatives by improving resolution of their analysis of operations.

The commenter stated that recognizing that important habitat areas imply the non-random distribution and density of marine mammals in space and time, both the spatial location and the timing of training and testing events in relation to those areas is a significant determining factor in the assessment of acoustic impacts. Levels of acoustic impact are likely to be under- or over-estimated depending on whether the location of the modeled event is further from the important habitat area, or closer to it, than the actual event. Thus, there is a need for the Navy to compile and provide more information regarding the number, nature, and timing of testing and training events that take place within, or in close proximity to, important habitat areas, and to refine its scale of analysis of operations to match the scale of the habitat areas that are considered to be important. And there is a need for NMFS to demand it.

The commenter stated that while the 2019 NWTT DSEIS/OEIS, in assessing environmental impacts on marine mammals, breaks down estimated impacts by population, little detail is provided about assumptions concerning modeled locations and times of year. See, *e.g.,* DSEIS at 2–28 to 2–38 (*e.g.,* defining numerous activities as simply occurring ''[o]ffshore''). The commenter further stated that the proposed rule notice adds nothing further, making it impossible for the public to assess the reasonableness of NMFS take estimates and negligible impact analysis in capturing the distribution of the activities proposed in the document. Additionally, the commenter asserts that the lack of definition in activity locations means that the agency cannot ensure takes are kept below authorized levels—and that sufficient measures are taken to protect particularly vulnerable marine mammal populations, such as the critically endangered Southern Resident killer whale and the struggling California gray whale.

The commenter recommended that NMFS require the Navy to produce further information on modeled locations and, if activities are not limited through the authorization process to specific geographic areas, to determine a worst-case take estimate for each species or population.

Another commenter stated that the Navy should provide NMFS with details on proposed timing of their training and testing activities and adjust the timing of their activities to minimize such overlap—such as through seasonal closures. The commenter stated that the DSEIS and the LOA application did not detail the times of year during which the proposed activities would take place. To issue a LOA, NMFS requires that proposed actions ''be well-planned with enough detailed information to allow for a robust analysis of the entire duration of your planned activity,'' which is lacking here. The Southern Resident killer whales have exhibited seasonality in their movements, and information from tagging studies, coastal surveys and passive acoustic monitoring allows some degree of understanding of seasonal areas for when and where they may be traveling and foraging. Any overlap in their seasonal movements and the Navy's testing and training activities will increase adverse impacts.

Response: This final rule and the 2020 NWTT FSEIS/OEIS are structured to provide flexibility in training and testing locations, timing, and number. Many factors influence actual training and testing locations that cannot be predicted in advance (*e.g.,* weather), so the analysis must allow for flexibility. The analysis must consider multiple Navy training and testing activities over large areas of the ocean for a seven-year period; therefore, analyzing activities in multiple locations over multiple seasons produces the best estimate of impacts/take to inform the 2020 NWTT FSEIS/OEIS and for NMFS to use to make its determinations. The scale at which spatially explicit density models are structured is determined by the data collection method and the environmental variables that are used to build the model. A number of variables that are meaningful to marine mammal species, such as sea surface temperature, do not vary or affect species on a fine scale. Expecting fine scale resolution from the Navy's density database may force artificial granularity on species for which it is not biologically meaningful at the population level. Therefore, given the variables that determine when and where the Navy trains and tests and the resolution of the density data, the analysis of potential impacts cannot be scaled to specific habitat areas, but the information included is at the appropriate resolution and provides the Navy and NMFS with the information necessary to determine potential impacts/take for a population of animals. Chapter 3.4 (Marine Mammals) of the 2020 NWTT SFEIS/OEIS estimates what portion of impacts to each species are expected to occur within different regions in the Study Area. NMFS has reviewed and concurs with the Navy's analysis and level of detail provided given these restrictions.

Additionally, specific modeled locations are not disclosed in public documents because of national security concerns, and information regarding the exact location of sonar usage is classified, although classified exercise reports with this information are provided to NMFS staff with the required security clearance. Furthermore, the Navy requires large areas of sea and air space to support the tactics, techniques, and procedures needed for certain activities, and training in large areas also helps the Navy avoid observation by potential adversaries. Modern sensing technologies make training on a large scale without observation more difficult. A foreign military's continual observation of U.S. Navy training in predictable (*e.g.,* compiled and publicly disclosed) geographic areas and timeframes would enable foreign nations to gather intelligence and subsequently develop techniques, tactics, and procedures to potentially and effectively counter U.S. naval operations.

Still, the Navy's rulemaking/LOA application and the 2020 NWTT FSEIS/OEIS provide a significant level of information about the locations of specific activities (see, *e.g.,* Chapter 2 (Description of Proposed Action and Alternatives) and Appendix A (Activity Descriptions) of the FSEIS/OEIS), which NMFS has used in its analysis of Navy activities and their impacts to marine mammals in the NWTT Study Area. Chapter 2 of the 2020 NWTT FSEIS/OEIS also describes Standard Operating Procedures that may influence activity location. Additionally, this final rule, and Chapter 5 (Mitigation) and Appendix K (Geographic Mitigation Assessment) of the 2020 NWTT FSEIS/OEIS describe mitigation measures,

including in specific mitigation areas, that the Navy is required to implement during 2020–2027 NWTT activities. In addition to the above considerations, conservative assumptions are used in the quantitative assessment process, as described in the technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing* (U.S. Department of the Navy, 2018c), an analysis which NMFS has reviewed and concurs with. The Navy also implements conservative application of marine mammal behavioral response data in the development of behavioral response criteria, as described in the technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)* (U.S. Department of the Navy, 2017h), which NMFS has also reviewed and concurs with. (Both technical reports are available at *www.nwtteis.com.*)

Additionally, implementation of the adaptive management process under the Letters of Authorization issued under this final rule further ensures that the Navy does not exceed the level of authorized take. Finally, the Navy's classified exercise reports are required to include information regarding activities conducted and sound sources used within specific mitigation areas, which provides the sort of geographically-explicit information the commenter is referencing and may be used to inform the adaptive management process and future rules.

Comment 14: A commenter stated that rather than using a fixed received level threshold for whether a take is likely to occur from exposure to mid-frequency sonar, the Navy has proposed a method for incorporating individual variation. Risk is predicted as a function of three parameters: (1) A basement value below which takes are unlikely to occur; (2) the level at which 50 percent of individuals would be taken; and (3) a sharpness parameter intended to reflect the range of individual variation. The commenter stated that even when parameters employed are based on the best available science, the implications of uncertainty in the values and biases and limitations in the model tend to lead to underestimation of the number of takes. The commenter asserts that data were incorrectly interpreted when calculating parameter values, resulting in a model that underestimates takes. The commenter states that errors included failure to recognize the difference between the mathematical basement plugged into the model, and the biological basement value, where the likelihood of observed and predicted takes becomes non-negligible; using the level where the probability of take was near 100 percent for the level where the probability of take was 50 percent; extrapolating values derived from laboratory experiments that were conducted on trained animals to wild animals without regard for the implications of training; and ignoring other available data, resulting in a further underestimation of takes. The commenter discusses several other points related to the development, interpretation, and application of the behavioral harassment thresholds used in prior Navy NWTT rules.

Response: The commenter is referring to the Phase II behavioral criteria, which were utilized in the previous NWTT rulemaking (2015–2020). In Phase III for this rulemaking, the Navy and NMFS incorporated the best available science into new BRFs that are described in the technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)* (U.S. Department of the Navy, 2017a), available at *www.nwtteis.com.* NMFS reviewed and concurs with the Phase III behavioral criteria described in the technical report.

Comment 15: A commenter recommends that NMFS (1) specify the total numbers of model-estimated Level A harassment (PTS) and mortality takes rather than reduce the estimated numbers of takes based on the Navy's post-model analyses, (2) include the model-estimated Level A harassment and mortality takes in its negligible impact determination analyses, and (3) authorize the model-estimated Level A harassment and mortality takes if the respective negligible impact determinations are able to be made and, if not, require the Navy to implement additional measures to mitigate such takes.

Another commenter stated that NMFS' post hoc adjustment for operational mitigation effectiveness is not a trivial or an abstract issue. It has the apparent effect of eliminating risk of mortality from explosives known to be of a power to kill marine mammals. Some experts have raised concerns that one Southern Resident killer whale mortality (whale L112) was caused by naval explosives or ordnance. NMFS should have made the Navy's approach transparent and explained the rationale for its acceptance of that approach. Its failure to do so has prevented the public from effectively commenting on its approach to this issue, in contravention of the APA, on a matter of obvious significance to the agency's core negligible impact findings. The commenter further states that, in estimating the number of instances of injury and mortality, NMFS makes two post hoc adjustments, significantly reducing the totals based on presumed animal avoidance and mitigation effectiveness. The commenter asserts that these two adjustments are arbitrary and non-conservative.

Response: First, we note that no mortality or non-auditory injury from exposure to explosives was modeled for any species in the NWTT Study Area, so the post-modeling approach was not applied in relation to mortality. Regarding the reference to concerns about the killer whale mortality, the comment references vague and unsupported claims that the author of a news article received from interviewees questioning a NMFS report. NMFS is unaware of information supporting the claim that Navy sonar or explosive use has caused the death of a killer whale.

The consideration of marine mammal avoidance and mitigation effectiveness is integral to NMFS' and the Navy's overall analysis of impacts from sonar and explosive sources. NMFS has independently evaluated the method and agrees that it is appropriately applied to augment the model in the prediction and authorization of injury and mortality as described in the rule. Details of this analysis are provided in the Navy's 2018 technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing.* Detailed information on the mitigation analysis was included in the proposed rule, including information about the technical report, and NMFS disagrees with the commenters' suggestions that there was not enough information by which to evaluate the Navy's post-modeling calculations or that the methods are arbitrary or non-conservative.

Sound levels diminish quickly below levels that could cause PTS. Specifically, behavioral response literature, including the recent 3S studies (multiple controlled sonar exposure experiments on cetaceans in Norwegian waters) and SOCAL BRS studies (multiple cetacean behavioral response studies in Southern California), indicate that multiple species from different cetacean suborders do in fact avoid approaching sound sources by a few hundred meters or more, which would reduce received sound levels for individual marine mammals to levels below those that could cause PTS (see Appendix B of the *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles*

Technical Report (U.S. Department of the Navy, 2017) and Southall *et al.* (2019a)). The ranges to PTS for most marine mammal groups are within a few tens of meters and the ranges for the most sensitive group, the HF cetaceans, average about 200 m, to a maximum of 330 m in limited cases. For blue whales and other LF cetaceans, the range to PTS is 67 m for MF1 30 sec duration exposure, which is well within the mitigation zones for hull-mounted MFAS. Therefore, the anticipated avoidance to the distances discussed would greatly reduce the likelihood of impacts to hearing such as TTS and PTS. As discussed in the proposed rule, this final rule, and the Navy's report, animats in the Navy's acoustic effects model do not move horizontally or ''react'' to sound in any way. Accordingly, NMFS and the Navy's analysis appropriately applies a quantitative adjustment to the exposure results calculated by the model (which otherwise does not consider avoidance or mitigation).

As discussed in the Navy's report, the Navy's acoustic effects model does not consider procedural mitigations (*i.e.,* power-down or shut-down of sonars, or pausing explosive activities when animals are detected in specific zones adjacent to the source), which necessitates consideration of these factors in the Navy's overall acoustic analysis. Credit taken for mitigation effectiveness is extremely conservative. For example, if Lookouts can see the whole area, they get credit for it in the calculation; if they can see more than half the area, they get half credit; if they can see less than half the area, they get no credit. Not considering animal avoidance and mitigation effectiveness would lead to a great overestimate of injurious impacts. NMFS concurs with the analytical approach used, *i.e.,* we believe the estimated take by Level A harassment numbers represent the maximum number of these takes that are likely to occur and it would not be appropriate to authorize a higher number or consider a higher number in the negligible impact analysis.

The Navy assumes that Lookouts will not be 100 percent effective at detecting all individual marine mammals within the mitigation zones for each activity. This is due to the inherent limitations of observing marine species and because the likelihood of sighting individual animals is largely dependent on observation conditions (*e.g.,* time of day, sea state, mitigation zone size, observation platform) and animal behavior (*e.g.,* the amount of time an animal spends at the surface of the water). The Navy quantitatively assessed the effectiveness of its mitigation measures on a per-scenario basis for four factors: (1) Species sightability, (2) a Lookout's ability to observe the range to permanent threshold shift (for sonar and other transducers) and range to mortality (for explosives), (3) the portion of time when mitigation could potentially be conducted during periods of reduced daytime visibility (to include inclement weather and high sea-state) and the portion of time when mitigation could potentially be conducted at night, and (4) the ability for sound sources to be positively controlled (*e.g.,* powered down). The Navy's report clearly describes how these factors were considered, and it is not necessary to view the many tables of numbers generated in the assessment to evaluate the method. Further, this information is not readily available in a format that could be shared and it would take extensive work to provide the necessary description of this data.

The g(0) values used by the Navy for their mitigation effectiveness adjustments take into account the differences in sightability with sea state, and utilize averaged g(0) values for sea states of 1–4 and weighted as suggested by Barlow (2015). Using g(0) values is an appropriate and conservative approach (*i.e.,* it underestimates the protection afforded by the Navy's mitigation measures) for the reasons detailed in the technical report. For example, during line-transect surveys, there are typically two primary observers searching for animals. Each primary observer looks for marine species in the forward 90-degree quadrant on their side of the survey platform and scans the water from the vessel out to the limit of the available optics (*i.e.,* the horizon). Because Navy Lookouts focus their observations on established mitigation zones, their area of observation is typically much smaller than that observed during line-transect surveys. The mitigation zone size and distance to the observation platform varies by Navy activity. For example, during hull-mounted mid-frequency active sonar activities, the mitigation zone extends 1,000 yd from the ship hull. During the conduct of training and testing activities, there is typically at least one, if not numerous, support personnel involved in the activity (*e.g.,* range support personnel aboard a torpedo retrieval boat or support aircraft). In addition to the Lookout posted for the purpose of mitigation, these additional personnel observe for and disseminate marine species sighting information amongst the units participating in the activity whenever possible as they conduct their primary mission responsibilities. However, as a conservative approach to assigning mitigation effectiveness factors, the Navy elected to account only for the minimum number of required Lookouts used for each activity; therefore, the mitigation effectiveness factors may underestimate the likelihood that some marine mammals may be detected during activities that are supported by additional personnel who may also be observing the mitigation zone.

Although the Navy Acoustic Effects Model (NAEMO) predicted PTS takes from the NWTT activities, no mortality or non-auditory injuries were predicted by NAEMO. For all of the reasons above, NMFS considers the estimated and authorized take (that was adjusted for aversion and mitigation) appropriate, and that is what has been analyzed in the negligible impact analysis. Accordingly, we decline the commenter's recommendation to analyze and authorize the model-estimated PTS, as it is neither expected to occur nor authorized. Given that we have declined a re-evaluation based on the PTS numbers the commenter recommends, the suggestion that we would subsequently then assess whether additional mitigation were necessary to satisfy the negligible impact standard is inapplicable. However, we reiterate that even when the estimated take has been determined to have a negligible impact on the affected species or stocks, it is still necessary, as a separate matter, to identify measures that will effect the least practicable adverse impact on the affected species or stocks and their habitat and, as described elsewhere, we have done so for this rule.

Comment 16: A commenter stated that while the cause remains unknown, the skinniness and emaciation of stranded gray whales associated with the current UME strongly suggests a decline in prey availability. A previous die-off in 1998–2000 of gray whales was associated with strong El Niño and La Niña events and a regime shift in the benthic prey base of the Bering Sea. For the scientific community, the present-day concern is that warming seas—caused by climate change—are reducing primary productivity in the whales' northern foraging range and that vanishing sea ice is constricting populations of ice-associated amphipods. If so, the die-off may be a ''harbinger of things to come,'' in the words of one NOAA ecologist, a diminished, more tenuous future for the species rather than a one- or two-year anomaly.

The commenter states that it is well established that animals already exposed to one stressor may be less capable of responding successfully to another; and that stressors can combine to produce adverse synergistic effects. Here, disruption in gray whale behavior can act adversely with the inanition caused by lack of food, increasing the risk of stranding and lowering the risk of survival in compromised animals. Further, starving gray whales may travel into unexpected areas in search of food—a likely contributing cause of some of the ship-strikes observed in recently stranded animals. NMFS estimates that the Navy's activities will cause as many as 43 takes of gray whales each year, including 15 cases of temporary hearing loss caused by underwater explosives, indicating the potential for adverse interactions with nutritionally-stressed animals.

The commenter states that in considering the effects of acoustic exposure on gray whales, NMFS must carefully consider the biological context of behavioral disruption in that species and evaluate the potential for severe consequences—including the clear potential mortality, which, in violation of the MMPA, is not authorized in the proposed rule.

Response: This final rule includes 43 takes by Level B harassment of gray whales, less than one percent of the Eastern North Pacific stock, and no Level A harassment (PTS or non-auditory injury) of gray whales is anticipated or authorized. As discussed in the Analysis and Negligible Impact Determination section, the take by behavioral disturbance for any affected gray whale is expected to be at a moderate or low level and likely to occur on no more than one day within a year for any individual. Nonetheless, NMFS shares the commenter's concern for this stock given the UME and, as discussed in the Mitigation Measures section and elsewhere in this section, measures have been added since the proposed rule that are expected to further reduce the number and severity of the takes of gray whales. However, even if the impacts of the expected take was exacerbated by the compromised condition of a given individual, which could happen, there is no reason to expect that the level and severity of take anticipated to result from the Navy's activities would result in mortality as the commenter has suggested. Further, this gray whale stock is considered to be increasing.

Further, the commenter incorrectly states that NMFS did not include mortality of gray whales in the proposed rule. The proposed rule, and this final rule, include one mortality over the seven years covered by this rule, or 0.14 mortality annually, which has been analyzed in the context of its impacts on the stock in the Analysis and Negligible Impact Determination section. However, this mortality is associated with ship strike, not behavioral disturbance, and given the severity and magnitude of the authorized Level B harassment take reiterated above, the effects of the take would not accumulate to impact annual rates of recruitment or survival.

Comment 17: A commenter stated that by itself, NMFS' avoidance adjustment effectively reduces the number of estimated auditory injuries by 95 percent, on the assumption that marine mammals initially exposed to three or four sonar transmissions at levels below those expected to cause permanent injury would avoid injurious exposures. While it is certainly true that some marine mammals will flee the sound, there are no data to inform how many would do so, let alone that 95 percent would move as expeditiously as the agency presumes. Marine mammals may remain in important habitat, and the most vulnerable individuals may linger in an area, notwithstanding the risk of harm; marine mammals cannot necessarily predict where an exercise will travel; and Navy vessels engaged in certain activities may move more rapidly than a marine mammal that is attempting to evacuate. Some commenters suggested that NMFS should not adjust for avoidance.

Response: The consideration of marine mammals avoiding the area immediately around the sound source is provided in the Navy's 2018 technical report titled *Quantitative Analysis for Estimating Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles* and additional discussion is provided in NMFS' response to Comment 15. As the commenter correctly articulates: ''For avoidance, the Navy assumed that animals present beyond the range to onset PTS for the first three to four pings are assumed to avoid any additional exposures at levels that could cause PTS. That equated to approximately 5 percent of the total pings or 5 percent of the overall time active; therefore, 95 percent of marine mammals predicted to experience PTS due to sonar and other transducers were instead assumed to experience TTS.''

As discussed in the Navy report, animats in the Navy's acoustic effects model do not move horizontally or ''react'' to sound in any way, necessitating the additional step of considering animal avoidance of close-in PTS zones. NMFS independently reviewed this approach and concurs that it is fully supported by the best available science. Based on a growing body of behavioral response research, animals do in fact avoid the immediate area around sound sources to a distance of a few hundred meters or more depending upon the species. Avoidance to this distance greatly reduces the likelihood of impacts to hearing such as TTS and PTS, respectively. Specifically, the ranges to PTS for most marine mammal groups are within a few tens of meters and the ranges for the most sensitive group, the HF cetaceans, average about 200 m, to a maximum of 270 m in limited cases. NMFS continues to consider the adjustments for avoidance appropriate and declines the recommendation that the adjustment not be included in the estimation of take.

In regard to the comment about vessels moving faster than animals' ability to get out of the way, animals do not need to predict where an exercise will occur—in the vast majority of cases they can hear it coming. Further, the fact that vessels may move more rapidly than animals just makes it less likely that the animal would remain close enough to the source for the duration necessary to incur injury. NMFS and the Navy have appropriately considered animal movement in relation to testing and training activities and the commenter's observation does not necessitate any changes in our methods.

Comment 18: A commenter recommends that NMFS ensure that its density estimates and abundance estimates used in the negligible impact determination analyses for harbor seals in Hood Canal, Washington Northern Inland Waters, and Southern Puget Sound are consistent, and if more recent abundance estimates from Navy monitoring efforts were used to inform the negligible impact determination analyses, use those same abundances estimates to inform its density estimates and re-estimate the numbers of takes accordingly. If NMFS intends to use the ''instances of total takes as a percentage of the abundance'' in the final rule, the commenter recommends that it ensure that the abundance estimates, total takes, and instances of total takes as a percentage of the abundance are accurately stipulated for all three metrics in the relevant tables.

Response: NMFS has updated the abundance estimates for inland stocks of harbor seals using data from Jefferson *et al.* (2017) and Smultea *et al.* (2017) in this final rule and the same has been done in the 2020 NWTT FSEIS/OEIS. The Analysis and Negligible Impact Determination section reflects these latest abundance estimates and includes

a complete explanation for how they were calculated. The new information does not change the in-water density estimates, and therefore the number of takes did not change.

Comment 19: A commenter stated that as it has done for every Navy offshore range in its third round of MMPA authorizations, NMFS finds, notwithstanding a long record, that the Navy's use of active sonar would not result in a single instance of serious injury or mortality in any cetacean species. In doing so, the agency is at pains to dismiss the scientific literature. It spends almost five columns of the **Federal Register** notice characterizing the leading scientific explanation for sonar-related injuries in beaked whales—maladaptive behavioral response—as a mere ''hypothesis'' about which more information is needed. In this, it elides the obvious fact that this ''hypothesis'' is supported by numerous papers along multiple lines of evidence, including forensic investigations, laboratory study of organ tissue, and theoretical work on dive physiology, and plainly constitutes best available science. And it concludes by opining that, even if the ''hypothesis'' were true, pathologies would occur only upon exposure ''at very close range over a prolonged period of time,'' which, it says, would not happen here. It provides no evidence for this conclusion, which should not come as a surprise since it is contradicted by the agency's own investigations into at least two prior mass stranding events.

The commenter stated that there is no question that sonar causes mortalities of beaked whales and other species, and that the severe injuries observed in beaked whales across multiple sonar-related mortality events occur independent of the animals' stranding. The commenter stated that NMFS' refusal to incorporate such impacts into its rulemaking violates the MMPA, which requires that decisions be based on best available science and which, consistent with the 1994 Amendments to the Act, implicitly sets a probability standard of potentiality for takes resulting in serious injury and mortality.

In a related comment, another commenter stated that while the Navy is aware of this correlation between sonar testing and stranded marine mammals, they choose to ignore the data and proceed with ''hopeful'' predictions that estimate no incidences of mortality or serious injury, despite contrary evidence from past use of sonar testing. The commenter states that the documented history of sonar related injuries and death cannot be ignored.

Response: NMFS does not conclude that there is no possibility for mortality to occur as a result of the Navy's sonar activities, rather, we reason that consideration of all applicable information (the best available science) does not indicate that such mortality is reasonably likely to result from the Navy's activities within the seven-year span of the NWTT rule.

NMFS has acknowledged that it is possible for naval activities using hull-mounted tactical sonar to contribute to the death of marine mammals in certain circumstances via strandings resulting from behaviorally mediated physiological impacts or other gas-related injuries. In the proposed rule, NMFS discussed these potential causes and outlined the few cases where active naval sonar (in the United States or, largely, elsewhere) had either potentially contributed to or (as with the Bahamas example) been more definitively causally linked with marine mammal mass strandings (more than two animals). There have been no documented mass strandings of beaked whales in the NWTT Study area since stranding data began to be collected.

As discussed in the proposed rule and the Estimated Take of Marine Mammals section of this final rule, there are a suite of factors that have been associated with these specific cases of strandings directly associated with sonar (steep bathymetry, multiple hull-mounted platforms using sonar simultaneously, constricted channels, strong surface ducts, *etc.*) that are not present together in the NWTT Study Area and during the specified activities (and which the Navy takes care across the world not to operate under without additional monitoring). The number of incidences of strandings resulting from exposure to active sonar are few worldwide, there are no major training exercises utilizing multiple hull-mounted sonar in the NWTT Study Area, the overall amount of active sonar use is low relative to other Navy Study Areas, and there have not been any documented mass strandings of any cetacean species in the NWTT Study Area. Appropriately therefore, the Navy has not requested, and NMFS does not anticipate or authorize, incidental take by mortality of beaked whales or any other species as a result of sonar use.

Comment 20: Some commenters stated that the Navy Acoustic Effects Model (NAEMO) has limitations as it does not consider social factors, and this is likely to result in the model underestimating takes (*i.e.,* since Southern resident killer whales travel in groups, one whale ignoring noise while another avoids it would result in separation of individuals). Thus, either all whales would respond at the threshold for the most sensitive individual present, or stress rather than avoidance in some or most individuals would be the response. Another commenter suggested that NMFS does not consider calving cycles and migration in the analysis.

In a related comment, a commenter stated that first, not only do takes occur at far greater distances than predicted by the Navy's risk model, the fact that larger areas are exposed to a given received level with increasing distance from the source further multiplies the number of takes. This implies takes of specific individuals will be of greater duration and be repeated more often, resulting in unexpectedly large cumulative effects. Second, corrections need to be made for bias, and corrections will need to be larger for species for which there are no data than for species for which there are poor data. Third, the greater range at which takes would occur requires more careful consideration of habitat-specific risks and fundamentally different approaches to mitigation.

Response: The NAEMO brings together scenario simulations of the Navy's activities, sound propagation modeling, and marine mammal distribution (based on density and group size) by species or stock to model and quantify the exposure of marine mammals above identified thresholds for behavioral harassment, TTS, PTS, non-auditory injury, and mortality. It includes social factors (*e.g.,* group sizes) typical of the species modeled. The Southern Resident killer whale densities inherently consider group size over large areas. We expect that on many days, the Navy's impacts will not affect Southern Resident killer whales, while on days that Southern Resident killer whales are affected, multiple individuals may be impacted, given group size. That said, all Southern Resident killer whale takes are expected to be takes by Level B harassment (behavioral disturbance and TTS) only.

Regarding the commenter's assertion that NMFS and the Navy have mischaracterized either the size of the ensonified area or the number of animals that will be exposed, we disagree. As discussed in the technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing* (U.S. Department of the Navy, 2018) available at *www.nwtteis.com,* marine mammal density data are provided as a 10×10 km grid in which each cell has a mean density and

standard error. In the NAEMO, species densities are distributed into simulation areas. Sixty distributions that vary based on the standard deviation of the density estimates are run per season (warm and cool) for each species to account for statistical uncertainty in the density estimate. The NAEMO also uses accepted propagation models and incorporates extensive databases of physical environmental data to accurately predict acoustic propagation, as described in this same technical report. This includes modeling for potential impacts at distances far from a sound source. The energy from multiple exposures during an event (*e.g.,* multiple sonar pings) are accumulated to assess auditory impacts. Takes of individuals are accurately accounted for in the quantitative analysis as described in 2020 NWTT FSEIS/OEIS and the above supporting technical report.

The Navy compiled data from multiple sources and developed a protocol to select the best available density estimates based on species, area, and time (*i.e.,* season), including those for species with poor data. This process is described in the technical report titled *U.S. Navy Marine Species Density Database Phase III for the Northwest Training and Testing Study Area* (U.S. Department of the Navy, 2019), available at *www.nwtteis.com.*

The commenter notes ''larger areas are exposed to a given received level with increasing distance from the source further multiplies the number of takes,'' seeming to suggest that this means that the take estimates should be higher than they are. However, this comment does not account for the behavioral harassment thresholds used by NMFS and the Navy, which include both BRFs describing how a smaller portion of exposed animals respond in a manner that qualifies as a take at lower received levels, as well as distance cutoffs—both of which counter the assertion that large numbers of animals will be taken at increasing distances from the source.

Regarding the comment about mitigation, while there is no specific recommendation, we note that NMFS has worked with the Navy to carefully consider the risks and to develop a suite of mitigation measures to avoid or reduce potential impacts to species (such as the Southern Resident killer whale) and their habitat to the maximum extent practicable, including numerous new mitigation measures developed for the final rule.

All models have limitations, and there is no way to fully incorporate all of the interactions of the biotic and abiotic components of a living system into a model. However, the Navy and NMFS have used the best available science in the approach outlined for this rule, and appropriately incorporated consideration of marine mammal social dynamics, as well as the likely area of ensonification, in the model used in the estimation of take. Further, the Potential Effects of Specified Activities on Marine Mammals and their Habitat section in the proposed rule included a comprehensive discussion of the different ways that marine mammals have been observed to respond to acoustic stimuli (*e.g.,* separation) and NMFS used this information qualitatively in addition to the quantitative modeling results to evaluate the impacts of anticipated take on individuals and the species or stock in the Analysis and Negligible Impact Determination section. Also, where available, other information regarding biologically important areas and times was considered in the development of mitigation measures.

Comment 21: A commenter stated that the proposed rule did not incorporate the latest, most seasonally specific distribution and hotspot information for Southern Resident killer whales. In particular, the commenter asserted that NMFS does not specifically propose to use recent monitoring evidence from NOAA's hydrophone network in its analysis. While the Navy did propose to work with NMFS to determine the likelihood of gray whale and Southern Resident killer whale presence, the commenter asserted that NMFS does not require itself or the Navy to rely on NOAA's hydrophone network. This omission is of particular concern because NOAA's monitoring shows considerable temporal and spatial overlap between high-use testing areas for active sonar and explosives and high-use areas by Southern Resident killer whales off Washington's north coast.

Response: The Navy and NMFS used the best available science regarding distribution and hotspots of Southern Resident killer whales both in the density numbers that informed the take estimates, as well as in the consideration of mitigation. The data the commenter is noting, Emmons *et al.,* 2019 (which is Navy-funded work utilizing the referenced hydrophones) was considered in both this final rule and the 2020 NWTT FSEIS/OEIS. The commenter has suggested that the Cape Flattery Offshore region is a ''high use'' area for the Navy based on findings from Emmons *et al.* (2019) and suggests that the Navy consider moving activities away from the Cape Flattery area in the spring (April, May, and June) when Southern Resident killer whale detections are highest. The Navy has clarified that it does not frequently conduct training or testing activities in the location of the Cape Flattery Offshore hydrophone since that area is highly utilized by commercial vessel traffic, making it an undesirable location for the Navy to conduct activities, especially sonar training or testing. Emmons *et al.* (2019) reported a number of sonar detections at the Cape Flattery Offshore hydrophone, but this was not normalized for effort, which was also highest at the Cape Flattery Offshore hydrophone location, which could have the effect of overstating detections in that area. Further, Emmons *et al.* (2019) reported on detections of mid-frequency active sonar, but did not distinguish between various sources (U.S. versus Canadian navies, among other users). Historically, the annual usage of MF1 sonar by the U.S. Navy in the Olympic Coast National Marine Sanctuary (which overlaps with the Cape Flattery Offshore hydrophone) over the last 10 years has been minimal. As described in the Mitigation Measures section, NMFS and the Navy developed additional mitigation measures to further avoid or reduce potential impacts from the Navy's activities on Southern Resident killer whales and other marine species in key foraging, breeding, and migration habitat areas. For example, NMFS and the Navy have included a new mitigation area known as the Juan de Fuca Eddy Marine Species Mitigation Area, which encompasses waters off Cape Flattery as recommended by the commenter. The Navy's mitigation now includes annual limits on hull-mounted mid-frequency active sonar and prohibits explosive Mine Countermeasures and Neutralization Testing in the Juan de Fuca Eddy Marine Species Mitigation Area. All other explosive activities are required to be conducted 50 nmi from shore in the Marine Species Coastal Mitigation Area. In addition, NMFS and the Navy developed a new mitigation for the Navy to issue annual awareness notification messages to alert Navy ships and aircraft to the possible presence of increased concentrations of Southern Resident killer whales seasonally, which will further help avoid potential impacts from vessel movements and training and testing activities on this stock.

Comment 22: A commenter stated that Tables 19–31 fail to include effects from ASW2 mid-frequency sonar on marine mammals. Although it appears that such tests will only occur 12 or more nmi offshore, the distribution of Southern

Resident killer whales and many other cetaceans still have considerable potential overlap with that zone. The commenter stated that NMFS must require the Navy to provide a table showing the ranges to temporary and permanent threshold shifts for the ASW2 sonar bin and clarify the predicted effects on marine mammals before approving the use of such sonar/activities.

Response: The range to impact tables that the commenter references are provided for the most impactful activities, and ASW2 sonar is not one of the most impactful activities. The Navy has provided, and NMFS has presented, information on representative bins from the Navy's activities to demonstrate the ranges to impacts for marine mammals. The Navy is unable to provide information on ranges to impact for bins that are classified, including ASW2 sonar. The Navy has reviewed the scenarios and events associated with the ASW2 bin and there are zero estimated Southern Resident killer whale exposures. NMFS has carefully reviewed this information and the Navy's methods and concurs with this conclusion.

Mitigation and Monitoring

Least Practicable Adverse Impact Determination

Comment 23: A commenter recommends that NMFS clearly separate its application of the least practicable adverse impact requirement from its negligible impact determination. Once NMFS determines that an applicant's proposed activities would have a negligible impact, it still has a responsibility to determine whether the activities would nevertheless have adverse impacts on marine mammal species and stocks and their habitat. If so, NMFS must condition the authorization to eliminate or reduce those impacts whenever, and to the greatest extent, practicable. As the statue is written, it is inappropriate to conflate the two standards, as NMFS seems to be doing.

Response: NMFS has made clear in this and other rules that the agency separates its application of the least practicable adverse impact requirement in the Mitigation Measures section from its negligible impact analyses and determinations for each species or stock in a separate section. Further, NMFS has made this separation clear in practice for years by requiring mitigation measures to reduce impacts to marine mammal species and stocks and their habitat for all projects, even those for which the anticipated take would clearly have a negligible impact, even in the absence of mitigation.

Comment 24: A commenter recommends that NMFS follow an analysis consisting of three elements to (1) determine whether the impacts of the proposed activities are negligible at the species or stock level, (2) if so, determine whether some of those impacts nevertheless are adverse either to marine mammal species or stocks or to key marine mammal habitat, and (3) if so, determine whether it is practicable for the applicant to reduce or eliminate those impacts through modifying those activities or by other means (*e.g.,* requiring additional mitigation measures to be implemented).

Response: In the Mitigation Measures section of the rule, NMFS has explained in detail our interpretation of the least practicable adverse impact standard, the rationale for our interpretation, and then how we implement the standard. The method the agency is using addresses all of the necessary components of the standard and produces effective mitigation measures that result in the least practicable adverse impact on both the species or stocks and their habitat. The commenter has failed to illustrate why NMFS' approach is inadequate or why the commenter's proposed approach would be better, and we therefore decline to accept the recommendation.

Comment 25: A commenter recommended that NMFS rework its evaluation criteria for applying the least practicable adverse impact standard to separate the factors used to determine whether a potential impact on marine mammals or their habitat is adverse and whether possible mitigation measures would be effective.

Response: In the Mitigation Measures section, NMFS has explained in detail our interpretation and application of the least practicable adverse impact standard. The commenter has recommended an alternate way of interpreting and implementing the least practicable adverse impact standard, in which NMFS would consider the effectiveness of a measure in our evaluation of its practicability. The commenter erroneously asserts that NMFS currently considers the effectiveness of a measure in a determination of whether the potential effects of an activity are adverse, but the commenter has misunderstood NMFS' application of the standard—rather, NMFS appropriately considers the effectiveness of a measure in the evaluation of the degree to which a measure will reduce adverse impacts on marine mammal species or stocks and their habitat, as a less effective measure will less successfully reduce these impacts on marine mammals. Further, the commenter has not provided information that shows that their proposed approach would more successfully evaluate mitigation under the LPAI standard, and we decline to accept it.

Comment 26: A commenter stated that although NMFS has written extensively on the least practicable adverse impact standard, it remains unclear exactly how each authorization's proposed ''mitigation measures are sufficient to meet the statutory legal standard,'' or even what standard NMFS is using. As such, the commenter recommends that NMFS address these shortcomings by adopting a simple, two-step analysis that more closely tracks the statutory provisions being implemented. The first step should be to identify impacts on marine mammal species or stocks or their habitat that, although negligible, are nevertheless adverse. If such impacts are identified, then NMFS must identify and require the applicant to adopt measures to reduce those impacts to the lowest level practicable. If NMFS is using some other legal standard to implement the least practicable adverse impact requirements, the commenter further recommends that NMFS provide a clear and concise description of that standard and explain why it believes it to be ''sufficient'' to meet the statutory legal requirements.

Response: NMFS disagrees with the commenter's assertion that analysis of the rule's mitigation measures under the least practicable adverse impact standard remains unclear or that the suggested shortcomings exist. Further, the commenter provides no rationale as to why the two-step process they describe is better than the process that NMFS uses to evaluate the least practicable adverse impact that is described in the rule, and therefore we decline to accept the recommendation.

Comment 27: Regarding the habitat component of the least practicable adverse impact standard, a commenter recommended that NMFS (1) adopt a clear decision-making framework that recognizes the species and stock component and the marine mammal habitat component of the least practicable adverse impact provision and (2) always consider whether there are potentially adverse impacts on marine mammal habitat and whether it is practicable to minimize them. The MMPA requires that NMFS address both types of impacts, not that there be no overlap between the mitigation measures designed to reduce those impacts.

Response: NMFS' decision-making framework for applying the least practicable adverse impact standard clearly recognizes the habitat component of the provision (see the Mitigation Measures section of the rule). NMFS does always consider whether there are adverse impacts on habitat and how they can be mitigated. Marine mammal habitat value is informed by marine mammal presence and use and, in some cases, there may be overlap in measures for the species or stock directly and for use of habitat. In this rule, we have required time-area mitigation measures based on a combination of factors that include higher densities and observations of specific important behaviors of marine mammal species themselves, but also that clearly reflect preferred habitat (*e.g.,* feeding habitat in the Juan de Fuca Eddy Marine Species Mitigation Area and areas that have also been designated as Southern Resident killer whale critical habitat in the Puget Sound and Strait of Juan de Fuca Mitigation Area). In addition to being delineated based on physical features that drive habitat function (*e.g.,* bathymetric features), the high densities and concentration of certain important behaviors (*e.g.,* reproduction, feeding, resting) in these particular areas clearly indicate the presence of preferred habitat. The MMPA does not specify that effects to habitat must be mitigated in separate measures, and NMFS has clearly included measures that provide significant reduction of impacts to both marine mammal species or stocks and their habitat, as required by the statute.

Comment 28: A commenter cited two judicial decisions and commented that the ''least practicable adverse impact'' standard has not been met. The commenter stated that contrary to the *Pritzker* Court decision, NMFS, while clarifying that population-level impacts are mitigated ''through the application of mitigation measures that limit impacts to individual animals,'' has again set population-level impact as the basis for mitigation in the proposed rule. Because NMFS' mitigation analysis is opaque, it is not clear what practical effect this position may have on its rulemaking. The commenter stated that the proposed rule is also unclear in its application of the ''habitat'' emphasis in the MMPA's mitigation standard, and that while NMFS' analysis is opaque, its failure to incorporate or even, apparently, to consider viable time-area measures suggests that the agency has not addressed this aspect of the *Pritzker* decision. The commenter argued that the MMPA sets forth a ''stringent standard'' for mitigation that requires the agency to minimize impacts to the lowest practicable level, and that the agency must conduct its own analysis and clearly articulate it and not just parrot what the Navy says. The baselessness of this approach can be seen from the outcome of the *Conservation Council* decision, where the parties were able to reach a settlement agreement establishing time-area management measures, among other things, on the Navy's Southern California and Hawaii Range Complexes notwithstanding NMFS' finding, following the Navy, that all such management measures would substantially affect military readiness and were not practicable. Unfortunately, there is no indication in the proposed rule that NMFS has, as yet, done anything different here.

Another commenter stated that NMFS ''cannot just parrot what the Navy says'' with respect to analysis of the practicability of mitigation measures, in reference to the opinion in *Conservation Council for Hawaii* v. *Nat'l Marine Fisheries Serv.* The commenter asserts that in the proposed rule, NMFS has done little more than parrot the Navy's position on mitigation for actions in the NWTT Study Area, asserting an independent review of the Navy's assertions of impracticability but providing no substantiation of that review. The commenter states that even if NMFS did conduct such a review, NMFS failed to consider and implement additional mitigation measures that are both practicable and effective to reduce the adverse impacts to marine mammals in the NWTT Study Area.

The commenter stated that it commented on the NWTT DSEIS and the Navy's request for authorization that outlined specific mitigation measures the Navy could incorporate into its training and testing activities. More specifically, the commenter states that it suggested that NMFS consider seasonal closures based on Southern Resident killer whale presence, require additional mitigation in the Southern Resident killer whale offshore habitat area, use of real-time whale reporting, and additional mitigation measures regarding impulsive sound and sonar exposure. The commenter stated that NMFS did not assess or incorporate these practicable and effective mitigation measures.

Response: First, the commenter's reference to mitigation measures implemented pursuant to a prior settlement agreement is entirely inapplicable to a discussion of NMFS' responsibility to ensure the least practicable adverse impact under the MMPA. Specifically, for those areas that were previously covered under the 2015 settlement agreement for the HSTT Study Area, it is essential to understand that: (1) The measures were developed pursuant to negotiations with the plaintiffs and were specifically not selected and never evaluated based on an examination of the best available science that NMFS otherwise applies to a mitigation assessment and (2) the Navy's agreement to restrictions on its activities as part of a relatively short-term settlement (which did not extend beyond the expiration of the 2013 regulations) did not mean that those restrictions were practicable to implement over the longer term.

Regarding the remainder of the comments, NMFS disagrees with much of what the commenters assert. First, we have carefully explained our interpretation of the least practicable adverse impact standard and how it applies to both stocks and individuals, including in the context of the *Pritzker* decision, in the Mitigation Measures section. Further, we have applied the standard correctly in this rule in requiring measures that reduce impacts to individual marine mammals in a manner that reduces the probability and/or severity of population-level impacts.

When a suggested or recommended mitigation measure that would reduce impacts is not practicable, NMFS has explored variations of that mitigation to determine if a practicable form of related mitigation exists. This is clearly illustrated in NMFS' independent mitigation analysis process explained in the Mitigation Measures section of the final rule. First, some types of mitigation required under this rule are area-specific and vary by mitigation area, demonstrating that NMFS has engaged in a site-specific analysis to ensure mitigation is tailored when practicability demands, *i.e.,* some forms of mitigation were practicable in some areas but not others. For instance, while it was not practicable for the Navy to prohibit surface ship hull-mounted MF1 mid-frequency active sonar during training or testing in all mitigation areas, NMFS did prohibit its use during all training and testing in the Point St. George Humpback Whale Mitigation Area, effective July 1 to November 30, and included caps on MF1 sonar use in the Olympic Coast National Marine Sanctuary Mitigation Area, the Juan de Fuca Eddy Marine Species Mitigation Area, and in the Marine Species Coastal Mitigation Area.

Regarding the comment about mitigation of habitat impacts, marine mammal habitat value is informed by

marine mammal presence and use and, in some cases, there may be overlap in measures for the species or stock directly and for use of habitat. In this rule, we have required time-area mitigations based on a combination of factors that include higher densities and observations of specific important behaviors of marine mammals themselves, but also that clearly reflect preferred habitat (*e.g.,* humpback whale feeding habitat in the Stonewall and Heceta Bank Humpback Whale Mitigation Area and gray whale feeding habitat in Northern Puget Sound Gray Whale Mitigation Area). In addition to being delineated based on physical features that drive habitat function (*e.g.,* bathymetric features), the high densities and concentration of certain important behaviors (*e.g.,* breeding, resting) in these particular areas clearly indicate the presence of preferred habitat. The commenter seems to suggest that NMFS must always consider separate measures aimed at marine mammal habitat; however, the MMPA does not specify that effects to habitat must be mitigated in separate measures, and NMFS has clearly identified measures that provide significant reduction of impacts to both ''marine mammal species and stocks and their habitat,'' as required by the statute.

NMFS agrees, however, that the agency must conduct its own analysis, which it has done here, and not just accept what is provided by the Navy. That does not mean, however, that NMFS cannot review the Navy's analysis of effectiveness and practicability of its proposed mitigation measures, which by regulation the Navy was required to submit with its application, and concur with those aspects of the Navy's analysis with which NMFS agrees. The commenters seem to suggest that NMFS must describe in the rule in detail the rationale for not adopting every conceivable permutation of mitigation, which is neither reasonable nor required by the MMPA. NMFS has described our well-reasoned process for identifying the measures needed to meet the least practicable adverse impact standard in the Mitigation Measures section in this rule, and we have followed the approach described there when analyzing potential mitigation for the Navy's activities in the NWTT Study Area. Responses to specific recommendations for mitigation measures provided by the commenters are discussed separately.

Regarding the commenter's statement that it commented on the NWTT DSEIS and the Navy's request for authorization with specific mitigation measures the Navy could incorporate into its training and testing activities, as noted above this final rule includes numerous additional mitigation measures, which are also included in the 2020 NWTT FSEIS/OEIS. For example, this final rule includes a new mitigation area in the NWTT Offshore Area, the Juan de Fuca Eddy Marine Species Mitigation Area, where the Navy will implement sonar restrictions and prohibit explosive mine countermeasure and neutralization activities to further avoid potential impacts on Southern Resident killer whales and humpback whales. In NWTT Inland Waters, the Navy will initiate communication with the appropriate marine mammal detection networks prior to certain activities, such as Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises and Small Boat Attack Exercises, to further avoid potential impacts on Southern Resident killer whales and gray whales.

Comment 29: A commenter stated that since NMFS has expounded on the least practicable adverse impact standard at some length in a series of proposed authorizations, it has been an evolutionary process that varies depending on each specific situation. The commenter recommends that NMFS adopt general regulations to govern the process and set forth the basic steps and criteria that apply across least practicable adverse impact determinations. Those standards should not be shifting on a case by-case basis, as now appears to be the case. Rather, the analytical framework and decision-making standards should be consistent across authorizations. Variations between authorizations should be based on the facts underlying each application, not the criteria that underpin the least practicable adverse impact standard.

Response: The commenter misunderstands the agency's process. Neither the least practicable adverse impact standard nor NMFS' process for evaluating it shifts on a case-by-case basis. Rather, as the commenter suggests should be the case, the evaluation itself is case-specific to the proposed activity, the predicted impacts, and the mitigation under consideration.

Regarding the recommendation to adopt general regulations, we appreciate the recommendation and may consider the recommended approach in the future. However, providing directly relevant explanations of programmatic approaches or interpretations related to the incidental take provisions of the MMPA in a proposed incidental take authorization is an effective and efficient way to provide information to and solicit focused input from the public. Further, this approach affords the same opportunities for public comment as a stand-alone rulemaking would.

Comment 30: A commenter stated that the Navy fails to establish that its harassment is the least practicable method to conduct its research. The commenter states that the MMPA mandates a finding that the planned activities ''. . . effect the least practicable impact on such species or stock and its habitat. . . .'' The commenter asserted that the Level A and Level B harassment that the Navy predicts will occur includes heavy use of sonar technology that has been correlated with the deaths and strandings of thousands of whales and dolphins during the past 20 years. The commenter further stated that the Navy fails to address how its proposed activities lessen the threat of injury and death. Akin to its failure to address population and abundance, the commenter says that the Navy fails to consider how decisions involving geography, timing, and other factors might lessen the ill effects of its actions.

Response: NMFS' application of the least practicable adverse impact standard is described in the *Implementation of Least Practicable Adverse Impact Standard* section of this final rule. This final rule requires the Navy to implement extensive mitigation measures to achieve the least practicable adverse impacts on the species and stocks of marine mammals and their habitat, including measures that are specific to certain times and areas as the commenter suggests, and including additional measures that have been added since the proposed rule. Mitigation measures include procedural mitigation measures, such as required shutdowns and delays of activities if marine mammals are sighted within certain distances, and geographic area mitigation measures, including limitations on activities such as sonar in areas that are important for certain behaviors such as feeding. These mitigation measures were designed to lessen the frequency and severity of impacts from the Navy's activities on marine mammals and their habitat, and ensure that the Navy's activities have the least practicable adverse impact on species and stocks. See the Mitigation Measures section of this final rule for additional detail on specific procedural mitigation measures and measures in mitigation areas.

Additionally, we disagree with the implications of the commenter's statement regarding ''the strandings of thousands of whales and dolphins''

being associated with the use of sonar. Please see the *Stranding and Mortality* section in the proposed rule for an accurate characterization of the far lower number of instances in which naval activities have been causally associated with marine mammal strandings. That section included an extensive discussion assessing the potential for Navy activities to result in stranding, and NMFS' response to Comment 19 describes why we do not expect the Navy's NWTT activities to result in the stranding or death of marine mammals from sonar use.

Mitigation Areas

Comment 31: A commenter recommended that NMFS expand the proposed mitigation measures to more comprehensively protect humpback whales at Stonewall and Heceta Bank between May and November. The commenter recommended that air-deployed mid-frequency active sonar (*i.e.,* dipping sonar) should be prohibited, as well as other activities involving sources of mid-frequency active sonar, including unit-level training and maintenance and system checks while vessels are in transit. The commenter states that expanded mitigation measures would benefit a variety of species, including noise-sensitive harbor porpoise, that are likely to be found in relatively higher densities within the Mitigation Area. The commenter recommended that NMFS also include mitigation measures that limit vessel speeds to reduce the likelihood of vessel strike.

Response: This final rule prohibits the Navy from conducting surface ship hull-mounted MF1 mid-frequency active sonar during training or testing activities in the Stonewall and Heceta Bank Humpback Whale Mitigation Area (effective May 1 to November 30), as included in the proposed rule. Additionally, this final rule includes new mitigation which prohibits the Navy from conducting more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area (which includes a portion of the Stonewall and Heceta Bank Humpback Whale Mitigation Area), the Juan de Fuca Eddy Marine Species Mitigation Area, and the Olympic Coast National Marine Sanctuary Mitigation Area combined. This measure is effective year round. Previously the proposed rule restricted the Navy to 33 hours of MF1 sonar annually within only the Olympic Coast National Marine Sanctuary Mitigation Area (excluding the portion of the mitigation area that overlapped the Quinault Range Site).

Additionally, regarding the use of dipping sonar, throughout the NWTT Study Area the Navy plans to conduct no more than one hour of MF4 sonar (helicopter-deployed dipping sonar) per year during training events over the seven-year duration of this final rule. Additionally, the Navy plans to conduct no more than 50 hours of MF4 sonar per year during testing events over the seven-year duration of this rule. Given the amount of dipping sonar and comparatively low associated impacts to marine mammals, along with the impracticability of including more restrictions, additional mitigation specific to dipping sonar is not warranted.

Additional geographic mitigation measures for active sonar beyond what is detailed in the *Mitigation Areas* section of this final rule and Section K.3 (Mitigation Areas to be Implemented) of the 2020 NWTT FSEIS/OEIS, such as prohibiting additional types of active sonar or further limiting active sonar hours in the Stonewall and Heceta Bank Humpback Whale Mitigation Area, would be impractical to implement for the reasons described in Appendix K (Geographic Mitigation Assessment) and Section 5.5.1 (Active Sonar) of the 2020 NWTT FSEIS/OEIS. NMFS has carefully reviewed this information and determined that additional mitigation measures would be impracticable.

Potential vessel speed restrictions in the NWTT Study Area are addressed in our response to Comment 38. Please refer to that comment for our full response.

Comment 32: A commenter stated that NMFS should expand the proposed mitigation measures to more comprehensively protect humpback whales at Point St. George Humpback Whale Mitigation Area between July and November. The commenter asserted that within the area the agency should prohibit air-deployed mid-frequency active sonar (*i.e.,* dipping sonar), as well as other activities involving sources of mid-frequency active sonar, including unit-level training and maintenance and system checks while vessels are in transit. NMFS should also include mitigation measures that limit vessel speeds to reduce the likelihood of vessel strike.

Response: This final rule includes new mitigation limiting the Navy to a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, the Juan de Fuca Eddy Marine Species Mitigation Area, and the Olympic Coast National Marine Sanctuary Mitigation Area combined. The expanded mitigation will offer additional protections for humpback whales in the portion of the Marine Species Coastal Mitigation Area that overlaps the Point St. George Humpback Whale Mitigation Area. Additional geographic mitigation measures for active sonar beyond what is detailed in the *Mitigation Areas* section of this final rule and Section K.3 (Mitigation Areas to be Implemented) of the 2020 NWTT FSEIS/OEIS, such as further expanding mitigation requirements in the Point St. George Humpback Whale Mitigation Area, would be impractical to implement for the reasons described in Appendix K (Geographic Mitigation Assessment) and Section 5.5.1 (Active Sonar) of the 2020 NWTT FSEIS/OEIS. NMFS has carefully reviewed this information and determined that additional mitigation measures would be impracticable.

Throughout the NWTT Study Area, the Navy plans to conduct no more than one hour of MF4 sonar (helicopter-deployed dipping sonar) per year during training events over the seven-year duration of this final rule. Additionally, the Navy plans to conduct no more than 50 hours of MF4 sonar per year during testing events over the seven-year duration of this rule. Please see the response to Comment 52 for additional information. Given the amount of dipping sonar and comparatively low associated impacts to marine mammals, along with the impracticability of including more restrictions, additional mitigation specific to dipping sonar is not warranted.

Potential vessel speed restrictions in the NWTT Study Area are addressed in our response to Comment 38. Please refer to that comment for our full response.

Comment 33: A commenter recommended that NMFS engage with the Navy in a more rigorous analysis of alternatives and mitigation options in the Puget Sound and Strait of Juan de Fuca Mitigation Area (year-round), with the aim of eliminating potential impacts on Southern Resident killer whales. The commenter recommended that NMFS (1) completely prohibit activity during periods of higher residency or occurrence of the population, viz., roughly May through October for the Salish Sea (another commenter recommended all year round) and roughly October through mid-February for the inland waters of Puget Sound (2) require noise isolation, particularly for activities such as pierside testing and maintenance that are concentrated in particular locations (3) set a transparent,

rigorous protocol for ensuring that Southern Resident killer whales will not be exposed to noise that can cause behavioral disruption, before an activity proceeds, including by using the region's existing real-time hydrophone networks and by establishing additional hydrophone sites in key areas as needed; and (4) consider measures to mitigate the impacts of the Navy's Growler overflights on Southern Resident killer whales and other marine species. The commenter stated that the mere assurance that Navy biologists will work with NMFS to determine the likelihood of species occurrence—a statement that does not imply use of any real-time detection systems—is plainly not sufficient. The commenter stated that NMFS should consider the likelihood of humpback whale presence in the planned training location, in addition to gray whales and Southern Residents, in prescribing mitigation. The commenter recommended that NMFS also include mitigation measures that limit vessel speeds in the area to reduce the likelihood of vessel strike. Another commenter noted that NMFS does not require the use of publicly available whale sighting data to reduce the chance of negative interactions between the Navy and marine mammals.

Response: The majority of locations in which training and testing activities occur within the NWTT Inland Waters do not overlap areas where Southern Resident killer whales occur. For instance, most training and testing occurs in the Hood Canal at Naval Base Kitsap Bangor and Dabob Bay Range, around Keyport, and Bremerton. None of these locations have had sightings of Southern Resident killer whales in over 20 years. The only locations with the potential to affect Southern Resident killer whales are training events conducted at Everett, in Crescent Harbor and which use Navy 3 OPAREA and Navy 7 OPAREA.

The *Mitigation Areas* section of this final rule and Section K.3.3. (Mitigation Areas for Marine Species in NWTT Inland Waters) of the 2020 NWTT FSEIS/OEIS include enhanced mitigation measures in NWTT Inland Waters for Southern Resident killer whales, gray whales, humpback whales, and other marine species. See the Changes from the Proposed Rule to the Final Rule and Mitigation Measures sections of this rule for a full discussion of these new measures. The new measures in the Puget Sound and Strait of Juan de Fuca Mitigation Area since publication of the proposed rule will result in training and testing activities being conducted in NWTT Inland Waters only when necessitated by mission-essential training or testing program requirements, as it would impracticable to ''completely prohibit'' all activity in the area. Furthermore, the Navy will implement additional mitigation measures for activities that are conducted in the mitigation area, such as seasonal awareness messages, communication with sighting information networks, limitations on the type and location of active sonar and explosive activities, and a prohibition on live fire activities. For example, NMFS and the Navy have formalized existing informal procedures already conducted for Navy biologists to initiate communication with the appropriate marine mammal detection networks in NWTT Inland Waters prior to conducting explosive mine neutralization activities involving the use of Navy divers, Unmanned Underwater Vehicle Training, Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises, and Small Boat Attack Exercises. This mitigation has also been expanded to include a greater number of activities in the inland waters, and will help the Navy plan activities in a way that minimizes the potential for exposure of Southern Resident killer whales and gray whales. Further, with implementation of the new mitigation measures included in this final rule, we do not anticipate any take of Southern Resident killer whales in NWTT Inland Waters due to NWTT training and testing activities.

Additionally, NMFS and the Navy have considered the impacts of Navy activities to all species in the development of mitigation areas, and the new mitigation in this area that reduces activity levels is likely to benefit other species such as humpback whales and gray whales. The commenter recommends ''noise isolation'' in relation to pierside training, but does not provide enough detail for NMFS to understand or address the issue. The mitigation as described in this final rule and the NWTT FSEIS/OEIS represents the maximum level of mitigation practical to implement, and any further mitigation in NWTT Inland Waters, such as mitigation for aircraft overflights, would be impracticable due to implications for safety, sustainability, and mission requirements for the reasons described in Chapter 5 (Mitigation) and Appendix K (Geographic Mitigation Assessment) of the 2020 NWTT FSEIS/OEIS. Further, NMFS does not anticipate, and has not authorized, take of marine mammals as a result of Growler or other overflights.

Regarding the suggestion that NMFS ensure that Southern Resident killer whales will not be exposed to noise that can cause behavioral disruption before an activity proceeds, including by using the region's existing real-time hydrophone networks and by establishing additional hydrophone sites in key areas as needed, please see NMFS' response to Comment 45 regarding the use of hydrophone networks in real-time mitigation. While it is not possible for the Navy to avoid all behavioral disruption of Southern Resident killer whales while also effectively carrying out their mission, the measures NMFS is requiring will ensure the least practicable adverse impact on Southern Resident killer whales and other species and stocks.

Potential vessel speed restrictions are addressed in the response to Comment 38. Please refer to that comment for our full response.

Comment 34: A commenter recommended that NMFS require the Navy to expand its mitigation measures to more comprehensively protect gray whales in the Northern Puget Sound Gray Whale Mitigation Area between March and May. The commenter stated that the Navy should not conduct any testing or training activities within the Mitigation Area from March through May. The commenter recommended that, in addition, NMFS should require mitigation measures that limit vessel speeds to reduce the likelihood of vessel strike.

Response: As described elsewhere in this Comments and Responses section, the *Mitigation Areas* section of this final rule and Section K.3.3 (Mitigation Areas for Marine Species in NWTT Inland Waters) of the 2020 NWTT FSEIS/OEIS discuss the enhanced mitigation measures in NWTT Inland Waters for gray whales as well as Southern Resident killer whales and other marine species. The Navy will implement additional geographic mitigation measures for activities that are conducted in the mitigation area, such as seasonal awareness messages for gray whales, limitations on the type and location of active sonar and explosive activities, and prohibition of live fire activities. The mitigation required from the Navy as described in this final rule and the 2020 NWTT FSEIS/OEIS represents the maximum level of mitigation practicable. Any further mitigation in NWTT Inland Waters, including entirely prohibiting training or testing activities within the Northern Puget Sound Gray Whale Mitigation Area between March and May, is

impracticable due to implications for safety, sustainability, and mission requirements for the reasons described in Chapter 5 (Mitigation) and Appendix K (Geographic Mitigation Assessment) of the 2020 NWTT FSEIS/OEIS.

Potential vessel speed restrictions are addressed in the response to Comment 38. Please refer to that comment for our full response.

Comment 35: A commenter recommended that the Navy conduct no training or testing activities with mid-frequency sonar within the vicinity of Grays Canyon, Guide Canyon, Willapa Canyon, Astoria Canyon, and Eel Canyon at any time of year to provide protection for deep-diving and/or noise-sensitive species, including endangered sperm whales and harbor porpoise. The commenter additionally recommended that the Navy observe the mitigation measures specified for the Marine Species Coastal Mitigation Area in these canyon areas, as appropriate.

Response: NMFS and the Navy assessed the practicability of implementing the commenter's additional mitigation recommendations. As described in Section K.3.2.2.2 (Operational Assessment) of the 2020 NWTT FSEIS/OEIS, training with active sonar in varying ocean floor topographies, such as near canyons, is essential to national security; therefore, additional restrictions on the use of active sonar near Quinault and in the vicinity of Grays, Guide, Willapa, Astoria, and Eel Canyons, are impracticable because such mitigation would preclude access to areas with the necessary environmental and oceanographic conditions that replicate military mission and combat conditions. Preventing access to critical training waterspace would have a significant impact on the ability of Navy units to meet their individual training and certification requirements (impacting the ability to deploy with the required level of readiness necessary to accomplish their missions), to certify forces to deploy to meet national security needs (limiting the flexibility of the Navy to project power, engage in multi-national operations, and conduct the full range of naval fighting capability in support of national security interests). NMFS concurs with the Navy's practicability assessment. While canyons can offer one form of valuable habitat for some species at certain times and a restriction on training and testing could potentially reduce the amount or severity of impacts to some degree for some species, given the protections offered by the procedural mitigation measures and the measures in other mitigation areas (including the measures added since the proposed rule), the high degree of impracticability described here supports the determination that this additional measure is not warranted, and therefore NMFS is not requiring the additional mitigation measures suggested by the commenter.

Comment 36: A commenter stated that NMFS should expand activity restrictions within the proposed Marine Species Coastal Mitigation Area to the greatest extent practicable. The commenter stated that NMFS should prohibit or at least significantly limit the use of mid-frequency active sonar from all sources, including dipping sonar (at least between December and June) within this Mitigation Area, at least out to the 200-meter isobath or 47 miles from shore; and, similarly, should further limit other activities, such as mine countermeasures and gunnery activities, that have the potential to result in species take. The commenter noted that the waters of greatest concern within the Mitigation Area extend between Cape Flattery, Washington, and Tillamook Head, Oregon, including the waters offshore of the Columbia River mouth, as these waters experience the highest relative habitat use for Southern Resident killer whales as indicated by presently available satellite telemetry data. These additional mitigation measures would also benefit other at-risk species, including the Central America and Mexico Distinct Population Segments of humpback whale.

Another commenter stated that NMFS should include temporal restrictions based on Southern Resident killer whale activity and to reflect the best available location data of marine mammals. The commenter stated that specifically, NMFS should consider limitations on the Navy's activities in the Marine Species Coastal Mitigation Area, which covers winter habitat areas for Southern Resident killer whales. The commenter stated that NMFS should limit naval activities, which have the capacity to harm Southern Resident killer whales, especially mid–frequency sonar, over the winter months in order to limit harm to this endangered species.

Response: This final rule includes extensive mitigation in the Marine Species Coastal Mitigation Area, including additional mitigation added since publication of the proposed rule. This final rule includes a new mitigation measure in this area which requires the Navy to issue seasonal awareness notification messages to alert Navy ships and aircraft operating within the mitigation area to the possible presence of increased concentrations of Southern Resident killer whales from December 1 to June 30, humpback whales from May 1 through December 31, and gray whales from May 1 to November 30. To assist in avoiding interactions with whales, the Navy will instruct vessels to remain vigilant to the presence of Southern Resident killer whales, humpback whales, and gray whales that may be vulnerable to vessel strikes or potential impacts from training and testing activities. Platforms will use the information from the awareness notification messages to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation. Additionally, as included in the proposed rule, the Navy will conduct a maximum of 32 hours of surface ship hull-mounted MF1 mid-frequency active sonar during training annually in the Olympic Coast National Marine Sanctuary Mitigation Area, which overlaps with the Marine Species Coastal Mitigation Area. The Navy will also implement annual restrictions on surface ship hull-mounted MF1 mid-frequency active sonar (no more than 33 hours total) during testing in three mitigation areas combined: The Marine Species Coastal Mitigation Area within 20 nmi from shore, the new Juan de Fuca Eddy Marine Species Mitigation Area, and the Olympic Coast National Marine Sanctuary Mitigation Area. The annual restriction for testing previously only applied to the Olympic Coast National Marine Sanctuary Mitigation Area. This final rule also removes an exception that excluded the Quinault Range Site from the annual sonar restrictions that was included in the proposed rule. Now, the annual restrictions will apply throughout the entire Olympic Coastal National Marine Sanctuary Mitigation Area, including within the portion of the mitigation area that overlaps the Quinault Range Site. This reduction in activities is in areas that are important for Southern Resident killer whale and humpback whale feeding and migration. The Navy does not generally schedule training and testing near Cape Flattery due to the high volume of commercial vessel traffic in that portion of the Study Area. Additional mitigation that was added since the proposed rule is discussed in the Mitigation Measures section. This new mitigation includes a new mitigation area, the Juan de Fuca Eddy Mitigation Area, which encompasses waters near Cape Flattery as the commenter recommended.

This final rule includes required procedural mitigation which is expected

to avoid or reduce potential impacts from active sonar on marine mammals wherever and whenever activities occur in the Study Area. Additionally, new procedural mitigation measures require the Navy to conduct Mine Countermeasure and Neutralization during daylight hours and in Beaufort sea state conditions of 3 or less, both of which increase the probability of marine mammal detection and, thereby, mitigation effectiveness. The Navy will also implement seasonal restrictions and distance-from-shore requirements for certain explosive bins, as described in detail in the *Mitigation Areas* section of this final rule. Additionally, the Navy will implement new annual and seven-year explosive ordnance limitations specific to explosive mine countermeasure and neutralization testing. These restrictions and limitations will further reduce impacts to marine mammals from explosives in nearshore and offshore habitats, including important feeding and migration areas for Southern Resident killer whales and humpback whales.

Additional geographic mitigation for active sonar beyond what is detailed in the *Mitigation Areas* section of this final rule, and in Section K.3 (Mitigation Areas to be Implemented) of the 2020 NWTT FSEIS/OEIS, would be impractical to implement for the reasons described in Appendix K (Geographic Mitigation Assessment) and Section 5.5.1 (Active Sonar) of the 2020 NWTT FSEIS/OEIS. NMFS has carefully reviewed this information and determined that additional mitigation measures would be impracticable.

The potential restriction of dipping sonar is discussed in the response to Comment 52. See that comment for our full response.

Comment 37: Commenters stated that additional mitigation measures are necessary and must be required, specifically additional mitigation and monitoring in Southern Resident killer whale offshore habitat. A commenter stated that this is necessary given the potential increased use of this area and the unique activities—such as active sonar—that take place in this portion of the NWTT range. A commenter stated that it is even more critical now that the offshore density numbers have been updated and have dramatically increased the anticipated incidents of level B harassment affecting Southern Resident killer whales. Approximately 92 percent of training impacts and 68 percent of testing impacts on killer whales are projected to occur in the offshore area.

Response: This final rule includes extensive mitigation designed to reduce impacts to Southern Resident killer whales, including mitigation in their offshore habitat, and new mitigation in this habitat since publication of the proposed rule. The Marine Species Coastal Mitigation Area, the Juan de Fuca Eddy Marine Species Mitigation Area, and the Olympic Coast National Marine Sanctuary Mitigation Area contain mitigation measures expected to reduce impacts to Southern Resident killer whales in their offshore habitat. Since the proposed rule, new mitigation measures have been added pertaining to the NWTT Offshore Area. One new measure requires the Navy to implement annual restrictions on surface ship hull-mounted MF1 mid-frequency active sonar (no more than 33 hours total) in three mitigation areas combined: Within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the new Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area. The annual restriction for testing previously only applied to the Olympic Coast National Marine Sanctuary Mitigation Area. This final rule also removes an exception that excluded the Quinault Range Site from the annual sonar restrictions that was included in the proposed rule. Now, the annual restrictions will apply throughout the entire Olympic Coastal National Marine Sanctuary Mitigation Area, including within the portion of the mitigation area that overlaps the Quinault Range Site. This reduction in activities is in areas that are important for Southern Resident killer whale and humpback whale feeding and migration. Additionally, the Navy will issue seasonal awareness notification messages within 50 nmi from shore to alert Navy ships and aircraft operating within the Marine Species Coastal Mitigation Area to the possible presence of increased concentrations of Southern Resident killer whales from December 1 to June 30, humpback whales from May 1 through December 31, and gray whales from May 1 to November 30. To assist in avoiding interactions with whales, the Navy will instruct vessels to remain vigilant to the presence of Southern Resident killer whales, humpback whales, and gray whales that may be vulnerable to vessel strikes or potential impacts from training and testing activities. Platforms will use the information from the awareness notification messages to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation. Please refer to the *Mitigation Areas* section of this final rule for additional information on the mitigation measures in the NWTT offshore waters.

Other Mitigation and Monitoring

Comment 38: A commenter stated that the proposed rule does not contain any indication that a practicability analysis was conducted, nor does it prescribe any speed reduction measure. The commenter states that this failure appears based on an unsupported finding that vessel noise generated by Navy vessels has de minimis or no impacts on Southern Resident killer whales and other marine mammals. Commenters recommended that NMFS require the Navy to engage in lowest practicable speed reductions in biologically important habitats to reduce noise, including in designated critical habitat for endangered Southern Resident killer whales and other biologically important habitat for vulnerable species. A commenter also stated that Washington State increased vessel regulations in 2019 to reduce noise and disturbance to Southern Resident killer whales from small vessels, including by enacting a 7-knot speed limit within half a nautical mile of the killer whales. The commenter also referenced the Vancouver Fraser Port Authority's Enhancing Cetacean Habitat and Observation (ECHO) Program which operates a voluntary slowdown of large ships transiting Southern Resident killer whale habitat and a lateral displacement trial to shift vessels away from high-use areas. The commenter recommended that the Navy implement similar measures for transiting vessels within the Salish Sea to reduce noise and disturbance in inland waters. Additionally, given that the speed of Navy ships during all aspects of their operations potentially impact marine mammals, the commenter recommended that NMFS require the Navy to collect and report data on ship speed as part of the rulemaking process. The commenter asserts that this will allow for objective evaluation by NMFS of ship-strike risk, of harassment resulting from vessel activity, and of the potential benefit of additional speed-focused mitigation measures. Finally, a commenter asserts that NMFS should require the Navy to take steps to quiet smaller support vessels used in the NWTT Study Area, by seeking and incorporating best commercial off-the-shelf technology for vessel retrofits and new builds.

Response: Generally speaking, it is impracticable (because of impacts to mission effectiveness) to further reduce ship speeds for Navy activities, and, moreover, given the maneuverability of

Navy ships at higher speeds and the presence of effective Lookouts, any further reduction in speed would be unlikely to reduce the already low probability of a ship strike. Navy ships generally operate at speeds in the range of 10–15 knots, and submarines generally operate at speeds in the range of 8–13 knots. Small craft (for purposes of this discussion, less than 40 ft), which are all support craft, have more variable speeds dependent on the mission. While these speeds are representative of most events, some vessels need to operate outside of these parameters under certain training and testing scenarios. The Navy is unable to impose a 7-knot ship speed limit because it would not be practical to implement and would impact the effectiveness of the Navy's activities by putting constraints on training, testing, and scheduling. The Navy requires flexibility in use of variable ship speeds for training, testing, operational, safety, and engineering qualification requirements. Navy ships typically use the lowest speed practical given individual mission needs. NMFS has reviewed the analysis of these additional suggested restrictions and the impacts they would have on military readiness and concurs with the Navy's assessment that they are impracticable (see section 5.3.4.1 *Vessel Movement* and section 5.5 *Measures Considered but Eliminated* in the 2020 NWTT FSEIS/OEIS). Therefore, the Navy is already planning to engage in the lowest practicable speed in biologically important habitats, including in designated critical habitat for endangered Southern Resident killer whales and other biologically important habitat for vulnerable species, as well as in all other areas.

The main driver for ship speed reduction is reducing the possibility and severity of ship strikes to large whales. However, even given the wide ranges of speeds from slow to fast that Navy ships must use to meet training and testing requirements, the Navy has a very low strike history to large whales in the NWTT Study Area. As further discussed in the *Estimated Take from Vessel Strikes by Serious Injury or Mortality* section, Navy vessel strike records have been kept since 1995, and since 1995 there have been two recorded strikes of whales by Navy vessels (or vessels being operated on behalf of the Navy) in the NWTT Study Area, one in 2012, and one in 2016. Neither strike was associated with training or testing activities.

As discussed in the 2015 NWTT FEIS/OEIS Section 5.1.2 (Vessel Safety), Navy standard operating procedures require that ships operated by or for the Navy have personnel assigned to stand watch at all times, day and night, when moving through the water (*i.e.,* when the vessel is underway). A primary duty of watch personnel is to ensure safety of the ship, which includes the requirement 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, a periscope, surfaced submarine, 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. As described in Section 5.3.4.1 (*Vessel Movement*) of the 2020 NWTT FSEIS/OEIS, Navy vessels are also required to operate in accordance with applicable navigation rules. Applicable rules include the Inland Navigation Rules (33 CFR part 83) and International Regulations for Preventing Collisions at Sea (72 Collision Regulations), which were formalized in the Convention on the International Regulations for Preventing Collisions at Sea, 1972. These rules require that vessels proceed at a safe speed so proper and effective action can be taken to avoid collision and so vessels can be stopped within a distance appropriate to the prevailing circumstances and conditions. In addition to standard operating procedures, the Navy implements mitigation to avoid vessel strikes, which includes requiring vessels to maneuver to maintain at least 500 yd away from whales, and 200 yd or 100 yd away from other marine mammals (depending on the size of the vessel). Additionally, please see the Estimated Take from Vessel Strikes by Serious Injury or Mortality section of this rule and section 3.4.2.4.1 of the 2020 NWTT FSEIS/OEIS for discussion regarding the differences between Navy ships and commercial ships which make Navy ships less likely to affect marine mammals.

When developing Phase III mitigation measures, the Navy analyzed the potential for implementing additional types of mitigation, such as vessel speed restrictions within the NWTT Study Area. The Navy determined that based on how the training and testing activities will be conducted within the NWTT Study Area, vessel speed restrictions would be incompatible with practicability criteria for safety, sustainability, and training and testing missions, as described in Chapter 5 (Mitigation), Section 5.3.4.1 (Vessel Movement) of the 2020 NWTT FSEIS/OEIS.

Regarding reporting of ship speed, as required through the Navy's Notification and Reporting Plan (Vessel Strike section), Navy vessels are required to report extensive information, including ship speed, pursuant to any marine mammal vessel strikes. Therefore, the data required for ship strike analysis discussed in the comment is already being collected. Any additional data collection requirement would create an unnecessary burden on the Navy. Regarding vessel noise from Navy ships, Navy vessels are intentionally designed to be quieter than civilian vessels, and given that adverse impacts from vessel noise are not anticipated to result from Navy activities (see the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section in the proposed rule), there is no anticipated harassment caused by vessel activity and therefore no need to collect and report data on ship speed for this purpose.

Regarding quieting small support vessels, most of the Navy's vessels already have state of the art quieting technologies employed to reduce their sound profile to assist them in avoiding detection by enemy forces, therefore, they are much quieter than commercial/recreational vessels of similar sizes.

Comment 39: A commenter stated that NMFS does not incorporate stand-off distances of any size within its requirements for the proposed mitigation areas, providing only that activities not take place ''within'' the defined areas. Thus, activities that are otherwise restricted or limited within a mitigation area could occur directly along the boundary and ensonify the area at levels capable of causing injury or increasing the risk or severity of behavioral disruption. The commenter asserts that stand-off distances are a reasonable mitigation measure that is routinely required by NMFS in authorizing take under the MMPA. The commenter recommended that NMFS consider establishing stand-off distances around its mitigation areas to the greatest extent practicable, allowing for variability in size given the location of the mitigation area, the type of operation at issue, and the species of concern.

Response: The mitigation areas included in the final rule and described in Appendix K (Geographic Mitigation Assessment) of the 2020 NWTT FSEIS/OEIS represent the maximum mitigation within mitigation areas and the maximum size of mitigation areas that are practicable for the Navy to implement under their specified activity. Implementing additional mitigation (*e.g.,* stand-off distances that

would extend the size of the mitigation areas) beyond what is included in the final rule is impracticable due to implications for safety, sustainability, and the Navy's ability to continue meeting its mission requirements. For example, as described in Section K.3.2.2.2 (Operational Assessment) of the 2020 NWTT FSEIS/OEIS, creating stand-off distances from the 12 nmi, 20 nmi, and 50 nmi limits within the Marine Species Coastal Mitigation Area would result in activities being conducted farther offshore. Moving activities farther offshore would be impractical due to decreased event realism, increased resource allocations and operational costs (due to extending the distance offshore and proximity to Navy support facilities, which would increase fuel consumption, maintenance, and time on station), increased safety risks (associated with conducting training and testing at extended distances offshore and farther away from critical medical and search and rescue resources), and accelerated fatigue-life of aircraft and ships (leading to increased safety risk and higher maintenance costs). Increased resource allocations and operational costs would serve as a limiting factor for Navy surface vessels whose available underway times are constrained by available manpower and fuel expenses. This would also reduce training or testing opportunities during a platform's limited available timeframes because increased time spent transiting to more distant training areas or test sites results in decreased time available for training or testing.

When practicable, NMFS sometimes recommends the inclusion of buffers around areas specifically delineated to contain certain important habitat or high densities of certain species, to allow for further reduced effects on specifically identified features/species. However, buffers are not typically considered necessary or appropriate in combination with more generalized and inclusive measures, such as coastal offsets or other areas that are intended to broadly contain important features for a multitude of species. In the case of this rulemaking, NMFS and the Navy have included an extensive array of broad protective areas that will reduce impacts on numerous species and habitats (including additions to what was described in the proposed rule) and, as described above, limitations in additional areas is not practicable.

Comment 40: A commenter noted that as with the consent order entered by the court in the *Conservation Council case,* the present proposed rule would allow the Navy to derogate from the measures associated with the mitigation areas where necessary for national security, if certain conditions are met. Specifically, authorization must be granted, the Navy must provide NMFS with advance notice of the derogation and with further information after the completion of events, and the Navy must provide information on those activities in its annual reports. Unlike the consent order, however, the proposed rule does not clearly restrict derogation authority to highest-level officers.

Under the consent order, authority could be invoked only by certain named officers representing the highest command authority, namely the Commander or Acting Commander of the Pacific Fleet, for training activities, and the Commander or Acting Commander of the various research branches for testing activities, and then only when the Navy ''deems it necessary for national defense.'' Similarly, at least some of the geographic areas adopted by the Navy in prior NEPA processes, such as the Humpback Whale Cautionary Area established in previous Hawaii-Southern California Training and Testing EISs, allowed for derogation only upon approval of the Pacific Fleet Commander. This requirement made it more likely that derogation decisions would be taken with the greatest seriousness and consideration. By contrast, the proposed rule is unclear in its designation, generally allowing units to obtain permission from ''the appropriate designated Command authority.'' NMFS should clarify that authorization may be given only by the highest-level Command authorities, consistent with the consent order in *Conservation Council.*

Response: The commenter references the terms of a 2015 settlement agreement approved by a court for a previous MMPA rulemaking for Navy activities in a different study area, none of which is applicable to the Navy's planned activities in this study area. In addition, as discussed in the response to Comment 28, the terms that were agreed to in that settlement agreement were never evaluated based on the best available science and under the two prongs that NMFS (and the Navy) apply to evaluate potential measures under the ''least practicable adverse impact'' standard.

For this rulemaking, NMFS along with the Navy considered the current conditions specific to the Navy's planned activities for the NWTT Study Area, the needs of the species and stocks along with their habitat, and the practicability of potential measures. As the commenter notes, for several of the measures in geographic mitigation areas the Navy may conduct an otherwise prohibited activity if necessary for national security, but only if Navy personnel have obtained permission from the appropriate designated Command authority prior to commencing the activity, provide NMFS with advance notification, and include information about the event in the annual activity reports to NMFS. It is not necessary to require permission from the highest-level Command authority to ensure that a valid national security need exists or that all other requirements of the provision will be complied with. The commenter has provided no information to indicate that the slightly different phrasing of the condition or that the differences in the level of Navy approval will lead to misapplication of the provision.

Comment 41: A commenter recommended that NMFS consider additional measures to address mitigation for explosive events at night and during periods of low-visibility, either by enhancing the observation platforms to include aerial and/or passive acoustic monitoring (such as glider use), as has been done here with sinking exercises, or by restricting events to particular Beaufort sea states (depending on likely species presence and practicability).

Response: This final rule includes new mitigation that requires the Navy to conduct explosive mine countermeasure and neutralization testing activities in daylight hours only and in Beaufort Sea state number 3 conditions or less. The Navy will also continue to implement mitigation that requires explosive mine neutralization training activities involving Navy divers to be conducted in Beaufort Sea state number 2 conditions or less and not in low visibility conditions. As described in Section 5.5.2 (Explosives) of the 2020 NWTT FSEIS/OEIS, when assessing and developing mitigation, NMFS and the Navy considered further restrictions on the use of explosives (*e.g.,* during periods of low visibility or in certain sea state conditions). The locations and timing of the training and testing activities that use explosives vary throughout the NWTT Study Area based on range scheduling, mission requirements, testing program requirements, and standard operating procedures for safety and mission success. Although activities using explosives typically occur during the daytime for safety reasons, it is impracticable for the Navy to prohibit every type of explosive activity at night or during low visibility conditions or during different Beaufort Sea states.

Doing so would diminish activity realism, which would impede the ability for Navy personnel to train and become proficient in using explosive weapons systems (which would result in a significant risk to personnel safety during military missions and combat operations), and would impede the Navy's ability to certify forces to deploy to meet national security needs.

Passive acoustic devices, whether vessel-deployed or using research sensors on gliders or other devices, can serve as queuing information that vocalizing marine mammals could be in the vicinity. Passive acoustic detection does not account for individuals not vocalizing. Navy surface ships train to localize submarines, not marine mammals. Some aviation assets deploying ordnance do not have concurrent passive acoustic sensors. Furthermore, Navy funded civilian passive acoustic sensors do not report in real-time. Instead, a glider is set on a certain path or floating/bottom-mounted sensor deployed. The sensor has to then be retrieved often many months after deployment (1–8 months), data is sent back to the laboratory, and then subsequently analyzed. Combined with lack of localization, gliders with passive acoustic sensors are therefore not suitable for mitigation.

The Navy does employ passive acoustic monitoring when practicable to do so (*i.e.,* when assets that have passive acoustic monitoring capabilities are already participating in the activity) and several of the procedural mitigation measures reflect this, but many platforms do not have passive acoustic monitoring capabilities. Adding a passive acoustic monitoring capability (either by adding a passive acoustic monitoring device (*e.g.,* hydrophone) to a platform already participating in the activity, or by adding a platform with integrated passive acoustic monitoring capabilities to the activity, such as a sonobuoy) for mitigation is not practicable. As discussed in Section 5.5.3 (Active and Passive Acoustic Monitoring Devices) of the 2020 NWTT FSEIS/OEIS, there are significant manpower and logistical constraints that make constructing and maintaining additional passive acoustic monitoring systems or platforms for each training and testing activity impracticable. The Navy is required to implement pre-event observation mitigation, as well as post-event observation when practical, for all in-water explosive events. If there are other platforms participating in these events and in the vicinity of the detonation area, they will also visually observe this area as part of the mitigation team.

The Mitigation Section (Chapter 5) of the 2020 NWTT FSEIS/OEIS includes a full discussion of the mitigation measures that the Navy will implement, as well as those that have been considered but eliminated, including potential measures that have been raised by NMFS or the public in the past. The Navy has explained that training and testing in both good visibility (*e.g.,* daylight, favorable weather conditions) and low visibility (*e.g.,* nighttime, inclement weather conditions) is vital because environmental differences between day and night and varying weather conditions affect sound propagation and the detection capabilities of sonar. Temperature layers that move up and down in the water column and ambient noise levels can vary significantly between night and day. This affects sound propagation and could affect how sonar systems function and are operated. While some small reduction in the probability or severity of impacts could result from the implementation of this measure, it would not be practicable for the Navy to restrict operations in low visibility and the measure is not, therefore, warranted.

Comment 42: A commenter recommended that sonar signals might be modified to reduce the level of impact at the source. Mitigating active sonar impacts might be achieved by employing down-sweeps with harmonics or by reducing the level of side bands (or harmonics). The commenter recommended that more research of this nature be carried out in order to understand the extent to which these results can be generalized across species. The commenter also recommended that the feasibility of implementing signal modifications (such as those recommended above) into Navy operations be explored.

Response: The commenter notes that NOAA's Ocean Noise Strategy Roadmap puts an emphasis on source modification and habitat modification as an important means for reducing impacts. However, where the modification of sources is discussed, the focus of the Roadmap is on modifying technologies for activities in which low frequency, broadband sound (which contributes far more significantly to increased chronic noise levels) is incidental to the activity (*e.g.,* maritime traffic). As described in the 2020 NWTT FSEIS/OEIS, at this time, the science on the differences in potential impacts of up or down sweeps of the sonar signal (*e.g.,* different behavioral reactions) is extremely limited and requires further development before a determination of potential mitigation effectiveness can be made. There is data on behavioral responses of a few captive harbor porpoises to varying signals. Although this very limited data set suggests that up or down sweeps of the sonar signal may result in different reactions by harbor porpoises in certain circumstances, the author of those studies highlights the fact that different species respond to signals with varying characteristics in a number of ways. In fact, the same signals cited here were also played to harbor seals, and their responses were different from the harbor porpoises. Furthermore, harmonics in a signal result from a high-intensity signal being detected in close proximity; they could be artificially removed for a captive study, but cannot be whitened in the open ocean. Active sonar signals are designed explicitly to provide optimum performance at detecting underwater objects (*e.g.,* submarines) in a variety of acoustic environments. If future studies indicate that modifying active sonar signals could be an effective mitigation approach, then NMFS with the Navy will investigate if and how the mitigation would affect the sonar's performance and how that mitigation may be applied in future authorizations, but currently NMFS does not have a set timeline for this research and how it may be applied to future rulemakings.

Comment 43: A commenter stated that while the Navy rejects modifying sonar sound sources as a mitigation measure, a decision that was summarily upheld by NMFS during its most recent proposed rule for Navy activities off Southern California and Hawaii, the Navy never explains why making the modifications implied by the marine mammal behavioral studies discussed Kastelein *et al.* (2012, 2014, 2015), Götz, T., and Janik (2011), and Hastie *et al.* (2014) would be impracticable. The commenter asserts that some of these modifications, such as converting up-sweeps to down-sweeps, would not alter the system's spectral output in any way. The commenter believes source modification requires greater validation across species and in more behavioral contexts before any decisions are made to alter signals, but given the preliminary data, and given the potential of this measure to reduce the instances and severity of behavioral harassment, the commenter recommended that NMFS require the Navy to expedite that research and set a timeline for this research within the context of the present rulemaking. The commenter asserted that the Navy's ongoing research off Southern California presents a strong opportunity for advancing mitigation research in this

area. The Navy's multi-year Southern California behavioral response studies provide baseline data and a vehicle for testing the effects of sonar modifications in the field. Research on modified signals can be incorporated into those ongoing behavioral response studies as a variant on exposure experiments on tagged animals, for which there already exists data on blue whales, fin whales, Cuvier's beaked whales, and other species.

Response: The Navy has explained that it explicitly designs its active sonar signals to provide optimum performance at detecting underwater objects (*e.g.,* submarines) in a variety of acoustic environments. The Navy assessed the potential for implementing active sonar signal modification as mitigation. At this time, the science on the differences in potential impacts of up or down sweeps of the sonar signal (*e.g.,* different behavioral reactions) is extremely limited and as noted by the commenter requires further development. For example, Kastelein *et al.* (2012) researched the behavioral responses of a single captive harbor porpoise to varying sonar signals. Although this very limited data set suggests up or down sweeps of the sonar signal may result in different reactions by harbor porpoises in certain circumstances, this science requires further development (*e.g.,* to determine potential reactions by other individual harbor porpoises and other marine mammal species). If future studies indicate that modifying active sonar signals (*i.e.,* up or down sweeps) could be an effective mitigation approach, then the Navy will investigate if and how the mitigation would affect the sonar's performance. As required by this final rule, the Navy will continue to implement robust monitoring and adaptive management, and NMFS and the Navy will consider the recommendations of the commenter, along with other needs, when developing and prioritizing future research and monitoring studies for the NWTT Study Area.

Comment 44: A commenter recommended that NMFS should consider requiring compensatory mitigation for the adverse impacts of the permitted activity on marine mammals and their habitat that cannot be prevented or mitigated.

Response: Compensatory mitigation is not required under the MMPA. Instead, authorizations must include means of effecting the least practicable adverse impact from the activities on the affected species or stocks and their habitat, which this rule has done through the required procedural and geographic area mitigation measures. Also, the commenter did not recommend any specific measures, rendering it impossible to consider its recommendation at a broader level.

Comment 45: A commenter stated that the mitigation zones required to mitigate the impact of the Navy's testing and training activities are based purely on animal sightings by vessel board Lookouts, and should any animals be underwater they could be easily missed.

Several commenters suggested that the Navy could use information from real-time whale alert systems, including NOAA's hydrophone network and data from the Whale Report Alert System (WRAS) used by the Washington State Ferries and other maritime professionals. A commenter stated that these additional, often-superior local sources of such time-sensitive information can help identify acoustically silent whales that have been sighted elsewhere that could be moving into training or testing areas. Another commenter stated that NMFS does not evaluate the possibility of using this data from either an effectiveness or practicability standpoint. Another commenter stated that this measure is indisputably both available and practical, per the factors that NMFS considers in its evaluation.

A commenter stated that this data is readily available and serves as a useful resource for the Navy to plan out its testing and training activities to reduce impacts to marine mammals. The commenter stated that in fact, it could even increase the effectiveness of the Navy's testing and training activities if it helps to reduce the number of delayed or canceled actions due to animal presence. The commenter recommended that NMFS amend its proposed authorization to require the Navy to utilize readily available whale location data as a form of mitigation.

A commenter stated that for mitigation for active sonar training and testing activities in Puget Sound, NMFS should require the Navy to consult regional real-time whale alert systems rather than relying solely on human observers on Navy vessels and communications with NMFS.

Response: NMFS acknowledges the fact that some animals in the mitigation zone could go unobserved by the Lookouts. We have taken that into consideration in the quantitative evaluation of mitigation effectiveness, and that is why some take by Level A harassment is authorized.

This final rule includes formalization of existing informal mitigation procedures already conducted by Navy biologists to initiate communication with the appropriate marine mammal detection networks in NWTT Inland Waters prior to conducting (1) explosive mine neutralization activities involving the use of Navy divers, (2) Unmanned Underwater Vehicle Training at four locations, (3) Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises, and (4) Small Boat Attack Exercises. This mitigation, which would increase real-time awareness of nearby cetaceans, increase the likelihood of detection, and enhance the success of procedural mitigations, has also been expanded to include a greater number of activities in the inland waters, and will help the Navy plan activities in a way that minimizes the potential for exposure of Southern Resident killer whales and gray whales, as described in the Mitigation Measures section of the rule and Section K.3.3 (Mitigation Areas for Marine Species in NWTT Inland Waters) of the 2020 NWTT FSEIS/OEIS.

The Navy also uses passive acoustic monitoring technology for some exercises. NMFS and the Navy considered the use of passive acoustic monitoring during additional exercises, but determined that it is not practicable. Please refer to Comment 47 for additional information about the implementation of passive acoustic monitoring.

NMFS is unaware of a hydrophone network, aside from some hydrophones NOAA has deployed for individual projects such as to research Southern Resident killer whales in offshore waters, a single noise reference station offshore the Strait of Juan de Fuca, and two to three assets in Olympic Coast National Marine Sanctuary. However, all of these hydrophone systems are bottom mounted passive acoustic monitoring devices with no real-time reporting capability, and therefore they cannot be used for real time assessment. There are other hydrophones deployed in NWTT Inland Waters by private individuals or entities (*i.e.* NGOs), but data availability and issues with the Navy accessing external sites remains an issue. The Navy will also continue to assess the practicality of other available monitoring techniques as technologies advance.

Additionally, a Navy team began participating in the Governor of Washington's Southern Resident Orca Task Force in 2019, including the Vessels Working Group. As part of the Vessels Working Group, the Navy began investigating potential mechanisms for broadcasting WRAS sightings of Southern Resident killer whales to Navy platforms conducting training or testing in the Inland Waters. The Navy has met

with the program developers of the WRAS to begin exploring potential applications for Navy use, considering factors such as the geographic extent of sighting reports as well as the Navy's stringent information security requirements (*e.g.,* associated with broadcasting unit location using an unsecured application). As the WRAS continues to expand into U.S. waters, NMFS and the Navy will continue to explore the opportunity to engage with this sightings network as a future mitigation tool. Any potential adoption of the system will be coordinated through the adaptive management provisions of this final rule.

Comment 46: A commenter recommended that NMFS should consider requiring the Navy to employ thermal detection in optimal conditions, or, alternatively, require the establishment of a pilot program for thermal detection, with annual review under the adaptive management system. According to the 2019 NWTT DSEIS/OEIS, the Navy ''plans to continue researching thermal detection technology to determine their effectiveness and compatibility with Navy applications.''

Response: Thermal detection systems are more useful for detecting marine mammals in some marine environments than others. Current technologies have limitations regarding water temperature and survey conditions (*e.g.,* rain, fog, sea state, glare, ambient brightness), for which further effectiveness studies are required. Thermal detection systems are generally thought to be most effective in cold environments, which have a large temperature differential between an animal's temperature and the environment. In addition, current thermal detection systems have proven more effective at detecting large whale blows than the bodies of small animals, particularly at a distance. The effectiveness of current technologies has not been demonstrated for small marine mammals. Research to better understand, and improve, thermal technology continues, as mentioned in the 2019 NWTT DSEIS/OEIS and described below.

The Navy has been investigating the use of thermal detection systems with automated marine mammal detection algorithms for future mitigation during training and testing, including on autonomous platforms. For example, the Defense Advanced Research Projects Agency funded six initial studies to test and evaluate infrared-based thermal detection technologies and algorithms to automatically detect marine mammals on an unmanned surface vehicle. Based on the outcome of these initial studies, the Navy is pursuing additional follow-on research efforts.

Thermal detection technology being researched by the Navy, which is largely based on existing foreign military grade hardware, is designed to allow observers and eventually automated software to detect the difference in temperature between a surfaced marine mammal (*i.e.,* the body or blow of a whale) and the environment (*i.e.,* the water and air). Technologies are advancing but continue to be limited by their (1) reduced performance in certain environmental conditions, (2) ability to detect certain animal characteristics and behaviors, (3) low sensor resolution and narrow fields of view, and (4) high cost and low lifecycle (Boebel, 2017; Zitterbart *et al.,* 2013).

Thermal detection systems for military applications are deployed on various Department of Defense (DoD) platforms. These systems were initially developed for night time targeting and object detection (*e.g.,* a boat, vehicle, or people). Existing specialized DoD infrared/thermal capabilities on Navy aircraft and surface ships are designed for fine-scale targeting. Viewing arcs of these thermal systems are narrow and focused on a target area. Furthermore, sensors are typically used only in select training events, not optimized for marine mammal detection, and have a limited lifespan before requiring expensive replacement. Some sensor elements can cost upward of $300,000 to $500,000 per device, so their use is predicated on a distinct military need.

Thermal detection systems are currently used by some specialized U.S. Air Force aircraft for marine mammal mitigation. These systems are specifically designed for and integrated into Air Force aircraft and cannot be added to Navy aircraft.

The effectiveness remains unknown in using certain DoD thermal systems for the detection of marine mammals without the addition of customized system-specific computer software to provide critical reliability (enhanced detection, cueing for an operator, reduced false positives, *etc.*).

Current DoD thermal sensors are not always optimized for marine mammal detections versus object detection, nor do these systems have the automated marine mammal detection algorithms the Navy is testing via its ongoing research program. The combination of thermal technology and automated algorithms are still undergoing demonstration and validation under Navy funding.

Thermal detection systems specifically for use in detecting marine mammals have been investigated by the Navy for more than a decade and are discussed in Section 5.5.4 of the 2020 NWTT FSEIS/OEIS. The effectiveness of even the most advanced thermal detection systems with technological designs specific to marine mammal surveys is highly dependent on environmental conditions, animal characteristics, and animal behaviors. At this time, thermal detection systems have not been proven to be more effective than, or equally effective as, traditional techniques currently employed by the Navy to observe for marine mammals (*i.e.,* naked-eye scanning, hand-held binoculars, high-powered binoculars mounted on a ship deck). The use of thermal detection systems instead of traditional techniques would compromise the Navy's ability to observe for marine mammals within its mitigation zones in the range of environmental conditions found throughout the NWTT Study Area. Focusing on thermal detection systems could also provide a distraction from and compromise the Navy's ability to implement its established observation and mitigation requirements. The mitigation measures discussed in the Mitigation Measures section include the maximum number of Lookouts the Navy can assign to each activity based on available manpower and resources; therefore, it would be impractical to add personnel to serve as additional Lookouts. For example, the Navy does not have available manpower to add Lookouts to use thermal detection systems in tandem with existing Lookouts who are using traditional observation techniques. Furthermore, high false positive rates of thermal detection systems could result in the Navy implementing mitigation for features incorrectly identified as marine mammals. Increasing the instances of mitigation implementation based on incorrectly identified features would have significant impacts on the ability for training and testing activities to accomplish their intended objectives, without providing any mitigation benefit to the species.

The Defense Advanced Research Projects Agency funded six initial studies to test and evaluate infrared-based thermal detection technologies and algorithms to automatically detect marine mammals on an unmanned surface vehicle. Based on the outcome of these initial studies, the Navy is pursuing additional follow-on research efforts. Additional studies are currently being planned for 2020+ but additional information on the exact timing and scope of these studies is not currently

available (still in the development stage).

The Office of Naval Research Marine Mammals and Biology program also funded a project (2018) to test the thermal limits of infrared-based automatic whale detection technology. That project focused on capturing whale spouts at two different locations featuring subtropical and tropical water temperatures, optimizing detector/classifier performance on the collected data, and testing system performance by comparing system detections with concurrent visual observations. Results indicated that thermal detection systems in subtropical and tropical waters can be a valuable addition to marine mammal surveys within a certain distance from the observation platform (*e.g.,* during seismic surveys, vessel movements), but have challenges associated with false positive detections of waves and birds (Boebel, 2017). While Zitterbart *et al.* (2020) reported on the results of land-based thermal imaging of passing whales, their conclusion was that thermal technology under the right conditions and from land can detect a whale within 3 km although there could also be lots of false positives, especially if there are birds, boats, and breaking waves at sea. Thermal detection systems exhibit varying degrees of false positive detections (*i.e.,* incorrect notifications) due in part to their low sensor resolution and reduced performance in certain environmental conditions. False positive detections may incorrectly identify other features (*e.g.,* birds, waves, boats) as marine mammals. In one study, a false positive rate approaching one incorrect notification per 4 min of observation was noted.

The Navy plans to continue researching thermal detection systems for marine mammal detection to determine their effectiveness and compatibility with Navy applications. If the technology matures to the state where thermal detection is determined to be an effective mitigation tool during training and testing, NMFS and the Navy will assess the practicability of using the technology during training and testing events and retrofitting the Navy's observation platforms with thermal detection devices. The assessment will include an evaluation of the budget and acquisition process (including costs associated with designing, building, installing, maintaining, and manning the equipment); logistical and physical considerations for device installment, repair, and replacement (*e.g.,* conducting engineering studies to ensure there is no electronic or power interference with existing shipboard systems); manpower and resource considerations for training personnel to effectively operate the equipment; and considerations of potential security and classification issues. New system integration on Navy assets can entail up to 5 to 10 years of effort to account for acquisition, engineering studies, and development and execution of systems training. The Navy will provide information to NMFS about the status and findings of Navy-funded thermal detection studies and any associated practicability assessments at the annual adaptive management meetings.

Evidence regarding the current state of this technology does not support the assertion that the addition of these devices would meaningfully increase detection of marine mammals beyond the current rate (especially given the narrow field of view of this equipment and the fact that a Lookout cannot use standard equipment when using the thermal detection equipment) and, further, modification of standard Navy equipment, training, and protocols would be required to integrate the use of any such new equipment, which would incur significant cost. At this time, requiring thermal equipment is not warranted given the prohibitive cost and the uncertain benefit (*i.e.,* reduction of impacts) to marine mammals. Likewise requiring the establishment of a pilot program is not appropriate. However, as noted above, the Navy continues to support research and technology development to improve this technology for potential future use.

Comment 47: Multiple commenters stated that the Navy should also use passive acoustic monitoring in addition to Lookouts to detect Southern Resident killer whales and other marine mammals when doing active sonar training and testing. This will further expand awareness beyond what can be accomplished with visual Lookouts. The Navy proposes to use passive acoustic monitoring to look for marine mammals when undertaking certain other activities (*e.g.,* explosive torpedoes), where passive acoustic assets are already part of an activity, but it does not include it as a mitigation measure for active sonar testing, which has the greatest anticipated impact on Southern Resident killer whales.

Another commenter recommended that NMFS require the Navy to use passive (*i.e.,* DIFAR and other types of sonobuoys) and active acoustic (*i.e.,* tactical sonars that are in use during the actual activity or other sources similar to fish-finding sonars) monitoring, whenever practicable, to supplement visual monitoring during the implementation of its mitigation measures for all activities that could cause injury or mortality beyond those explosive activities for which passive acoustic monitoring already was proposed—at the very least, sonobuoys deployed and active sources and hydrophones used during an activity should be monitored for marine mammals.

Response: The Navy does employ passive acoustic monitoring to supplement visual monitoring when practicable to do so (*i.e.,* when assets that have passive acoustic monitoring capabilities are already participating in the activity). We note, however, that sonobuoys have a narrow band that does not overlap with the vocalizations of all marine mammals, and there is no bearing or distance on detections based on the number and type of devices typically used; therefore it is not possible to use these to implement mitigation shutdown procedures. For explosive events in which there are no platforms participating that have passive acoustic monitoring capabilities, adding passive acoustic monitoring capability, either by adding a passive acoustic monitoring device (*e.g.,* hydrophone) to a platform already participating in the activity or by adding a platform with integrated passive acoustic monitoring capabilities to the activity (such as a sonobuoy), for mitigation is not practicable. As discussed in Section 5.5.3 (Active and Passive Acoustic Monitoring Devices) of the 2020 NWTT FSEIS/OEIS, which NMFS reviewed and concurs accurately assesses the practicability of utilizing additional passive or active acoustic systems for mitigation monitoring, there are significant manpower and logistical constraints that make constructing and maintaining additional passive acoustic monitoring systems or platforms for each training and testing activity impracticable. The Navy's existing passive acoustic monitoring devices (*e.g.,* sonobuoys) are designed, maintained, and allocated to specific training units or testing programs for specific mission-essential purposes. Reallocating these assets to different training units or testing programs for the purpose of monitoring for marine mammals would prevent the Navy from using its equipment for its intended mission-essential purpose. Additionally, diverting platforms that have passive acoustic monitoring capability would impact their ability to meet their Title 10 requirements and reduce the service life of those systems.

Regarding the use of instrumented ranges for real-time mitigation, the commenter is correct that the Navy

continues to develop the technology and capabilities on its Ranges for use in marine mammal monitoring, which can be effectively compared to operational information after the fact to gain information regarding marine mammal response. There is no calibrated hydrophone array present in the NWTT area that is similar to the instrumented range off Kauai in the Hawaiian Islands or the range off San Clemente Island, California where such marine mammal monitoring has occurred. Further, the Navy's instrumented ranges were not developed for the purpose of mitigation. The manpower and logistical complexity involved in detecting and localizing marine mammals in relation to multiple fast-moving sound source platforms in order to implement real-time mitigation is significant. Although the Navy is continuing to improve its capabilities to use range instrumentation to aid in the passive acoustic detection of marine mammals, at this time it is not effective or practicable for the Navy to monitor instrumented ranges for the purpose of real-time mitigation for the reasons discussed in Section 5.5.3 (Active and Passive Acoustic Monitoring Devices) of the 2020 NWTT FSEIS/OEIS.

Regarding the use of active sonar for mitigation, we note that during Surveillance Towed Array Sensor System low-frequency active sonar (which is not part of this rulemaking, and uses a high-powered low frequency source), the Navy uses a specially designed adjunct high-frequency marine mammal monitoring active sonar known as ''HF/M3'' to mitigate potential impacts. HF/M3 can only be towed at slow speeds (significantly slower than those used for ASW and the other training and testing uses contemplated for the NWTT activities) and operates like a fish finder used by commercial and recreational fishermen. Installing the HF/M3 adjunct system on the tactical sonar ships used during activities in this rule would have implications for safety and mission requirements due to impacts on speed and maneuverability. Furthermore, installing the system would significantly increase costs associated with designing, building, installing, maintaining, and manning the equipment. For these reasons, installation of the HF/M3 system or other adjunct marine mammal monitoring devices as mitigation under the rule would be wholly impracticable. Further, NMFS does not generally recommend the use of active sonar for mitigation, except in certain cases where there is a high likelihood of injury or mortality (*e.g.,* gear entanglement) and other mitigations are expected to be less effective in mitigating those effects. Active sonar generates additional noise with the potential to disrupt marine mammal behavior, and is operated continuously during the activity that it is intended to mitigate. On the whole, adding this additional stressor is not beneficial unless it is expected to offset, in consideration of other mitigations already being implemented, a high likelihood or amount of injury or mortality. For the Navy's NWTT activities, very few mortalities are authorized or anticipated, injury is of a small amount of low-level PTS, and the mitigation is expected to be effective at minimizing impacts. Further, the species most likely to incur a small degree of PTS from the Navy's activities are also the species with high frequency sensitivity that would be more likely to experience behavioral disturbance by the operation of the high frequency active source. For all of these reasons, NMFS does not recommend the use of active sonar to mitigate the Navy's training and testing activities in the NWTT Study Area.

Comment 48: A commenter recommended that NMFS require the Navy to (1) allocate additional resources to the Lookout effectiveness study, (2) consult with the University of St. Andrews to determine how much additional data are necessary to analyze the data in a statistically meaningful manner, and (3) develop a plan to maximize the number of sightings (*e.g.,* conducting cruises in Southern California rather than Hawaii) and complete the study as soon as possible.

Response: The Lookout effectiveness study referenced by the commenter is still ongoing. This type of study has never been conducted, is extremely complex to ensure data validity, requires a substantial amount of data to conduct meaningful statistical analysis, and the Navy is committed to completing it. As noted by the commenter, there has not been enough data collected to conduct a sufficient analysis; therefore, drawing conclusions on an incomplete data set is not scientifically valid.

However, NMFS has provided that the results of the Lookout effectiveness study will be made available by including a Term and Condition in the Endangered Species Act (ESA) Incidental Take Statements associated with this final rule and NMFS' 2020 final rule for Navy training and testing activities in the MITT Study Area, which requires the Navy to provide a report summarizing the status of and/or providing a final assessment on the Navy's Lookout Effectiveness Study following the end of Calendar Year (CY) 2021. The report must be submitted no later than 90 days after the end of CY2021. The report will provide a statistical assessment of the data available to date characterizing the effectiveness of Navy Lookouts relative to trained marine mammal observers for the purposes of implementing the mitigation measures.

Comment 49: A commenter recommended that NMFS (1) require the Navy to determine whether it would be practicable to implement the proposed revised Southern Resident killer whale critical habitat areas, as depicted in the associated proposed rule (50 CFR 226.206(d)) and that fall within the NWTT Study Area but are not proposed to be excluded for national security purposes in section 226.206(c) of the proposed rule, as a mitigation area(s) that limits MF sonar and explosive training and testing activities and (2) if it is practicable, include the areas as a mitigation area(s) in the final rule or, if it is not practicable, justify why the areas were not included as a mitigation area(s) in the preamble to the final rule. If the mitigation area(s) is included in the final rule, the commenter further recommends that NMFS expand the mitigation area(s) as necessary if new information is made available (*e.g.,* the proposed revised critical habitat is expanded in an associated final rule and the expanded area(s) overlaps the NWTT Study Area) during the timeframe under which the final rule would be valid. Another commenter also supported restricting activities in the proposed Southern Resident killer whale critical habitat.

Response: NMFS and the Navy worked collaboratively during the ESA consultation and MMPA authorization processes to determine the effectiveness and practicability of implementing additional mitigation measures for marine mammals, including Southern Resident killer whales. NMFS worked with the Navy to refine the mitigation area measures pertaining to the use of explosives during Mine Countermeasure and Neutralization Testing to be more protective of ESA-listed species, including within areas that overlap proposed Southern Resident killer whale and proposed humpback whale critical habitats. Also, the final rule includes a new additional mitigation area, the Juan de Fuca Eddy Marine Species Mitigation Area, which includes important migration habitat for Southern Resident killer whales as they transit between Inland Waters and the Offshore Area (see the *Mitigation Areas*

section of this final rule and Section K.3.2.1.3 (Southern Resident Killer Whale) of the 2020 NWTT FSEIS/OEIS). Further expanding geographic mitigation requirements to include additional mitigation for proposed ESA critical habitat beyond this would be impractical for the Navy to implement for the reasons described in Appendix K (Geographic Mitigation Assessment) of the 2020 NWTT FSEIS/OEIS. For example, such further mitigation would encroach upon the primary water space where those training and testing activities occur in the NWTT Offshore Area for safety, sustainability, and mission requirements.

Comment 50: A commenter recommended that NMFS (1) require the Navy to determine whether it would be practicable to implement both the Northern Washington Humpback Whale Feeding Area and the portion of the Northwest Washington Gray Whale Feeding Area that is within the NWTT offshore area as mitigation areas that limit MF sonar and explosive training and testing activities from May–November, consistent with the Humpback Whale Mitigation Areas proposed to be included and (2) if it is practicable, include the areas as mitigation areas in the final rule or, if it is not practicable, justify why the areas were not included as mitigation areas in the preamble to the final rule.

Response: The Northwest Washington Gray Whale Feeding Area is located entirely within 12 nmi from shore in the Marine Species Coastal Mitigation Area and entirely within the Olympic Coast National Marine Sanctuary Mitigation Area. Therefore, due to the overlapping nature of the Navy's mitigation areas, mitigation within 12 nmi, 20 nmi, and 50 nmi from shore in the Marine Species Coastal Mitigation Area and within the Olympic Coast National Marine Sanctuary Mitigation Area will be implemented throughout the Northwest Washington Gray Whale Feeding Area. Based on NMFS' mitigation requirements, the Navy will implement restrictions on the use of surface ship hull-mounted MF1 mid-frequency active sonar, will not use any explosives, and will not conduct Anti-Submarine Warfare Tracking Exercise—Helicopter,—Maritime Patrol Aircraft,—Ship, or—Submarine training activities or non-explosive Anti-Submarine Warfare Torpedo Exercise—Submarine training activities (which involve the use of mid-frequency or high-frequency active sonar) within this gray whale feeding area.

The Northern Washington Humpback Whale Feeding Area is located entirely within 50 nmi from shore, and partially within 20 nmi and 12 nmi from shore in the Marine Species Coastal Mitigation Area. In addition, 90 percent of this feeding area is located within the Olympic Coast National Marine Sanctuary Mitigation Area. Based on NMFS' mitigation requirements, the Navy will implement restrictions on the use of surface ship hull-mounted MF1 mid-frequency active sonar in a portion of this feeding area, will not use explosives during training or testing (except explosive Mine Countermeasure and Neutralization Testing, which could occur in the 10 percent of this feeding area located outside of the Sanctuary Mitigation Area), and will not conduct Anti-Submarine Warfare Tracking Exercise—Helicopter,—Maritime Patrol Aircraft,—Ship, or—Submarine training activities or non-explosive Anti-Submarine Warfare Torpedo Exercise—Submarine training activities (which involve the use of mid-frequency or high-frequency active sonar) within a portion of this humpback whale feeding area. Expanding geographic mitigation requirements (including developing additional mitigation for these humpback whale or gray whale feeding areas) is not practicable for the Navy to implement for the reasons described in Appendix K (Geographic Mitigation Assessment) of the 2020 NWTT FSEIS/OEIS. For example, such further mitigation would encroach upon the primary water space where those training and testing activities occur in the NWTT Offshore Area for safety, sustainability, and mission requirements.

Comment 51: Commenters highlighted the need for NMFS to review the Navy's plans to rapidly increase its use of emerging technologies, including the use of unmanned underwater systems in Puget Sound and off the Washington coastline and the use of sonar, high-energy lasers, payload systems, kinetic energy weapons, and biodegradable polymers. One commenter stated that the proposed rule did not include a detailed analysis of potential impacts from these activities, and recommended that NMFS thoroughly analyze the impacts of these emerging technologies on marine mammals and prescribe any necessary mitigation measures, including seasonal restrictions and monitoring of short- and long-term impacts and careful testing and monitoring of the impacts of new technologies, to ensure that the Navy's activities have the least practicable adverse impact on marine mammals.

Response: The analysis that the commenter has suggested is included in the Navy's rulemaking/LOA application, in the 2020 NWTT FSEIS/OEIS, and in the 2015 NWTT FEIS/OEIS. However, the effects conclusions and mitigation for emerging technologies are not broken out separately; they are included in the stressor-based analysis with other current technologies. NMFS has thoroughly reviewed and concurs with this analysis and it has been considered in the development of the final rule. NMFS and the Navy have coordinated extensively regarding which of the Navy's training and testing activities (including emerging technologies) are likely to result in the take of marine mammals. Some of the stressors the commenter noted were not identified as sources that would cause the incidental take of marine mammals, which is why they are not included in the Navy's MMPA application or discussed further in the rule. The commenter has offered no evidence showing that these emerging technologies (high energy lasers, kinetic energy weapons, or biodegradable polymers) would result in the incidental take of marine mammals.

NMFS and the Navy clearly have considered the impacts of unmanned vehicles, and mitigation measures specific to these systems have been included in the rule. Mitigation in the Puget Sound and Strait of Juan de Fuca Mitigation Area specifically includes a limit of one Unmanned Underwater Vehicle Training activity annually at the Navy 3 OPAREA, Navy 7 OPAREA, and Manchester Fuel Depot (*i.e.,* a maximum of one event at each location), and prohibits the use of low-frequency, mid-frequency, or high-frequency active sonar during training or testing within the Puget Sound and Strait of Juan de Fuca Mitigation Area, unless a required element necessitates that the activity be conducted in NWTT Inland Waters during Unmanned Underwater Vehicle Training, and other activities as described in the *Mitigation Areas* section of this final rule. Also, since publication of the proposed rule, an additional measure has been added that requires Navy event planners to coordinate with Navy biologists prior to conducting Unmanned Underwater Vehicle Training at the Navy 3 OPAREA, Manchester Fuel Depot, Crescent Harbor Explosive Ordnance Disposal Range, and Navy 7 OPAREA. In addition, Unmanned Underwater Vehicle Training events at the Navy 3 OPAREA, Manchester Fuel Depot, Crescent Harbor Explosive Ordnance Disposal Range, and Navy 7 OPAREA will be cancelled or moved to another training location if the presence of Southern Resident killer whales is reported through available monitoring networks during the event planning

process, or immediately prior to the event, as applicable. Additionally, since publication of the proposed rule, another additional measure has been added, limiting the Navy to conducting a maximum of one Unmanned Underwater Vehicle Training event within 12 nmi from shore at the Quinault Range Site, and requiring the Navy to cancel or move Unmanned Underwater Vehicle Training events if Southern Resident killer whales are detected within 12 nmi from shore at the Quinault Range Site. This measure is expected to help avoid any potential impacts on Southern Resident killer whales during Unmanned Underwater Vehicle Training events.

Comment 52: A commenter stated that dipping sonar, like hull-mounted sonar, has been shown to be a significant predictor of deep-dive rates in beaked whales. Evidence indicates that beaked whales dive deeper and stay at depth during exposure to mid-frequency active sonar (possibly to escape from the sound, as the lowest sound pressure levels occur at depth), behavior that also extends the inter-deep-dive-interval (''IDDI,'' a proxy for foraging disruption). IDDIs were found to significantly lengthen upon exposure to mid-frequency sonar, with the longest, lasting 541 and 641 minutes, recorded during helicopter-deployer sonar use at distances of about 17 and 11 km, respectively. These effects have been documented at substantially greater distances (about 30 km) than would otherwise be expected given the systems' source levels and the response thresholds developed from research on hull-mounted sonar. Deep-dive duration increases as distance to the helicopter decreases.

The commenter states that helicopters deploy mid-frequency active sonar from a hover in bouts generally lasting under 20 minutes, moving rapidly between sequential deployments in an unpredictable pattern. That unpredictability may well explain the comparatively strong response of whales to these exposures, even though their duration of use and source level (217 dB) are generally well below those of hull-mounted mid-frequency active sonar (235 dB). This finding is consistent with the wider stress literature, for which predictability is a significant factor in determining stress-response from acoustic and other stimuli (Wright *et al.,* 2007). It should thus be presumed conservatively to apply to marine mammal species other than beaked whales. Notably, dipping sonar is deployed at depth, which may be another reason why it is relatively more impactful.

The commenter states that NMFS has proposed authorizing take from as many as 41–50 annual testing events—amounting to 298 events across the seven-year authorization (as well as one training event across the seven-year period). The commenter states that NMFS must consider restricting or limiting use of dipping sonar during the present MMPA process.

Response: The commenter appears to have misinterpreted the number of dipping sonar hours during testing events with the number of dipping sonar testing events. The Navy plans to conduct a maximum of one hour of MF4 sonar (Helicopter-deployed dipping sonars) for training over the seven-year period of this rule, and 41–50 hours of MF4 sonar annually for testing (298 hours total over the seven-year period of this rule). The final rule does include mitigation for and some restrictions on mid-frequency active sonar, including dipping sonar. For example, as described in the proposed rule, mitigation requirements within 12 nmi from shore prohibit Anti-Submarine Warfare Tracking Exercise—Helicopter, Maritime Patrol Aircraft, Ship, or Submarine training activities (which involve mid-frequency active sonar, including MF4 dipping sonar). The mitigation zone sizes and mitigation requirements were developed specifically for each applicable training and testing activity category or stressor. These mitigation zones are the largest area that (1) Lookouts can reasonably be expected to observe during typical activity conditions (*i.e.,* most environmentally protective); and (2) can be implemented by the Navy without impacting safety, sustainability, or the ability to meet mission requirements. The mitigation measures included in this final rule represent the maximum level of mitigation that is practicable for the Navy to implement when balanced against impacts on safety, sustainability, and the ability of the Navy to continue meeting its mission requirements. Given the amount of dipping sonar and comparatively low associated impacts to marine mammals, along with the impracticability of including more restrictions, additional mitigation specific to dipping sonar is not warranted.

Comment 53: Commenters stated that the Navy needs to incorporate better techniques to improve their detection rates of marine mammals, extend their exclusion zones around detected marine mammals, and utilize exclusion zones based on specific areas and times in their mitigation strategies.

Response: The Navy uses active sonar during military readiness activities only when it is essential to training missions or testing program requirements since active sonar has the potential to alert opposing forces to the operating platform's presence. Passive sonar and other available sensors are used in concert with active sonar to the maximum extent practicable. The Navy, in coordination with NMFS, customized its mitigation zone sizes and mitigation requirements for each applicable training and testing activity category or stressor. Each mitigation zone represents the largest area that (1) Lookouts can reasonably be expected to observe during typical activity conditions (*i.e.,* most environmentally protective) and (2) the Navy can commit to implementing mitigation without impacting safety, sustainability, or the ability to meet mission requirements. The current exclusion zones represent the maximum distance practicable for the Navy to implement, as described in Chapter 5 of the FSEIS/OEIS and, further, they encompass the area in which any marine mammal would be expected to potentially be injured. This final rule includes procedural mitigation and mitigation areas to further avoid or reduce potential impacts from active sonar on marine mammals in areas where important behaviors such as feeding and migration occur. For example, this final rule requires the Navy to restrict certain activities or types of sonar year-round within 12 nmi from shore in the Marine Species Coastal Mitigation Area, seasonally within the Point St. George Humpback Whale Mitigation Area and Stonewall and Heceta Bank Humpback Whale Mitigation Area, and year-round in the Puget Sound and Strait of Juan de Fuca Mitigation Area to help avoid potential impacts from active sonar on marine mammals in important foraging and migration areas. Also, new mitigation requiring the Navy to only conduct explosive mine countermeasure and neutralization testing in daylight hours and in Beaufort Sea state number 3 conditions or less will increase the probability of detection of marine mammals and further increase the effectiveness of procedural mitigation zones. Additional information about the required mitigation is included in the Mitigation Measures section of this final rule, and in Appendix K (Geographic Mitigation Assessment) of the 2020 NWTT FSEIS/OEIS.

Comment 54: A commenter stated that other agencies and operators are taking new, meaningful steps to reduce noise and disturbance affecting Southern Resident killer whales. The commenter stated that the Navy must also increase

its protections, or it will become responsible for a larger share of the cumulative impact and potentially negate some of the benefits of the other actions being taken. In 2019, Washington state took big steps to reduce impacts on Southern Resident killer whales from other vessel types, recognizing that noise and disturbance have significant adverse consequences for this endangered population. In May of that year, Governor Inslee signed into law a bill that increases the distance that vessels must stay away from Southern Resident killer whales and enacts a 7-knot speed limit within a half nautical mile of these killer whales. The legislature also allocated funding for a new hybrid ferry and funding to convert some ferries to hybrid-electric power. Washington State Ferries also started conducting a baseline noise inventory and working to develop solutions to address noise and frequencies of concern. In 2020, the Washington Department of Fish and Wildlife is developing rules for a commercial whale-watching license program to reduce the daily and cumulative impacts of vessel noise and disturbance on the Southern Resident killer whales. Meanwhile, in 2020, voluntary ship slowdowns will continue and expand through the Vancouver Fraser Port Authority-led Enhancing Cetacean Habitat and Observation (ECHO) Program—a Canadian program that directly benefits Southern Resident orcas in the inland waters. In 2019, 82 percent of large commercial ships participated in the slowdown. The Navy's contributions will take up a larger share of the underwater noise and disturbance as others reduce their impacts and the Navy continues to scale its activities up. The Navy should increase its own mitigation efforts so that there is still a significant net benefit to the Southern Resident killer whales in terms of reduced noise and disturbance when all these other entities are increasing their protective measures.

Response: Please see the response to Comment 74 for more information regarding the low magnitude and severity of the anticipated impacts on Southern Resident killer whales. Also, of note, the standard operating procedures and mitigation the Navy uses to help avoid vessel strike would further help reduce exposure to vessel noise. Further, unlike commercial vessels, Navy vessel design generally incorporates quieting technologies in propulsion components, machinery, and the hull structure to reduce radiated acoustic energy. As a result, and in addition to comprising approximately one-tenth of one percent of total vessel traffic in Inland Waters, Navy vessels when present do not add significantly to ambient noise levels.

Nonetheless, the number and/or intensity of incidents of take of Southern Resident killer whales will be minimized through the incorporation of mitigation measures, and NMFS has added mitigation measures for marine mammals, including Southern Resident killer whales, in this final rule. New measures include additional procedural mitigation during explosive mine countermeasure and neutralization testing; a new Juan de Fuca Eddy Marine Species Mitigation Area; and additional mitigation in the Marine Species Coastal Mitigation Area and the Olympic Coast National Marine Sanctuary Mitigation Area (both offshore areas that overlap with proposed Southern Resident killer whale critical habitat), as well as in the Puget Sound and Strait of Juan de Fuca Mitigation Area. This new mitigation is expected to benefit Southern Resident killer whales, in some cases by limiting or prohibiting certain activities in certain areas during times in which Southern Resident killer whales engage in important behaviors such as feeding and migration, and in other cases, by augmenting the effectiveness of procedural mitigation measures by requiring seasonal awareness messages or limiting activities to lower sea states when visibility is higher. With implementation of the new mitigation measures included in this final rule, we do not anticipate any take of Southern Resident killer whales in NWTT Inland Waters due to NWTT training and testing activities. These new mitigation measures are described in detail in the Mitigation Measures section of this final rule.

These new measures, in combination with those included in the proposed rule, will reduce the severity of impacts to Southern Resident killer whales by reducing interference in feeding and migration that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good foraging opportunities or migration routes. Procedural mitigations that alleviate the likelihood of injury, such as shutdown measures, also further reduce the likelihood of more severe behavioral responses.

Additionally, the Navy has been a key contributor to marine species monitoring projects for a number of years to advance scientific knowledge of Southern Resident killer whales and the salmon they rely on. For decades, the Navy has implemented habitat improvement projects on its installations in Puget Sound that benefit Southern Resident killer whales.

Comment 55: A commenter stated that although the Navy proposes to use surface-level Lookout systems for whales, these Lookouts are inadequate because (1) the visual range of human Lookouts is limited and (2) historically one-quarter of Navy tests have occurred at night, further limiting visibility.

Response: NMFS acknowledges the limitations of Lookouts, does not assume that all marine mammals will be detected, and incorporates this information into its take estimates. Information about the quantitative analysis process, including the consideration of mitigation effectiveness, is described in detail in the 2018 technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing.* The Navy quantitatively assessed the effectiveness of its mitigation measures on a per-scenario basis for four factors: (1) Species sightability, (2) a Lookout's ability to observe the range to PTS (for sonar and other transducers) and range to mortality (for explosives), (3) the portion of time when mitigation could potentially be conducted during periods of reduced daytime visibility (to include inclement weather and high sea state) and the portion of time when mitigation could potentially be conducted at night, and (4) the ability for sound sources to be positively controlled (*e.g.,* powered down).

Appendix A (Navy Activities Descriptions) of the 2020 NWTT FSEIS/OEIS includes details on seasonality and day/night requirements of the Navy's activities. Additionally, this final rule includes mitigation which prohibits the Navy from conducting explosive Mine Countermeasure and Neutralization Testing at night, as described in the Mitigation Measures section of this final rule, and in Chapter 5 (Mitigation) of the 2020 NWTT FSEIS/OEIS. As described in Section 5.5.1 (Active Sonar) of the 2020 NWTT FSEIS/OEIS, the Navy has a requirement to conduct some active sonar training and testing at night due to environmental differences between day and night and varying weather conditions that affect sound propagation and the detection capabilities of sonar. Temperature layers that move up and down in the water column and ambient noise levels can vary significantly between night and day. This affects sound propagation and could affect how sonar systems function and are operated. Therefore, it is not practicable to prohibit all active sonar activities

from being conducted at night due to impacts on mission requirements; however, after sunset and prior to sunrise, Lookouts and other Navy watch personnel employ night visual search techniques, which could include the use of night vision devices, as described in Section 5.2.1 (Procedural Mitigation Development) of the 2020 NWTT FSEIS/OEIS. Please see the response to Comment 46 for discussion regarding use of thermal detection systems as a mitigation tool. Also, we note that visual mitigation is not the only tool; the Navy currently uses passive acoustic devices to the maximum extent practicable to aid in the detection of marine mammals.

Comment 56: Commenters suggested that NMFS require the Navy to use an alternative method of training that does not have such a negative impact on marine life, such as sophisticated simulators and virtual explosives.

Response: The Navy uses the necessary amounts of simulated and live training to accomplish their mission. As discussed in the 2015 NWTT Final EIS/OEIS Section 1.4.1 (Why the Navy Trains), simulators and synthetic training are critical elements that provide early skill repetition and enhance teamwork; however, they cannot replicate the complexity and stresses faced by Navy personnel during military missions and combat operations to which the Navy trains (*e.g.,* anti-submarine warfare training using hull-mounted mid-frequency active sonar). Just as a pilot would not be ready to fly solo after simulator training, operational Commanders cannot allow military personnel to engage in military missions and combat operations based merely on simulator training. In addition, as discussed in Section 2.4.1.5 (Simulated Training and Testing Only) of the 2020 NWTT FSEIS/OEIS, the Navy currently uses simulation whenever possible (*e.g.,* initial basic systems training, emergency procedures, and command and control exercises that are conducted without operational forces) and simulation plays a role in both antisubmarine warfare training and testing aboard ships, submarines, and aircraft and in aircrew training and testing.

Comment 57: Commenters recommended that NMFS require the Navy to postpone or cancel any exercises when Lookouts detect marine mammals, specifically killer whales, within 1,000 yd (914.4 m) of the exercise, rather than the smaller zones included in the proposed rule, to mitigate long-term effects of noise exposure over an animal's lifetime. The commenters note that this minimum distance aligns with Washington State law which requires most vessels to slow down to 7 knots when within 0.5 nmi (0.9 km) of Southern Resident killer whales in order to mitigate noise impacts and disturbance. Other commenters recommended that the Navy cease any active mid-frequency sonar testing and exercises if any killer whales are sighted within .5 nmi, rather than the proposed 200-yd or 100-yd shutdown mitigation zone which is much closer than even the 300-yd and 400-yd approach distance for commercial whale watch operators and recreational boaters. Additionally, commenters stated that the Navy's use of mid-frequency sonar can impact wildlife within 2,000 mi^2 (5180 km^2), much farther than the 100 yd (91.4 m) proposed for some of the Navy's proposed activities. The commenter stated that although these activities may affect a wide range of marine mammals, the potential impact of these activities on endangered Southern Resident killer whales is of particular concern, given their dangerously low population size.

Response: As described in the 2020 NWTT FSEIS/OEIS regarding shutdown requirements, the mitigation zone sizes and mitigation requirements in this rule are customized for each applicable training and testing activity category or stressor to protect specific biological resources from an auditory injury (PTS), non-auditory injury (from impulsive sources), or direct strike (*e.g.,* vessel strike) to the maximum extent practicable. Mitigation zones were developed to be the largest area that (1) Lookouts can reasonably be expected to observe during typical activity conditions (*i.e.,* most environmentally protective) and (2) the Navy can commit to implementing mitigation without impacting safety, sustainability, or the ability to meet mission requirements. NMFS has evaluated these recommendations for larger shutdown zones, and while larger shutdown zones might further reduce the potential or severity of the small amount of anticipated Level A harassment to some degree, we concur with the evaluation presented by the Navy indicating that increases in these zones are impracticable and have accordingly determined that larger shutdown zones are not warranted. The shutdown zones currently required for Navy activities, especially as coupled with other procedural mitigations and the required geographic mitigations, will effect the least practicable adverse impact on marine mammal species or stocks and their habitat.

Regarding statements related to the areal extent of Navy effects, or distances noted in Washington State law, we note that the analysis conducted by the Navy and NMFS includes consideration of large areas such as those referenced by the commenters, through the application of the BRFs and the associated cutoff distances—in other words, effects at these distances are considered. However, avoiding all Level B harassment would be impossible to do while also conducting the activities analyzed, which is why the Navy has requested authorization. Further, we note that reference to Washington State measures is not comparable to mitigation required pursuant to an incidental take authorization, as the goal there is to minimize the likelihood of any take for unauthorized entities.

The Navy has conducted active sonar and explosives training and testing activities in the Study Area for decades, and there is no evidence that routine Navy training and testing has negatively impacted marine mammal populations in the Study Area. NMFS' and the Navy's analyses were completed using the best available science, and include results from recently completed acoustic modeling. As discussed in the Mitigation Measures section of this final rule, and Chapter 5 (Mitigation) of the 2020 NWTT FSEIS/OEIS, required mitigation will avoid or reduce potential impacts from NWTT activities on marine mammals, including Southern Resident killer whales (see response to Comment 74 for additional discussion regarding impacts to Southern Resident killer whales).

Monitoring

Comment 58: A commenter stated that the Navy should clearly state that all appropriate personnel must have completed relevant training modules prior to participating in training and testing activities. Ensuring ''environmental awareness of event participants,'' including the possible presence of Southern Resident killer whales in the training location, implies that it is real-time situational awareness of potential killer whale presence. But it is in fact a series of modules in the Afloat Environmental Compliance Training Program, and ''appropriate personnel'' will complete some or all of these modules at some time, with no defined timeline. There should be clear timeframes in which personnel will complete this training program. The commenter asserts that this mitigation measure is indisputably both available and practical.

Response: As stated in the rule, ''All bridge watch personnel, Commanding Officers, Executive Officers, maritime patrol aircraft aircrews, anti-submarine

warfare and mine warfare rotary-wing aircrews, Lookouts, and equivalent civilian personnel must successfully complete the Marine Species Awareness Training prior to standing watch or serving as a Lookout.'' Please see Table 35 for additional information regarding training requirements.

Comment 59: A commenter recommended that, in addition to requiring long-term monitoring studies, NMFS should prioritize Navy research projects that aim to quantify the impact of training and testing activities at the individual, and ultimately, population-level. The commenter recommended detailed, individual-level behavioral-response studies, such as focal follows and tagging using DTAGs, carried out before, during, and after Navy operations, which can provide important insights for these species and stocks. The commenter stated that recent studies using DTAGs have also been used to characterize social communications between individuals of a species or stock, including between mothers and calves. The commenter recommended studies be prioritized that further characterize the suite of vocalizations related to social interactions. The commenter also stated that the use of unmanned aerial vehicles is also proving useful for surveying marine species, and can provide a less invasive approach to undertaking focal follows. Imagery from unmanned aerial vehicles can also be used to assess body condition and, in some cases, health of individuals. The commenter recommended that NMFS require the Navy to use these technologies for assessing marine mammal behavior before, during, and after Navy operations (*e.g.,* swim speed and direction, group cohesion). The commenter also stated that studies into how these technologies can be used to assess body condition should be supported as this can provide an important indication of energy budget and health, which can inform the assessment of population-level impacts.

Response: First, the Navy is pursuing many of the topics that the commenter identifies, either through the monitoring required under the MMPA or under the ESA, or through other Navy-funded Office of Naval Research (ONR) and Living Marine Resources (LMR) research programs. We are confident that the monitoring conducted by the Navy satisfies the requirements of the MMPA. A list of the monitoring studies that the Navy will be conducting under this rule is at the end of the Monitoring section of this final rule. Broadly speaking, in order to ensure that the monitoring the Navy conducts satisfies the requirements of the MMPA, NMFS works closely with the Navy in the identification of monitoring priorities and the selection of projects to conduct, continue, modify, and/or stop through the adaptive management process, which includes annual review and debriefs by all scientists conducting studies pursuant to the MMPA authorization. The process NMFS and the Navy have developed allows for comprehensive and timely input from NMFS, the Navy, the Marine Mammal Commission, and researchers conducting monitoring under the rule, which is based on rigorous reporting out from the Navy and the researchers doing the work. With extensive input from NMFS, the Navy established the Strategic Planning Process for Marine Species Monitoring to help structure the evaluation and prioritization of projects for funding. The Monitoring section of this rule provides an overview of this Strategic Planning Process. More detail, including the current intermediate scientific objectives, is available in section 5 (Mitigation), Section 5.1.2.2.1.3 (Strategic Planning Process) of the 2020 NWTT FSEIS/OEIS and on the monitoring portal (*https://www.navymarinespeciesmonitoring.us/*) as well as in the Strategic Planning Process report. The Navy's evaluation and prioritization process is driven largely by a standard set of criteria that help the internal steering committee evaluate how well a potential project would address the primary objectives of the monitoring program. Given that the Navy's Monitoring Program applies to all of the Navy's major Training and Testing activities and, thereby spans multiple regions and Study Areas to encompass consideration of the entire U.S. EEZ and beyond, one of the key components of the prioritization process is to focus monitoring in a manner that fills regionally specific data gaps, where possible (*e.g.,* more limited basic marine mammal distribution data in the MITT Study Area), and also takes advantage of regionally available assets (*e.g.,* instrumented ranges in the HSTT Study Area). NMFS has opportunities to provide input regarding the Navy's intermediate scientific objectives as well as to provide feedback on individual projects through the annual program review meeting and annual report. For additional information, please visit: *https://www.navymarinespeciesmonitoring.us/about/strategic-planning-process/.*

The Navy's involvement with future research will continue to be developed and refined by the Navy and NMFS through the consultation and adaptive management processes, which regularly consider and evaluate the development and use of new science and technologies for Navy applications. Further, the Navy also works with NMFS to target and prioritize data needs that are more appropriately addressed through Navy research programs, such as the ONR and LMR programs. The Navy has indicated that it will continue to be a leader in funding of research to better understand the potential impacts of Navy training and testing activities and to operate with the least possible impacts while meeting training and testing requirements. Some of the efforts the Navy is leading or has recently completed are described below.

(1) Individual-level behavioral-response studies—There are no ONR or LMR behavioral response studies in the NWTT Study Area given the limited number of activities conducted in NWTT in comparison to other ranges in the Pacific. However, many of the studies on species-specific reactions are designed to be applicable across geographic boundaries (*e.g.,* Cuvier's beaked whale studies in the HSTT Study Area).

(2) Tags and other detection technologies to characterize social communication between individuals of a species or stock, including mothers and calves—DTAGs are just one example of animal movement and acoustics tags. From the Navy's ONR and LMR programs, Navy funding is being used to improve a suite of marine mammal tags to increase attachment times, improve data being collected, and improve data satellite transmission. The Navy has funded a variety of projects that are collecting data that can be used to study social interactions amongst individuals. For example, as of September 2020 the following studies are currently being funded: Assessing performance and effects of new integrated transdermal large whale satellite tags 2018–2021 (Organization: Marine Ecology and Telemetry Research); Autonomous Floating Acoustic Array and Tags for Cue Rate Estimation 2019–2020 (Organization: Texas A&M University Galveston); Development of the next generation automatic surface whale detection system for marine mammal mitigation and distribution estimation 2019–2021 (Organization: Woods Hole Oceanographic Institution); High Fidelity Acoustic and Fine-scale Movement Tags 2016–2020 (Organization: University of Michigan); Improved Tag Attachment System for Remotely-deployed Medium-term Cetacean Tags 2019–2023 (Organization: Marine Ecology and Telemetry

Research); Next generation sound and movement tags for behavioral studies on whales 2016–2020 (Organization: University of St. Andrews); On-board calculation and telemetry of the body condition of individual marine mammals 2017–2021 (Organization: University of St. Andrews, Sea Mammal Research Unit); wide-band detection and classification system 2018–2020 (Organization: Woods Hole Oceanographic Institution); and Extended Duration Acoustic Tagging 2016–2021 (Organization: Syracuse University).

(3) Unmanned Aerial Vehicles to assess marine mammal behavior (*e.g.,* swim speed and direction, group cohesion) before, during, and after Navy training and testing activities—Studies that use unmanned aerial vehicles to assess marine mammal behaviors and body condition are being funded by ONR's Marine Mammals and Biology program. Although the technology shows promise (as reviewed by Verfuss *et al.,* 2019), the field limitations associated with the use of this technology have hindered its useful application in behavioral response studies in association with Navy training and testing events. For safety, research vessels cannot remain in close proximity to Navy vessels during Navy training or testing events, so battery life of the unmanned aerial vehicles has been an issue. However, as the technology improves, the Navy will continue to assess the applicability of this technology for the Navy's research and monitoring programs. An example project is integrating remote sensing methods to measure baseline behavior and responses of social delphinids to Navy sonar 2016–2019 (Organization: Southall Environmental Associates Inc.).

(4) Modeling methods that could provide indicators of population-level effects—NMFS asked the Navy to expand funding to explore the utility of other, simpler modeling methods that could provide at least an indicator of population-level effects, even if each of the behavioral and physiological mechanisms are not fully characterized. The ONR Marine Mammals and Biology program has invested in the Population Consequences of Disturbance (PCoD) model, which provides a theoretical framework and the types of data that would be needed to assess population level impacts. Although the process is complicated and many species are data poor, this work has provided a foundation for the type of data that is needed. Therefore, in the future, the relevant data pieces that are needed for improving the analytical approaches for population level consequences resulting from disturbances will be collected during projects funded by the Navy's marine species monitoring program. However, currently, PCoD models are dependent on multiple factors, one or more of which are often unknown for many populations, which makes it challenging to produce a reliable answer for most species and activity types, and further work is needed (and underway) to develop a more broadly applicable generalized construct that can be used in an impact assessment. As discussed in the Monitoring section of this rule, the Navy's marine species monitoring program typically supports 10–15 projects in the Pacific at any given time. Current projects cover a range of species and topics from collecting baseline data on occurrence and distribution, to tracking whales, to conducting behavioral response studies on beaked whales and pilot whales. The Navy's marine species monitoring web portal provides details on past and current monitoring projects, including technical reports, publications, presentations, and access to available data and can be found at: *https://www.navymarinespeciesmonitoring.us/regions/pacific/current-projects/.*

In summary, NMFS and the Navy work closely together to prioritize, review, and adaptively manage the extensive suite of monitoring that the Navy conducts in order to ensure that it satisfies the MMPA requirements. NMFS has laid out a broad set of goals that are appropriate for any entity authorized under the MMPA to pursue, and then we have worked with the Navy to manage their projects to best target the most appropriate goals given their activities, impacts, and assets in the NWTT Study Area. Given the scale of the NWTT Study Area and the variety of activities conducted, there are many possible combinations of projects that could satisfy the MMPA standard for the rule. The commenter has recommended more and/or different monitoring than NMFS is requiring and the Navy is conducting or currently plans to conduct, but has in no way demonstrated that the monitoring currently being conducted does not satisfy the MMPA standard. NMFS appreciates the commenter's input, and will consider it, as appropriate, in the context of our adaptive management process, but is not requiring any changes at this time.

Comment 60: Consistent with its responsibilities under the MMPA's provisions on unusual mortality events (section 1421c of the MMPA), as well as requirements under NEPA to obtain information essential to its analysis of reasonable alternatives (40 CFR 1502.22; now section 1502.21), NMFS should urgently fund research to assess the extent of prey availability loss for California gray whales and to determine the cause of that loss of prey.

Response: This comment is outside of the scope of this rulemaking, which must use the best available science to determine whether incidental take authorization should be issued under section 101(a)(5)(A) of the MMPA, and which includes requirements for the Navy to implement certain mitigation and monitoring measures related to that incidental take. There is no information to indicate that prey availability loss for gray whales is related to the Navy's testing and training activities in the NWTT Study Area. Comments regarding NMFS' responsibilities under separate sections of the MMPA or NEPA, or recommendations that NMFS fund specific research under other sections of the MMPA, should be addressed to the appropriate NMFS office.

Comment 61: A commenter stated that the Navy says it will make reports but questioned how their activities will be monitored. Another commenter requested an accounting of past operations and the damage done in the 10 years prior to this authorization.

Response: Please refer to the Monitoring and Reporting sections of this final rule for an explanation of how the Navy's activities will be monitored and reported on. Additionally, the Navy's marine species monitoring web portal provides exercise reports for previous activities in the NWTT Study Area, as well details on past and current monitoring projects, including technical reports, publications, presentations, and access to available data. The Navy's marine species monitoring web portal can be found at: *https://www.navymarinespeciesmonitoring.us/reporting/pacific/.*

Comment 62: A commenter stated that the Navy should reconsider the impacts of its proposed activities being imposed on Southern Resident killer whales, and examine alternatives and additional mitigation measures to ensure the protection and recovery of this population. The commenter recommended that if marine mammals are sighted or detected within acoustic range, then exercises should be shut down, if in progress, and postponed or moved elsewhere if the exercises have not yet started. The commenter stated that an appropriate threshold for such a decision is whenever noise levels from naval operations as well as other sources at the location of Southern Resident killer whales are expected to be greater than 130 dB re 1μPa, the pain

threshold of killer whales. The commenter states that these lower thresholds will extend far beyond the range at which marine mammals can be sighted from vessels responsible for explosives and mid-frequency active sonar. This will require the use of remote sensing technology such as drones (with infrared sensing capability for use at night) and sonobuoys. Two commenters suggested that the use of permanent hydrophone arrays wired to shore would allow more thorough tracking of marine mammal movement throughout the training range. In addition, exercises should be moved further offshore than currently planned to compensate for the greater ranges at which Level B takes could be expected under the criteria recommended here than for the 120 dB contour.

Another commenter stated that the Navy should fund the installation of an array of underwater microphones along the coast of Washington state to provide near real-time information on the whereabouts of the Southern Resident killer whales as well as other cetaceans. This would serve as an important early warning system in the offshore area to complement the boat-based observers who have a limited visual range. Activities could then be planned based on Southern Resident killer whales movements and halted when Southern Resident killer whales are approaching well before they reach the 0.5 nmi distance. Hanson (2018) noted that 28 recorders would achieve a high probability of detection all along the Washington coast. The array would have the added benefit of improving monitoring of other killer whale populations, pilot whales, sperm whales, and beaked whales, allowing for improved implementation of mitigation measures to reduce incidental take of those species as well.

Response: The Navy, in consultation with NMFS, used the best available science on marine mammal behavioral responses during acoustic exposures to develop appropriate behavioral response criteria and BRFs, which for odontocetes (including killer whales) predict that approximately 10–17 percent of exposures at 120–130 dB will result in behavioral responses that qualify as Level B harassment. For more information about the Phase III criteria, please refer to the technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)* (June 2017), available at *www.nwtteis.com.* NMFS and the Navy have also consulted with NMFS' ESA Interagency Cooperation Division under section 7 of the Endangered Species Act and will continue to coordinate on criteria and thresholds for assessing impacts to marine mammals.

Additionally, as referenced in other comment responses, this final rule includes extensive mitigation that will minimize impacts to Southern Resident killer whales, including many additional measures added since the proposed rule. For example, the Navy is required to communicate with available sighting detection networks prior to the conduct of applicable activities in NWTT Inland Waters. Additionally, this final rule includes a new mitigation area in the NWTT Offshore Area known as the Juan de Fuca Eddy Marine Species Mitigation Area, where annual mid-frequency active sonar hours will be limited and explosives will be prohibited. It would not be practicable for the Navy to implement additional distance-from-shore restrictions or additional passive acoustic monitoring for the reasons provided in Appendix K (Geographic Mitigation Assessment) and Chapter 5 (Mitigation) of the 2020 NWTT FSEIS/OEIS. NMFS has reviewed the analysis of additional potential restrictions and the impacts they would have on military readiness, and concurs with the Navy's assessment that they are impracticable. Additionally, the mitigation zones included in this final rule represent the largest zones practicable for the Navy to implement, as discussed in Comment 52. Therefore, the larger zones suggested by the commenter are not included in this final rule. Regarding the use of infrared and thermal technologies, please see the response to Comment 46.

Regarding the installation of permanent hydrophone arrays wired to shore along the coast of Washington state to provide near real-time information on the whereabouts of the Southern Resident killer whales as well as other cetaceans, the cost and installation of such a system in and of itself would be a major federal undertaking that would require separate NEPA and permitting (Clean Water Act, essential fish habitat consultation, *etc.*) and is beyond the scope of mitigation that is necessary to meet the least practicable adverse impact standard. Further, given the low numbers and density of Southern Resident killer whales, combined with the relatively low number of training and testing activities, the benefits of such a detection network would be limited *(i.e.,* we would expect few instances in which whales would be detected in an exact place and time that would intersect with a potential exercise, and thereby allow for an opportunity to mitigate). This recommendation is not warranted and, accordingly, NMFS has not included a requirement to install a hydrophone array for real-time mitigation monitoring.

Negligible Impact Determination

Comment 63: A commenter stated that NMFS tabulates takes of marine mammal species but has not adequately assessed the aggregate impacts. The commenter asserted that, on the contrary, NMFS assumes, without any explanation, that the accumulated annual mortalities, injuries, energetic costs, temporary losses of hearing, chronic stress, and other impacts would not affect vital rates in individuals or populations, even though the Navy's activities would affect the same populations over time. This assumption seems predicated, for many species, on the unsupported notion that transient activity will not accumulate into population-level harm. The commenter stated that the proposed rule makes this assertion even for populations such as Hood Canal harbor seals and Washington Inland harbor porpoises, for which it estimates auditory injury, temporary hearing loss, and behavioral disruption at high numbers relative to the size of individual populations.

Multiple commenters noted concern that the Hood Canal population of harbor seals would be taken 30.84 times its abundance each year, for seven years. Commenters said that NMFS observes that such high numbers of takes make it likely that females will suffer reproductive loss, yet it argues—without any quantitative support—that any such effects would be negligible on the population level because only a small number of individual females would be affected. Nowhere does NMFS consider the potential for sensitization, permanent habitat displacement, or other effects of repeated exposure that could exacerbate the already high numbers of takes.

Commenters noted that other parties have conducted quantitative analysis of population consequences of disturbance, both in cases where substantial information is available for modeling and in cases where it is not—as is evident even in a three-year-old report from the National Academy of Sciences. NMFS cannot, the commenter asserts, discount the results of its take estimation without any quantitative or meaningful analysis. Its attempt to do so here for populations with high levels of take is unreasonable on its own terms and insupportable under the MMPA's standard of ''best available science.''

Response: NMFS fully considered the potential for aggregate effects from all Navy activities and has applied a reasoned and comprehensive approach

to evaluating the effects of the Navy activities on marine mammal species and their habitat.

No mortalities or non-auditory injuries are predicted from sonar or explosives for any marine mammal species, including harbor porpoises and harbor seals. The vast majority of impacts to marine mammals are instances of behavioral response, followed by instances of temporary threshold shift, both considered Level B harassment under the MMPA. A small proportion of a few species such as harbor porpoises are estimated to receive instances of mild PTS, however there is no information to indicate that the small amount of predicted PTS will affect the fitness of any individual. NMFS has explained in detail in the proposed rule and again in this final rule how the estimated takes were calculated for marine mammals, and then how the size of the Study Area across which activities may be distributed (and the ASW activities utilizing MF1 sonar, which account for the majority of the takes may occur anywhere in the Study Area and predominantly more than 12 nmi from shore) combined with the comparatively small number of takes as compared to the abundance of the species or stock in the area does not support that any individuals, other than Hood Canal harbor seals, will likely be taken over more than a few non-sequential days. We also considered UMEs (for species or stocks where applicable) to inform the baseline levels of both individual health and susceptibility to additional stressors, as well as stock status. Further, the species-specific assessments in the Analysis and Negligible Impact Determination section pull together and address the combined injury, behavioral disturbance, and other effects of the aggregate NWTT activities (and in consideration of applicable mitigation) as well as other information that supports our determinations that the Navy activities will not adversely affect any species or stocks via impacts on rates of recruitment or survival.

NMFS acknowledges that for the Hood Canal stock of harbor seals, though the majority of impacts are expected to be of a lower to sometimes moderate severity, the repeated takes over some number of sequential days for some individuals in this stock makes it more likely that some small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year (energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal). However, we first note that the predicted potential number of repeated days of take for any individual has decreased significantly since the proposed rule (a reduction of more than 50 percent) as a result of harbor seal abundance corrections. Specifically, whereas the proposed rule suggested an average of 31 days of take with some subset of individuals experiencing more, the final rule predicts an average of 10 days of incurred take per individual, with some potentially experiencing up to 21. The fewer the days per year on which take is likely incurred by any individual, the less likely those days will be sequential, and the lower the maximum number of sequential days, all of which makes it less likely that the behavioral impacts to any individuals would impact energetic budgets in a manner that would affect reproduction. Further, foregone reproduction (especially for only one year within seven, which is the maximum predicted because the small number anticipated in any one year makes the probability that any individual will be impacted in this way twice in seven years very low) has far less of an impact on population rates than mortality, and a relatively small number of instances of foregone reproduction would not be expected to adversely affect the stock through effects on annual rates of recruitment or survival, especially when the stock is increasing. As discussed in the Analysis and Negligible Impact Determination section for this analysis, there is documented evidence of an increasing population for Hood Canal harbor seals, including pupping on the Naval Base Kitsap Bangor waterfront in recent years (an area with high levels of human activity, including nearby pile driving, and associated noise). Further of note, the Navy has been conducting monitoring of harbor seals and porpoises in the vicinity of Naval Base Kitsap Bangor where pierside sonar use occurs, and harbor seals are noted in the waters around the piers daily and have become habituated to the high levels of noise at the industrial piers to the extent that they do not avoid the piers during active pile driving with impact hammers, which produce sounds almost as high as tactical sonar.

Additionally, in the NWTT Study Area unit-level military readiness activities occur over a small spatial scale with few participants, typically over a short duration (a few hours or less), while larger-scale training and testing events occur in locations outside of the Study Area. While data with which to quantify or analyze potentially synergistic impacts of multiple stressors are limited, substantial efforts are underway to better understand aggregate effects through data collection and improved analytical methods, such as the Population Consequences of Disturbance model (see Section 3.4.2.1.1.7, Long-Term Consequences in the 2020 NWTT FSEIS/OEIS). However, until there are sufficient data to inform such models, the best mechanism for assessing the impacts from Navy training and testing activities on marine mammal reproduction and survival includes monitoring the populations over time on Navy ranges. The Navy has conducted active sonar and explosives training and testing activities in the Study Area for decades, and there is no evidence that routine Navy training and testing has negatively impacted marine mammal populations in the Study Area (or at any Navy Range Complex). In addition, the Navy's research and monitoring programs described in the Monitoring section are focused on filling data gaps and obtaining the most up-to-date science to inform impact assessment. Information about prior and current research being conducted on marine mammals on Navy ranges is in Chapter 3.4 (Marine Mammals) of the 2020 NWTT FSEIS/OEIS and can be found at *www.navymarinespeciesmonitoring.us.*

Comment 64: A commenter stated that NMFS did not meet the legal standard in the MMPA to find that the Navy's proposed actions ''will have a negligible impact on'' the species and stocks of marine mammals living in the NWTT Study Area. NMFS defines ''[n]egligible impact'' as an impact ''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.'' NMFS must make the negligible impact finding based on the ''best available science.'' However, the commenter says that NMFS does not adequately engage with identified impacts to vulnerable species, including Southern Resident killer whales and gray whales, analyze impacts of Naval aircraft, or address the role of climate change in exacerbating anticipated impacts of Naval activities. Another commenter also noted that multiple studies demonstrate behavior

impacts to cetaceans from aircraft, disagreed with the conclusion that aircraft do not result in harassment, and asked that NMFS ensure that any effects from aircraft result in a negligible impact on marine mammals (especially Southern Resident killer whales, given their status). For these reasons, the commenter asserts that NMFS cannot justify its finding of negligible impact based on the record in the proposed rule.

Response: NMFS fully considered the potential for aggregate effects from all Navy activities, and discusses its consideration of these impacts, and its negligible impact determination for each species and stock in the Analysis and Negligible Impact Determination section of this final rule. As described throughout the rule, NFMS relied on the best available science in considering the impacts of the Navy's activities and in making the negligible impact determinations. NMFS fully considered the status of Southern Resident killer whales, gray whales, and all other marine mammals in its analysis, as discussed in the Description of Marine Mammals and Their Habitat in the Area of the Specified Activities and the Analysis and Negligible Impact Determination sections of the proposed and final rules. NMFS is required to analyze the impacts of the proposed authorized take in its negligible impact analysis—the effects of climate change are considered in the baseline of the status of marine mammal stocks in the rule, and further considered through the 2020 NWTT FSEIS/OEIS cumulative impact analysis (Chapter 4, *Cumulative Impacts*). NMFS acknowledges that climate change is impacting the marine environment in ways that could change our assessment of effects on marine mammals in the future, but the precise manner in which these changes would impact marine mammals and their habitat in the next seven years is both unpredictable and unquantifiable in the context of our analysis of the impacts of Navy activities, and NMFS' analysis is based on the best available scientific data.

NMFS acknowledges the data demonstrating that marine mammals sometimes respond to aircraft overflights, however, we have evaluated the best available data and the Navy's activities and do not expect marine mammals to be affected in a manner that qualifies as Level B harassment. Information regarding behavioral reactions of marine mammals to aircraft is provided in Section 3.4.2.1.1.5 (Behavioral to Aircraft Noise) of the 2020 NWTT FSEIS/OEIS. Marine mammals have variable responses to aircraft, but overall little change in behavior has been observed during flyovers. Some odontocetes dove, slapped the water, or swam away from the direction of the aircraft during overflights; others did not visibly react (Richardson *et al.,* 1995b). Beaked whales are more sensitive than other cetaceans (Würsig *et al.,* 1998). Killer whales demonstrated no change in group cohesion or orientation during survey airplane or unmanned aerial system flyovers (Durban *et al.,* 2015; Smultea and Lomac-ManNair, 2016). It is unlikely that aircraft will randomly fly close enough to marine mammals (much less close enough over water at the moment that a cetacean surfaces) to evoke any response, and further unlikely that a marine mammal response to such an instantaneous exposure would result in that marine mammal's behavioral patterns being ''significantly altered or abandoned.'' Accordingly, the Navy did not request authorization for take resulting from aircraft overflights, and NMFS does not anticipate or authorize it.

Comment 65: A commenter stated that the rates of take for populations of Dall's porpoises (131 percent of population abundance) and the populations of harbor porpoises on the Northern OR/WA Coast (244 percent of population abundance) and in Washington Inland Waters (265 percent of population abundance) are exceptionally high. As noted by NMFS, these porpoises are particularly vulnerable to the impacts of anthropogenic sound. NMFS recognizes that this level of take could also lead to reproductive loss, but again asserts, without thorough analysis, that it ''would not be expected to adversely impact annual rates of recruitment or survival.'' However, NMFS goes on to authorize these very high levels of take. The commenter asserts that such ''cursory'' statements are not enough under the MMPA. Rather NMFS has a legal obligation to assess these impacts using the best available science.

Response: The vulnerability of Dall's porpoise and harbor porpoise to sound is captured in the higher take estimate (as compared to other species in the NWTT Study Area), as this sensitivity is accounted for in the Navy's NAEMO model. NMFS erroneously indicated in the *Preliminary Analysis and Negligible Impact Determination* section of the proposed rule that the impacts to Dall's porpoises and harbor porpoises may cause them to forgo reproduction for a year. Given the expected low-level impacts and the mitigation included in this final rule, NMFS does not expect individuals from these species and stocks to forego reproduction, and NMFS has corrected this error in the final rule. The Analysis and Negligible Impact Determination section of this final rule includes a full discussion of NMFS' analysis of the impacts of the Navy's activities, and its negligible impact determinations for impacts to Dall's porpoise and harbor porpoise.

Comment 66: A commenter stated that it strongly urges NMFS to revise its proposed authorization and mitigation measures to better protect Washington's marine mammals, including endangered Southern Resident killer whales, in accordance with the MMPA. The commenter stated that NMFS bases its authorization on inadequate data and does not require sufficient mitigation measures. The commenter asserted that as a result, NMFS' findings of negligible impact and least practicable adverse impact and proposed approval violate the MMPA and are further arbitrary and capricious under the Administrative Procedure Act.

Response: In the final rule, NMFS fully considered the best available science, with the key scientific studies fully referenced throughout the rule. Additional science that was considered by both NMFS and the Navy is referenced in the 2020 NWTT FSEIS/OEIS.

The rule also includes extensive mitigation measures for Southern Resident killer whales and other marine mammals that occur in Washington, including new measures since publication of the proposed rule. As discussed in the Mitigation Measures section of the rule, and in Chapter 5 (Mitigation) of the 2020 NWTT FSEIS/OEIS, the Navy will implement extensive mitigation to avoid or reduce potential impacts from the NWTT activities on marine mammals. These mitigation measures include mitigation areas that restrict certain activities in places and during times that are particularly important to Southern Resident killer whales and other marine mammals. One of these mitigation areas, the Puget Sound and Strait of Juan de Fuca Mitigation Area, encompasses the entire extent of NWTT Inland Waters in the state of Washington, including Southern Resident killer whale critical habitat. New mitigation measures in the Puget Sound and Strait of Juan de Fuca Mitigation Area will result in training and testing activities being conducted in NWTT Inland Waters only when necessitated by mission-essential training or testing program requirements. With implementation of the new mitigation measures included in this final rule, we do not anticipate any take of Southern Resident killer whales in NWTT Inland Waters due to

NWTT training and testing activities. This final rule also includes additional mitigation measures for Southern Resident killer whales in other mitigation areas, including the Marine Species Coastal Mitigation Area and the Olympic Coast National Marine Sanctuary Mitigation Area. Please refer to the Mitigation Measures section of this final rule for further discussion of the required mitigation measures in the NWTT Study Area.

Having considered all of the pertinent science available to the agency (of which just the key studies have been referenced in the rule) and the full suite of mitigation measures to reduce impacts, the final rule provides a thorough discussion of the least practicable adverse impact and negligible impact analyses and determinations in the Mitigation Measures and Analysis and Negligible Impact Determination sections, respectively.

Comment 67: Gray whales are currently undergoing an unexplained die-off leading to 352 strandings between January 2019 and July 2020, including 44 strandings along the coast of Washington alone. NOAA is investigating the die-off as an Unusual Mortality Event. While it is not clear what specifically is driving this event, many animals show signs of ''poor to thin body condition.'' The commenter states that in the proposed rule, NMFS relies on the increasing population of the stock to assert that the Navy's proposed takes will not be exacerbated by the Unusual Mortality Event to the point of affecting annual rates of recruitment or survival. However, as the exact cause of the Unusual Mortality Event is not known, NMFS also cannot know if the current Unusual Mortality Event is indicative of a longer–term trend in the population, potentially linked to the impacts of climate change. NMFS' reliance on an increasing stock may be misplaced, particularly in light of the fact that NMFS will authorize the Navy's activities for a seven-year period during which the health of the gray whale population could decline.

Response: NMFS does not rely solely on the increasing stock size for gray whales as the commenter suggests. As discussed in the Analysis and Negligible Impact Determination section of this final rule, NMFS is authorizing one mortality over the seven years covered by this rule, or 0.14 mortality annually. The addition of this 0.14 annual mortality still leaves the total annual human-caused mortality well under both the insignificance threshold and residual PBR (which is 661.6). No mortality from explosives and no Level A harassment is anticipated or authorized. Altogether, while we have considered the impacts of the gray whale UME, this population of gray whales is not endangered or threatened under the ESA and the best available science at this time indicates the stock is increasing. Additionally, only a very small portion of the stock is anticipated to be impacted by Level B harassment (less than 1 percent) and any individual gray whale is likely to be disturbed at a low-moderate level. This low magnitude and moderate-lower severity of harassment effects is not expected to result in impacts to reproduction or survival for any individuals, nor are these harassment takes combined with the authorized mortality of one whale over the seven-year period expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, NMFS determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Eastern North Pacific stock of gray whales.

Additionally, this final rule includes extensive mitigation for gray whales, including in the Marine Species Coastal, Olympic Coast National Marine Sanctuary, Stonewall and Heceta Bank Humpback Whale, Point St. George Humpback Whale, and Northern Puget Sound Gray Whale Mitigation Areas, which overlap with important gray whale foraging and migration areas.

NEPA

Comment 68: Commenters stated that NMFS cannot rely on the Navy's deficient EIS to satisfy NMFS' NEPA obligations when issuing regulations or permits under the MMPA. The commenter states that NMFS must prepare a separate EIS, or, at minimum, a supplemental EIS, before proceeding with the proposed action. The commenter stated that the Navy's DSEIS is deficient on its face. One commenter asserted that those deficiencies include, but are not limited to: Failing to take a hard look at the effects of the action to endangered Southern Resident killer whales and other sensitive species, failing to take a hard look at the effects of the proposed training and testing activities, including modeling, thresholds, and assumptions about harm that underestimate the extent and severity of marine mammal take (both behavioral impacts and injury), failing to take a hard look at the effects of the entire action, failing to evaluate a full range of reasonable alternatives, failing to evaluate a full range of reasonable mitigation measures, failing to accurately estimate the amount of take and impact of all the activity covered by the SEIS, and failing to consider the cumulative impacts of noise and other stressors in conjunction with other reasonably foreseeable activities. Commenters stated that the final rule should not be issued until after NMFS completes a proper NEPA analysis.

Response: Consistent with the regulations published by the Council on Environmental Quality (CEQ), it is common and sound NEPA practice for NMFS to participate as a cooperating agency and adopt a lead agency's NEPA analysis when, after independent review, NMFS determines the document to be sufficient in accordance with 40 CFR 1506.3. Specifically here, NMFS is satisfied that the 2020 NWTT FSEIS/OEIS adequately addresses the impacts of issuing the MMPA incidental take authorization (including in its assessment of effects to Southern Resident killer whales, and in consideration of the effects of the entire action) and that NMFS' comments and concerns have been adequately addressed. The FSEIS/OEIS takes a hard look at all of the issues specifically raised by the commenter. NMFS' early participation in the NEPA process and role in shaping and informing analyses using its special expertise ensured that the analysis in the 2020 NWTT FSEIS/OEIS is sufficient for purposes of NMFS' own NEPA obligations related to its issuance of incidental take authorization under the MMPA.

Regarding the alternatives and mitigation measures, NMFS' involvement in development of the 2020 NWTT FSEIS/OEIS and role in evaluating the effects of incidental take under the MMPA ensured that the 2020 NWTT FSEIS/OEIS includes adequate analysis of a reasonable range of alternatives. The 2020 NWTT FSEIS/OEIS includes a No Action Alternative specifically to address what could happen if NMFS did not issue an MMPA authorization. The FSEIS/OEIS also includes and analyzes two action alternatives (including mitigation measures incorporated into the action alternatives) to evaluate the impacts of an MMPA incidental take authorization that would also meet the current and future (seven-year) training and testing requirements to ensure the Navy meets its Title 10 responsibilities, which includes to maintain, train, and equip combat ready forces. As noted, these alternatives fully analyze a comprehensive variety of mitigation measures. This NEPA mitigation analysis supported NMFS' evaluation of our mitigation options in potentially issuing an MMPA authorization, which, if the authorization can be issued under

the negligible impact standard, primarily revolves around the appropriate mitigation to prescribe. This approach to evaluating a reasonable range of alternatives is consistent with NMFS policy and practice for issuing MMPA incidental take authorizations. NMFS has independently reviewed and evaluated the 2020 NWTT FSEIS/OEIS, including the range of alternatives, and determined that the 2020 NWTT FSEIS/OEIS fully satisfies NMFS' NEPA obligations related to its decision to issue the MMPA final rule and associated LOAs, and we have adopted it.

Comment 69: Commenters stated that NMFS cannot rely on the 2020 NWTT FSEIS/OEIS to fulfill its obligations under NEPA because it does not adequately address NMFS' own actions and responsibilities under the MMPA. The commenter stated that the MMPA requires NMFS to protect and manage marine mammals, allowing incidental take of marine mammals only in limited circumstances when such take satisfies the Act's statutory requirements, including the ''negligible impact'' and ''least practicable adverse impact'' standards. In other words, NMFS is charged under the MMPA with prioritizing the protection of species. The commenter states that the Navy, on the other hand, seeks primarily to maximize its opportunities for training and testing activities. Thus, the Navy's SEIS is framed around a fundamentally different purpose and need—one that is incongruent with NMFS' obligations under the MMPA.

Response: The proposed action is the Navy's proposal to conduct testing and training activities in the NWTT Study Area. NMFS is a cooperating agency, as it has jurisdiction by law and special expertise over marine resources impacted by the Navy's action, including marine mammals and federally-listed threatened and endangered species. As discussed in Comment 68, NMFS has adopted the 2020 NWTT FSEIS/OEIS after determining that the document is sufficient under the CEQ regulations at 40 CFR 1506.3. Specifically, NMFS is satisfied that the FSEIS/OEIS adequately addresses the impacts of issuing the MMPA incidental take authorization and that NMFS's comments and concerns have been adequately addressed. There is no requirement in the CEQ regulations that NMFS, as a cooperating agency, have a separate purpose and need statement in order to ensure adequacy and sufficiency for adoption. Nevertheless, the statement of purpose and need in the 2020 NWTT FSEIS/OEIS explicitly acknowledges NMFS' purpose of evaluating the Navy's proposed action and making a determination whether to issue the MMPA regulations and LOAs. NMFS' early participation in the NEPA process and role in shaping and informing analyses using its special expertise ensured that the analysis in the 2020 NWTT FSEIS/OEIS is sufficient for purposes of NMFS' own NEPA obligations related to its issuance of incidental take authorization under the MMPA.

Comment 70: Commenters stated that their organizations are aware that on July 16, one day before the conclusion of the comment period, CEQ issued new regulations governing the preparation of environmental assessments and environmental impact statements under NEPA. The commenters stated that they believe these new regulations contain numerous provisions that are contrary to law and destructive of federal environmental decision-making. Agencies that have begun the NEPA process for a particular agency action prior to September 14, 2020, as is the case with NWTT, have discretion under the new regulations at 40 CFR 1506.13 to decide whether to apply them. The commenters stated that given the legal infirmities of the new CEQ regulations, they strongly recommend that NMFS elect not to apply them here; and NMFS should make that choice clear in its EIS.

Response: The effective date of the 2020 CEQ NEPA regulations was September 14, 2020. As noted by the commenter, NEPA reviews initiated prior to the effective date of the 2020 CEQ regulations may be conducted using the 1978 version of the regulations. The NEPA review for this rulemaking and the Navy's proposed action began prior to September 14, 2020, and the agencies decided to proceed under the 1978 CEQ regulations. Therefore, the new CEQ regulations were not applied to the 2020 NWTT FSEIS/OEIS, and the FSEIS/OEIS was prepared using the 1978 CEQ NEPA regulations.

Comment 71: A commenter stated that the Navy's MMPA application was premature because the 2020 NWTT FSEIS/OEIS had not been finalized. The commenter questioned what activities would occur in the Olympic Coast National Marine Sanctuary prior to finalization of the 2020 NWTT FSEIS/OEIS.

Response: The commenter misunderstands the timing of the analysis of environmental impacts under NEPA and NMFS' consideration of an application for MMPA incidental take authorization. The NEPA analysis, along with consideration of other applicable laws, must be completed before a decision is made to issue a final rule authorizing incidental take under the MMPA, but the NEPA analysis does not need to be completed before an MMPA application is submitted. The Navy submitted their application while the NWTT SEIS/OEIS was in development. NMFS and the Navy coordinated on development of the NWTT SEIS/OEIS, and the final rule authorizes Navy training and testing activities beginning in November 2020. Any Navy testing and training activities occurring in the Olympic Coast National Marine Sanctuary prior to finalization of this rule and the 2020 NWTT FSEIS/OEIS were conducted under the previous MMPA incidental take authorization and its accompanying NEPA analysis.

ESA

Comment 72: A commenter stated that NMFS must ensure that the Navy's activities will not jeopardize endangered species in the NWTT Study Area, including the Southern Resident killer whale population, as required by the ESA, and that NMFS and the Navy must fully comply with their obligations under the ESA. Another commenter stated that NMFS' consultation must also evaluate the impacts of the proposed action beyond ESA-listed marine mammals and their habitat, to include the other threatened and endangered species that will be affected by the Navy activities. The commenter specifically references designated critical habitat for endangered Pacific leatherback sea turtles in the NWTT Study Area, and that more than two dozen listed populations of Pacific salmon and Steelhead occur in the Study Area. The commenter states that NMFS has a duty to ensure against jeopardy for each of these, and any other, imperiled species in this area. Another commenter stated that this authorization violates NMFS' own Recovery Plan for U.S. Pacific Populations of the Leatherback Turtle. Another commenter stated that NMFS should require the Navy to shift testing and training activities away from locations and seasonal windows that endangered species are present.

Response: NMFS' Permits and Conservation Division has completed ESA consultation with NMFS' ESA Interagency Cooperation Division on whether the promulgation of this rule and issuance of the associated LOAs are likely to jeopardize the continued existence of any ESA-listed species or destroy or adversely modify any designated critical habitat, while the Navy has consulted on all ESA-listed

species that may be affected by their action. NMFS' ESA Interagency Cooperation Division's biological opinion includes analysis and determinations regarding all ESA-listed species and designated critical habitat that may be affected by the Navy's or NMFS' actions in the NWTT Study Area. The biological opinion concluded that NMFS' and the Navy's proposed actions are not likely to jeopardize the continued existence of any endangered or threatened species and are not likely to destroy or adversely modify designated critical habitat.

The commenter does not explain in what manner they think authorizing incidental take of marine mammals under the MMPA would violate the ESA recovery plan for U.S. Pacific populations of leatherback turtles. ESA recovery plans are guidance documents that provide recommended recovery actions for NMFS, other federal agencies, States, tribes, NGOs, and other stakeholders to recover the species, and as such it is not possible to ''violate'' a recovery plan. That said, we have reviewed the recovery plan and there are no recovery actions related to Navy activities or authorization of incidental take of marine mammals.

Neither the ESA nor the MMPA preclude activities in locations and times where endangered species are present. As described in the ESA biological opinion, NMFS made the preliminary findings necessary to allow for incidental take of ESA-listed marine mammals in the proposed MMPA rule. The biological opinion is accompanied by an ESA incidental take statement that, among other things, exempts the incidental take from ESA section 9 liability and identifies reasonable and prudent measures to minimize the impact of the anticipated incidental take. As described in the Mitigation Measures section of this rule, geographic mitigations required by this rule limit activities in some areas where ESA-listed species (*e.g.,* the Southern Resident killer whale) are present in higher densities or exhibit important behaviors.

Comment 73: A commenter stated that NMFS cannot finalize the proposed incidental take regulations or issue any LOAs until it completes consultation and imposes limits to mitigate the hazards of Navy's training and testing on threatened and endangered species and their habitats and also must require additional mitigation. The commenter further stated that in complying with the ESA, NMFS must consider the appreciable impact of the proposed activities on listed species and their habitats. The commenter stated that the consultation must evaluate the programmatic impact of seven years of Navy training and testing as authorized by NMFS in final regulations, and in addition to completing programmatic consultation, NMFS must also consult on a site-specific basis prior to issuing or modifying LOAs. The commenter states that NMFS, however, cannot avoid programmatic consultation by deferring to partial, LOA-specific consultations.

The commenter asserts that if other activities or conditions also harm an endangered species or its habitat, the effects of NMFS' authorization of the Navy's activities must be added to that baseline and analyzed together to determine whether the proposed activity jeopardizes the species or adversely modifies critical habitat, and states that in the NWTT Study Area, threatened and endangered species along the coast are exposed to a variety of threats from ship strikes, oil and gas activities, noise from vessels, entanglement or bycatch in fishing gear, wastewater discharge, oil spills, as well as other cumulative impacts from fishing, shipping, military activities, and climate change. The commenter states that the aggregate impact of these activities must be considered in the consultation.

Response: NMFS agrees that we could not finalize these regulations or issue LOAs until we completed consultation under section 7 of the ESA. NMFS' Permits and Conservation Division, which developed this rule, consulted with NMFS' ESA Interagency Cooperation Division on the promulgation of this seven-year rule and issuance of the associated LOAs which authorize incidental take of marine mammals in the NWTT Study Area. As required, the consultation included the necessary consideration of the environmental baseline, impacts on ESA listed species and their habitat over the seven years of the rule, and cumulative effects. As noted in the *Endangered Species Act* section of this rule, NMFS' ESA Interagency Cooperation Division has issued a biological opinion concluding that the promulgation of this seven-year rule and issuance of subsequent LOAs are not likely to jeopardize the continued existence of threatened and endangered species under NMFS' jurisdiction and are not likely to result in the destruction or adverse modification of designated (or proposed) critical habitat in the NWTT Study Area. The Biological Opinion for this rulemaking is available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

As discussed in the Mitigation Measures section and multiple responses to Comments, this final rule includes extensive mitigation measures to lessen the frequency and severity of impacts from the Navy's activities on marine mammals and their habitat, including those that are listed as threatened or endangered. Please refer to the biological opinion for additional information about ESA-listed species and additional mitigation required for ESA-listed species other than marine mammals.

Southern Resident Killer Whale

Comment 74: Multiple commenters noted that the amended Navy application and NMFS' proposed rule now predict and would allow for a vastly increased level of incidental take—formerly 2 takes of Southern Resident killer whales, now 51 takes—every year. One commenter stated that approval of such a high level of incidental take without requiring any additional mitigation measures represents gross neglect of the agency's management responsibilities under the ESA and the MMPA to avoid or mitigate impacts to this highly endangered and iconic species. A commenter also stated that many organizations and Washington state agencies have asked for enhanced mitigation measures to reduce adverse impacts on Southern Resident killer whales; other commenters echoed this recommendation. The commenter asserted that these measures are not expected to impact the Navy's ability to carry out its national security mission, and yet they do not seem to have been considered, let alone adopted in the proposed rule. Furthermore, mitigation measures considered sufficient when the Navy thought the density of Southern Resident killer whales offshore was much lower should not be considered sufficient now that the Navy knows it is higher based on more recent data. Commenters also urged NMFS to change its preliminary determination of ''negligible impact'' and require additional monitoring and mitigation measures to significantly reduce the incidental take of Southern Resident killer whales so that it does in fact warrant a ''negligible impact'' determination.

A commenter stated that while the MMPA allows permitted incidental take of certain activities if the take is of small numbers, with no more than a ''negligible impact,'' defined as one 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,'' a take of 51 individual Southern Resident killer whales per year cannot be considered to be ''of small numbers'' nor unlikely to ''adversely affect'' the species. Multiple commenters echoed this concern. A commenter also stated that displacement from preferred foraging areas will cause population-level effects that could extend into the future given the highly social nature of the Southern Resident killer whale community and transmission of information between associated individuals. The commenter stated that there are documented cases of naval activities causing Southern Resident killer whales to abruptly change their behavior and abandon foraging activities and areas, most notably the USS *Shoup* active sonar incident in 2003. More recently, the Canadian Navy set off explosives near a group of Southern Resident killer whales from L pod, in federally protected critical habitat, causing them to flee the area.

Response: This increase in incidental take of Southern Resident killer whales between Phase II and Phase III of the Navy's activities is partially due to new offshore Southern Resident killer whale density estimates and analytical factors, and partially due to increased activity levels in the Navy's Phase III activities.

The number and/or intensity of incidents of take will be minimized through the incorporation of mitigation measures, which were expanded from the last rule in the Navy's application and the proposed rule. Further, since publication of the proposed rule NMFS has added mitigation measures for marine mammals, including Southern Resident killer whales, in this final rule. New measures include additional procedural mitigation during explosive mine countermeasure and neutralization testing and new geographic mitigation measures, including a new Juan de Fuca Eddy Marine Species Mitigation Area and additional mitigation in the Marine Species Coastal Mitigation Area and the Olympic Coast National Marine Sanctuary Mitigation Area (both of which are offshore areas that overlap with ESA proposed Southern Resident killer whale critical habitat), as well as in the Puget Sound and Strait of Juan de Fuca Mitigation Area. This new mitigation will benefit Southern Resident killer whales, in some cases by limiting or prohibiting certain activities in certain areas during times in which Southern Resident killer whales engage in important behaviors such as feeding and migration, and in other cases, by augmenting the effectiveness of procedural mitigation measures by requiring seasonal awareness messages or limiting activities to lower sea states when visibility is higher. These new mitigation measures are described in detail in the Mitigation Measures section of this final rule.

These new measures, in combination with those included in the proposed rule, will reduce the severity of impacts to Southern Resident killer whales by reducing interference in feeding and migration that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good foraging opportunities or migration routes. Procedural mitigations that avoid the likelihood of injury, such as shutdown measures, also further reduce the likelihood of more severe behavioral responses.

The 51 takes of Southern Resident killer whales, only two of which are estimated to involve TTS, each represent a day in which one individual whale is predicted to be exposed above the behavioral harassment threshold (or in two cases, above the TTS threshold), which is discussed in detail in the Analysis and Negligible Impact Determination section of this final rule as well as the Navy's 2017 *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)* report. This means that either 51 individual whales are exposed above these thresholds on one day within a year, or some fewer number of individuals might be exposed on two or three days (but no more than 51 total exposure days so, for example, 25 individuals exposed on two days each within a year and one individual exposed on one day). Also, modeling supports the prediction that, given the movement of the animals and the characteristics of the testing and training activities, the duration of any exposure is expected to be relatively short, not more than seconds or minutes, or occasionally hours. As discussed in the Analysis and Negligible Impact Determination section of this final rule, even acknowledging the small and declining stock size of the Southern Resident DPS of killer whales (which is the same as the Eastern North Pacific Southern Resident stock under the MMPA), this low magnitude and severity of harassment effects is unlikely to result in impacts on individual reproduction or survival, let alone have impacts on annual rates of recruitment or survival of this stock. Additionally, no mortality or Level A harassment is anticipated or authorized for the Eastern North Pacific Southern Resident stock of killer whales.

In reference to the ''small numbers'' determination mentioned by the commenter, this determination does not apply to military readiness activities, including the Navy's activities in the NWTT Study Area. The National Defense Authorization Act for Fiscal Year 2004 amended section 101(a)(5) of the MMPA for military readiness activities to remove the ''small numbers'' and ''specified geographical region'' provisions, as well as amending the definition of ''harassment'' as applied to a ''military readiness activity.''

Comment 75: A commenter stated that in the 2019 Southern Resident Orca Task Force ''Final Report and Recommendations,'' the Task Force noted that ''the final decisions on training and testing activities conducted in the NWTT Study Area between November 2020 and November 2027 should eliminate impacts from current, new or additional exercises involving mid-frequency sonar, explosives and other activities with the potential to adversely affect Southern Resident killer whale recovery or incorporate enhanced mitigation measures to reduce impacts.'' The commenter asserted that the proposed incidental takes clearly conflict with recommendations from the Southern Resident Orca Task Force.

Response: NMFS and the Navy are aware of (and NMFS participated on) the 2019 Southern Resident Orca Task Force. See Comment 74 for information on mitigation measures, including measures added since publication of the proposed rule, that will reduce the number and/or intensity of expected incidental takes of Southern Resident killer whales. NMFS and the Navy have worked hard to put in place mitigation measures to ensure as much as possible that any relatively minor, short-term impacts that may occur will not affect that individual's reproduction or survival and are also practicable (*i.e.,* allow the Navy to meet its statutorily required mission along with ensuring Navy personnel safety). See Comment 74 also for discussion of the effects of the remaining expected incidental takes on Southern Resident killer whales that cannot be avoided. With the additional mitigation measures, NMFS has ''eliminate[d] impacts . . . with the potential to adversely affect Southern Resident [killer whale] recovery'' and ''incorporate[d] enhanced mitigation measures to reduce impacts.''

Comment 76: Multiple commenters stated that NMFS and the Navy must consider the highly endangered status and continuing decline of the endangered Southern Resident killer whale. The commenter stated that

NMFS must also recognize the threat of population level effects and greater than negligible impact from harm to individual killer whales. Another commenter stated that Level B harassment by Navy activities that interfere with feeding or displace killer whales from preferred foraging areas should be of significant concern, and that this cannot possibly constitute ''negligible impact'' to an already vulnerable population. Finally, a commenter noted that, given the imperiled nature of Southern Resident killer whales, the number of proposed takes threatens a significant impact on the population from the Navy's training and testing activities.

Response: NMFS has carefully considered the status of Southern Resident killer whales in its analysis, as discussed in the Description of Marine Mammals and Their Habitat in the Area of the Specified Activities sections of the proposed and final rules and the Analysis and Negligible Impact Determination section of this final rule. Additionally, this final rule includes significant mitigation, as described in the response to Comment 74, and further in the Mitigation Measures section of this final rule, including additional mitigation added since publication of the proposed rule, to minimize impacts to marine mammals, with an emphasis on further reducing both the amount and severity of any take of Southern Resident killer whales.

As also discussed in the response to Comment 74, NMFS' analysis indicates that either 51 individual whales are exposed above the behavioral harassment threshold (or in two of the 51 cases, above the TTS threshold) on one day within a year, or some fewer number of individuals might be exposed on two or three days (but no more than 51 total exposure days, so for example, 25 individuals exposed on two days each within a year). Also, modeling supports the prediction that, given the movement of the animals and the characteristics of the testing and training, the duration of any exposure is expected to be relatively short, not more than seconds or minutes, or occasionally hours. As noted in the Analysis and Negligible Impact Determination section of this final rule, even acknowledging the small and declining stock size of the Southern Resident DPS of killer whales (which is the the MMPA Eastern North Pacific Southern Resident stock), this low magnitude and severity of harassment effects is unlikely to result in impacts on individual reproduction or survival, let alone have impacts on annual rates of recruitment or survival of this stock. Additionally, no mortality or Level A harassment is anticipated or authorized for the Eastern North Pacific Southern Resident stock of killer whales.

Comment 77: A commenter noted that, according to the Navy's analysis, the Washington Inland Waters population of harbor porpoises and the Hood Canal population of harbor seals will be subjected to some of the highest estimated take, strongly suggesting that some activities with the potential to harm killer whales are concentrated in the Salish Sea and the interior waters of Puget Sound. The proposed activities overlap with areas of proposed critical habitat that NMFS itself recognizes as a ''high-use foraging area'' for Southern Resident killer whales. Another commenter stated that the lack of sensitivity to the Southern Resident killer whales' dwindling population and its need for a protected home in accordance with its endangered species status in 2005 remains a critical concern. The commenter stated that in a perfect world, training should be excluded from their critical habitat. Another commenter stated that the Navy should identify high-use areas in both inland and offshore killer whale habitat for seasonal or permanent closures to NWTT activities to minimize overlap with Southern Resident killer whales.

Response: NMFS fully considered the status of Southern Resident killer whales in its analysis, as discussed in the Description of Marine Mammals and Their Habitat in the Area of the Specified Activities sections of the proposed and final rules and the Analysis and Negligible Impact Determination section of this final rule. Potential impacts to marine mammals from acoustic and explosive sources, which are part of the Navy's planned activities in the NWTT Study Area, are analyzed in the Potential Effects of Specified Activities on Marine Mammals and their Habitat and Analysis and Negligible Impact Determination sections of the proposed and final rules, and in Section 3.4.2.1 and Section 3.4.2.2, of the 2020 NWTT FSEIS/OEIS, respectively. These effects analyses considered multiple factors, such as seasonal Southern Resident killer whale's abundance across the Study Area and the type, amount, and location of planned Navy activities.

A greater number of incidental takes are estimated for harbor porpoises and harbor seals in comparison to other species, including Southern Resident killer whales, due to their much higher abundances in the Study Area. Additionally, the impacts to harbor porpoises and harbor seals in the Inland Waters occur in areas where Southern Resident killer whales do not. The majority of locations where the Navy conducts training and testing in the Inland Waters do not overlap with areas where Southern Resident killer whales occur. For instance, most testing occurs in Hood Canal (Dabob Bay) and at Keyport; Southern Resident killer whales are not present in either location. There has not been a sighting of Southern Resident killer whales in Hood Canal since 1995 (25 years ago). The locations where there is potential overlap of training and Southern Resident killer whale habitat include Everett, Crescent Harbor, and Navy OPAREA 3 and Navy OPAREA 7.

As it did for all marine mammals, NMFS worked with the Navy during the MMPA rulemaking process to enhance mitigation measures for Southern Resident killer whales (*i.e.,* the MMPA Eastern North Pacific Southern Resident stock) to ensure the least practicable adverse impact on the stock. As described in the Mitigation Measures section, this final rule includes additional mitigation in the Puget Sound and Strait of Juan de Fuca Mitigation Area, which includes the full extent of NWTT Inland Waters and overlaps with existing ESA Southern Resident killer whale critical habitat, designed to further avoid or reduce potential impacts on Southern Resident killer whales. New mitigation in this area includes a requirement for the Navy to use the lowest active sonar source levels practical to successfully accomplish each event, a prohibition on the use of explosives during testing, and seasonal awareness messages regarding the possible presence of concentrations of Southern Resident killer whales and gray whales, among other new measures, as described in the *Assessment of Mitigation Measures for NWTT Study Area* section of this final rule and in Appendix K (Geographic Mitigation Assessment) of the 2020 NWTT FSEIS/OEIS.

The commenter also referenced proposed critical habitat for Southern Resident killer whales in inland waters; however, NMFS notes that the proposed ESA Southern Resident killer whale critical habitat is in offshore waters, rather than in the Salish Sea and Puget Sound. This final rule includes additional mitigation that overlaps with the proposed ESA Southern Resident killer whale critical habitat, including in the Marine Species Coastal Mitigation Area and the Olympic Coast National Marine Sanctuary Mitigation Area.

Comment 78: Commenters stated that NMFS should analyze the cumulative impacts over the full extent of training and testing activities that would be

authorized by this permit, and one commenter noted that the Navy's testing and training activities have already been authorized twice before, and are likely to continue into the future. A commenter stated that killer whales are long-lived and it is likely that the same individuals would be affected in multiple years. This level of ongoing, perpetual take (68 percent, as one commenter noted) to specific individuals in a small population is a significant threat, commenters assert, that could result in displacement or physical harm over extended periods of time, and should be more clearly factored into the analysis impact. Further, one commenter asserted that instances of temporary hearing loss, such as the TTS contemplated in NMFS' authorization, can be cumulative and lead to long-term hearing loss. Commenters stated that NMFS and the Navy must also consider that harassment and behavioral impacts are likely to have a compounded effect on individuals that are already in compromised condition. Research currently being compiled into a health database for the Southern Resident killer whale community shows multiple individuals have been seen in poor body condition, and compared to Northern Resident killer whales, the Southern Resident population has lower survival and reproductive rates. The commenters asserted that given the many stresses already faced by this endangered population, ongoing, repeated, and cumulative impacts from NWTT activities could place additional stress on both individuals already in poor health, perhaps even leading to mortality, as well as on the population as a whole. Commenters asserted that NMFS has thus failed to show that these impacts are negligible under the MMPA.

Response: NMFS has analyzed the cumulative impacts of the Navy's training and testing activities over the full seven-year extent of the regulations. Further, NMFS has fully considered the status of Southern Resident DPS killer whale (which is the same as the Eastern North Pacific Southern Resident stock under the MMPA) and the compromised health of some of the individuals of that stock in its analysis and negligible impact determination, as described in the Analysis and Negligible Impact Determination section of this final rule. No mortality or Level A harassment is anticipated or authorized for the Southern Resident DPS of killer whales. The 51 takes of Southern Resident killer whales, only two of which are estimated to involve TTS, each represent a day in which one individual whale is predicted to be exposed above the behavioral harassment threshold, which is described in detail in the Analysis and Negligible Impact Determination section of this final rule as well as the Navy's 2017 *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)* report. This means that either 51 individual whales are exposed above this threshold on one day within a year, or some fewer number of individuals might be exposed on two or three days (but no more than 51 total exposure days so, for example, 25 individuals exposed on two days each within a year and one individual exposed on one day). Also, modeling supports the prediction that, given the movement of the animals and the characteristics of the testing and training activities, the duration of any exposure is expected to be relatively short, not more than minutes, or occasionally hours. Even if these impacts occurred to an individual of compromised health, the behavioral impacts would not be expected to impact reproduction or health, much less result in a mortality, given the low severity and duration of effect that any individual killer whale is expected to experience within a year. Similarly, while significant repeated exposure to noise levels associated with TTS could, in certain circumstances (*e.g.,* numerous exposures, long durations, with no time for recovery in between exposures) lead to PTS, there is no reason to expect that the number (no more than a single instance of TTS to either of the two individuals taken within a year) and nature (low level) of the exposures anticipated from Navy training and testing activities would lead to PTS for Southern Resident killer whales.

Further, as discussed in detail in the Mitigation Measures section of this rule and the response to Comment 74, this rule includes extensive mitigation for Southern Resident killer whales that will reduce both the probability and severity of impacts to this stock, including additional measures that have been added since the proposed rule. Even acknowledging the small and declining stock size of the Southern Resident DPS of killer whales, the low magnitude and severity of effects is unlikely to result in impacts on individual reproduction or survival, let alone have impacts on annual rates of recruitment or survival of this stock. Further, given the absence of any expected impacts on individual fitness or annual rates of recruitment or survival, there is no possibility that the impacts of the authorized take could accrue over the seven-year period of the rule in a manner that could exceed a negligible impact. Last, we note that the MMPA does not prohibit the authorization of incidental take for activities that continue in an area, as long as the necessary findings have been made within the period of the requested authorization.

Comment 79: A commenter stated that the proposed Navy activities do not account for the Southern Resident killer whales' seasonal behaviors. Another commenter stated that additional mitigation and avoidance measures should include establishing seasonal limitations on the use of sonars in traditional Southern Resident killer whale foraging areas.

Response: Seasonal behaviors and locations of marine mammals, including Southern Resident killer whales, were accounted for in both the effects analysis (*e.g.,* density estimate input into the modeling of take) and in consideration and inclusion of mitigation measures (*e.g.,* geographic mitigation measures targeted at protecting Southern Resident killer whales) in the NWTT Study Area. This final rule includes extensive mitigation for Southern Resident killer whales, including mitigation that is seasonally applicable, such as required seasonal awareness notification messages that the Navy will issue for the Puget Sound and Strait of Juan de Fuca Mitigation Area and the Marine Species Coastal Mitigation Area during times when Southern Resident killer whales and gray whales may be present in the area in higher concentrations. The rule includes seasonal restrictions on explosive Mine Countermeasure and Neutralization Testing in the Marine Species Coastal Mitigation Area. This final rule also includes mitigation areas in which mitigation requirements limit or prohibit the use of sonar during certain activities. Seasonal and year-round mitigation measures, including those that have been added since publication of the proposed rule, and their benefits to marine mammals (including Southern Resident killer whales specifically) are discussed further in the response to Comment 74 and the Mitigation Measures section of this final rule, as well as Appendix K (Geographic Mitigation Assessment) of the 2020 NWTT FSEIS/OEIS.

Comment 80: A commenter stated that increasing the Navy's testing and training activities at this time is counter to what the endangered Southern Resident killer whales need to have a chance at recovery. Without bold and immediate actions, the Southern Resident killer whales are likely to go extinct. The commenter stated that

everything that can be done now to protect the Southern Resident killer whales is critical. Despite being listed under the ESA for nearly 15 years, this unique population is not recovering and is continuing to decline. The commenter further stated that it is obvious that status quo actions, including the Navy's training and testing activities, are not serving the Southern Resident killer whales. In a time when everyone should be acting to address and decrease threats facing the population, including reducing noise and disturbance, the Navy's proposed activities increase the risks from ocean noise, vessel strikes and disturbance, potential direct harm and injury to Southern Resident killer whales, and displacement from preferred habitat. The commenter stated that given the Southern Resident killer whale's highly endangered status and continuing decline, the Navy should adjust its training and testing activities to reduce impacts and increase protections for these iconic animals.

Response: The Navy has conducted active sonar training and testing activities in the NWTT Study Area for decades, and there is no evidence that routine Navy training and testing has negatively impacted Southern Resident killer whale populations in the Study Area. Based on the best available science summarized in the 2020 NWTT FSEIS/OEIS Section 3.4.3.4 (Summary of Monitoring and Observations During Navy Activities Since 2015), long-term consequences for Southern Resident killer whales, including for the seven-year period of this rule, are unlikely to result from Navy training and testing activities in the Study Area.

As discussed in the Mitigation Measures section of this final rule, elsewhere in this section, and in Chapter 5 (Mitigation) of the 2020 NWTT FSEIS/OEIS, the Navy will implement extensive mitigation to avoid or reduce potential impacts from the NWTT activities on Southern Resident killer whales. These mitigation measures include mitigation areas that restrict certain activities in places and during times that are particularly important to Southern Resident killer whales (and other marine mammals). One of these mitigation areas, the Puget Sound and Strait of Juan de Fuca Mitigation Area, encompasses the entire extent of NWTT Inland Waters, including Southern Resident killer whale ESA-designated critical habitat. New mitigation measures in the Puget Sound and Strait of Juan de Fuca Mitigation Area will result in training and testing activities being conducted in NWTT Inland Waters only when necessitated by mission-essential training or testing program requirements. With implementation of the new mitigation measures included in this final rule, we do not anticipate any take of Southern Resident killer whales in NWTT Inland Waters due to NWTT training and testing activities. This final rule also includes additional mitigation measures for Southern Resident killer whales in other mitigation areas, including the Marine Species Coastal Mitigation Area and the Olympic Coast National Marine Sanctuary Mitigation Area. Please refer to the Mitigation Measures section of this final rule for further discussion of the required mitigation measures in the NWTT Study Area.

Additionally, NMFS considered the status of Southern Resident killer whales in its analysis, as discussed in the Analysis and Negligible Impact Determination section of this final rule. Modeling supports NMFS' conclusion that, given the movement of the animals and the characteristics of the testing and training, the duration of any exposure of a Southern Resident killer whale is expected to be relatively short, not more than minutes, or occasionally hours. As noted in the Analysis and Negligible Impact Determination section and the response to Comment 78, even acknowledging the small and declining stock size of Southern Resident killer whales, this low magnitude and severity of harassment effects is unlikely to result in impacts on individual reproduction or survival, let alone have impacts on annual rates of recruitment or survival of this stock. Additionally, no mortality or Level A harassment is anticipated or authorized for the Eastern North Pacific Southern Resident stock.

Comment 81: A commenter stated that with the apparent loss of three whales last summer, Southern Resident killer whales appear to have a population of just 73 whales—the lowest population size in more than 40 years. Given this declining population, the loss of even one more whale could greatly undermine recovery efforts for decades. The commenter stated that NMFS does not consider the most up-to-date information on the Southern Resident killer whale population. The commenter stated that while NMFS purports to rely on the ''best available science'' in developing stock numbers, NMFS actually assesses impacts based on a potentially outdated population size of 75, and does not note the data indicating the population may sit at just 73 whales. As a result, NMFS fails to ensure its reliance on the best and most-up-to-date scientific information, which could result in NMFS underestimating the harm of the Navy's activities on this vulnerable population. With such a small and shrinking population, the impact of each take is amplified within the population.

Response: NFMS relied on the 2019 Stock Assessment Reports (published in August 2020) for the latest abundance information for all stocks, except the inland water stocks of harbor seals, as the stock assessments are outdated and did not reflect the best available science, as described in this final rule. The 2019 Southern Resident killer whale stock assessment indicates that the minimum population estimate (Nmin) for the Eastern North Pacific Southern Resident stock of killer whales is 75 animals. The stock assessment indicates that this estimate serves as both the Nmin, as well as the best estimate of abundance because the assessment is a ''direct count of individually identifiable animals [and] it is thought that the entire population is censused every year.'' Therefore, NMFS based its analysis on this population estimate, as it reflects the best available science given that it is the most recent, peer-reviewed literature that NMFS is aware of. Separately, we note that two calves have been born in 2020 (Orca Network, 2020) and are not included in the 2019 SAR.

Comment 82: A commenter stated that additional datasets are available for killer whale response to noise. For example, in Bain and Dahlheim's (1994) study of captive killer whales exposed to band-limited white noise in a band similar to that of mid-frequency sonar at a received level of 135 dB re 1uPa, abnormal behavior was observed in 50 percent of the individuals. This is far lower than the level observed in bottlenose dolphins. In addition, Bain (1995) observed that 100 percent of wild killer whales appeared to avoid noise produced by banging on pipes (fundamental at 300 Hz with higher harmonics) to 135 dB re 1uPa contour. This indicates the difference between wild and captive killer whales (non-zero risk in captive marine mammals might correspond to 100 percent risk in wild individuals of the same species), as well as implying that risk of 100 percent may occur by 135 dB re 1uPa for this genus in the wild. The commenter stated that while more emphasis needs to be placed on the captive-wild difference, there are also species differences, like Dall's porpoises, harbor seals, and California sea lions being relatively noise tolerant, and harbor porpoises, killer whales, and Steller sea lions being relatively noise intolerant.

The commenter stated further that killer whales responded to vessel traffic at around 105–110 dB with conspicuous

behavioral changes such as increased rates of threat displays and evasive swimming patterns, although the commenter provided no scientific source for this assertion. The commenter stated that subtle behavioral changes, such as inhibition of foraging behavior, were observed at lower levels. While inhibition of foraging is a Level B take, in a food limited population, inhibition of foraging is likely to result in increased mortality and/or reduced recruitment.

Response: It is clear in some parts of their comment that the commenter is referring to the Phase I and II behavioral criteria, *i.e.,* criteria that we used in previous rules and not this one, and therefore some of the comment is inapplicable. In this rule, NMFS and the Navy have incorporated emergent best available science into new BRFs for Phase III, and this rule specifically, that are described in the technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)* (U.S. Department of the Navy, 2017a) available at *www.nwtteis.com,* including data on exposures to wild killer whales.

The Phase III behavioral criteria appropriately incorporate data from behavioral response studies that were designed to record behavioral observations and contained detailed data on reactions at specific received sound levels. Specifically, data needed to meet both of the following criteria to be used in the quantitative derivation: (1) Observations of individual/group animal behavior were related to known or estimable received levels, and (2) The study was primarily designed to observe behavioral changes during controlled exposures or actual Navy activities (*i.e.,* monitoring). The data referenced in this comment (Bain, 1995 and Bain and Dahlheim, 1994) were not specifically included in the criteria because they do not meet either of these two criteria for BRF inclusion and, further, we note that the sound source referenced is a notably lower frequency than the majority of the Navy's sources used for training and testing, and the signal would be characterized as an impulse, rather than non-pulse like active sonar is. The best available science is documented in the technical report referenced above and Section 3.4.2.1.1.5 (Behavioral Reactions) of the 2020 NWTT FSEIS/OEIS. Nonetheless, the BRFs used in the final rule predict that close to 20 percent of odontocetes exposed to received levels of 135dB will respond in a manner that would qualify as a take, so the data presented by the commenter is not at odds with the criteria used here. As shown in the technical report, the Navy considered how captive and wild animals may respond differently to acoustic stressors when analyzing response severity. NMFS has carefully reviewed the Navy's criteria, *i.e.,* BRFs and cutoff distances for these species, and agrees that they are the best available science and the appropriate method to use at this time for determining impacts to marine mammals from sonar and other transducers and for calculating take and to support the determinations made in this rule.

NMFS explained in the response to Comment 38 why responses to vessel noise alone are unlikely to qualify as Level B harassment and further described that Navy vessels are also much quieter than typical vessels because they are designed that way to evade detection by adversaries.

Comment 83: A commenter stated that the Navy's characterization of the killer whale dataset [used in the behavioral harassment thresholds] is incorrect. The commenter stated that the Navy indicates the effects observed in the presence of mid-frequency sonar in Haro Strait were confounded by the presence of vessels. However, the effects of vessels on killer whales have been extensively studied, both prior to and subsequent to exposure. The commenter asserted that behavioral responses attributed to mid-frequency sonar are qualitatively different than those observed to vessels alone. The commenter further stated that while the observations were based on a small sample, they were not inconsistent. The sonar signal was blocked from reaching the whales with full intensity by shallow banks or land masses during three segments of the observation period. The commenter said that the ''inconsistencies'' can be attributed to differences in behavior depending on whether there was a direct sound path from the USS *Shoup* (the vessel emitting sonar in the vicinity) to the whales. The commenter stated that there was extensive study of this population prior to exposure, as well as extensive post-exposure monitoring.

The commenter also stated that the Navy incorrectly concludes that additional datasets are unavailable. In addition to the three data sets the Navy relies upon; captive cetaceans, killer whales, and right whales, they suggest that the data set illustrating the use of acoustic harassment and acoustic deterrent devices on harbor porpoises illustrates exclusion from foraging habitat. Data are also available showing exclusion of killer whales from foraging habitat, although additional analysis would be required to assess received levels involved. The devices which excluded both killer whales and harbor porpoises had a source level of 195 dB re 1μPa, a fundamental frequency of 10 kHz, and were pulsed repeatedly for a period of about 2.5 seconds, followed by a period of silence of similar duration, before being repeated. Devices used only with harbor porpoises had a source level of 120–145 dB re 1μPa, fundamental frequency of 10 kHz, a duration on the order of 300 msec, and were repeated every few seconds. Harbor porpoises, which the Navy treats as having a B+K value of 120 dB re 1μPa (with A large enough to yield a step function) in the Atlantic Fleet Active Sonar Training (AFAST) DEIS, 45 dB lower than the average value used in the Hawaii Range Complex (HRC) SDEIS, may be representative of how the majority of cetacean species, which are shy around vessels and hence poorly known, would respond to mid-frequency sonar. Even if harbor porpoises were given equal weight with the three species used to calculate B+K, including them in the average would put the average value at 154 dB re 1μPa instead of 165 dB re 1μPa.

Response: Regarding the datasets used to develop behavioral criteria, the commenter is referring to the Phase I and II behavioral criteria, *i.e.,* criteria that we used in previous rules and not this one, and therefore much of the comment is inapplicable. In this rule, NMFS and the Navy incorporated emergent best available science into new BRFs that are described in the technical report titled Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III) (U.S. Department of the Navy, 2017a), available at *www.nwtteis.com.*

Regarding the Haro Strait data, in May 2003, killer whales in Haro Strait, Washington, exhibited what were believed by some observers to be aberrant behaviors, during which time the USS *Shoup* was in the vicinity and engaged in mid-frequency active sonar operations. Sound fields modeled for the USS *Shoup* transmissions (Fromm, 2009; National Marine Fisheries Service, 2005; U.S. Department of the Navy, 2004) estimated a mean received SPL of approximately 169 dB re 1 μPa at the location of the killer whales at the closest point of approach between the animals and the vessel (estimated SPLs ranged from 150 to 180 dB re 1 μPa). However, attributing the observed behaviors during that particular exposure to any one cause is problematic given there were six nearby whale watch vessels surrounding the pod, and subsequent research has demonstrated that ''Southern Residents

modify their behavior by increasing surface activity (breaches, tail slaps, and pectoral fin slaps) and swimming in more erratic paths when vessels are close'' (National Oceanic and Atmospheric Administration, NOAA Fisheries, 2014). Data from this study were not used in the Phase III BRFs because they did not meet the criteria to be used in the quantitative derivation (see response to Comment 82 for description of criteria). Nonetheless, the BRFs used in this 2020–2027 NWTT rule indicate a likelihood of approximately 30 to 95 percent that the estimated received levels during this exposure would be associated with Level B harassment by behavioral disturbance.

Regarding the harbor porpoise data, the data referenced in this comment was a study of acoustic harassment devices and do not meet either criteria for BRF inclusion. Further, NMFS and the Navy continue to use a behavioral harassment threshold for harbor porpoises that predicts that 100 percent of harbor porpoises exposed at levels above 120 dB will respond in a manner that qualifies as Level B harassment, which encompasses the results the commenter references. However, we disagree that harbor porpoise data should be combined with other odontocete data to create one behavioral harassment threshold for odontocetes, given the extensive literature documenting the heightened sensitivity of harbor porpoises to sound. The best available science is documented in *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)* (U.S. Department of the Navy, 2017a), available at *www.nwtteis.com,* and Section 3.4.2.1.1.5 (Behavioral Reactions) of the 2020 NWTT FSEIS/OEIS.

Comment 84: A commenter stated that NMFS should address problems in the proposed rule, which the commenter asserts underestimate and discount potential take of Southern Resident killer whales, and reconsider its negligible impact determination for the population. The commenter asserted that NMFS' conclusory statement that the Navy's activities are ''unlikely to result in impacts on individual reproduction or survival'' or cause greater than negligible impacts on the Southern Resident killer whale population is arbitrary and capricious. The commenter stated that conclusion is based in part on the premise that the Navy would cause as many as 51 Southern Resident killer whale takes each year, a number that, like the Navy's original calculation of two annual takes, makes little sense given that the whales travel together in pods, making it far more likely that every member of the pod would be affected. Nor does it make sense that take estimates for Washington Inland Waters harbor porpoises and Hood Canal harbor seals would number in the hundreds of thousands, while Southern Resident killer whale takes account for a handful. The commenter argued that the agency has provided little rationale for why the abandonment or significant alteration in vital activities that these take numbers represent would have a negligible impact on Southern Resident killer whales, given the low vital rates that currently prevail in this endangered, declining population.

In addition, the commenter stated that although some form of command approval is required before mid-frequency sonar is used in the Salish Sea, this requirement does little to ensure that such activities do not occur. The commenter also stated that NMFS has grossly overstated the effectiveness of the Navy's mitigation in preventing mortalities.

The commenter additionally states that mitigation areas for Southern Resident killer whales fail to include the whales' offshore habitat, where most of the agency's estimated takes are expected to occur.

Response: The basis for NMFS' conclusions about the effects of the estimated, and now authorized, Level B harassment takes of Southern Resident killer whales, both on affected individuals and on the stock's annual rates of recruitment and survival, has been fully and carefully explained in the proposed rule and again in this final rule. The Navy consulted with Southern Resident killer whale experts in the development of the density layers used for modeling and the acoustic modeling process used in this rule accounts for the population occurring in 3 large pods, composed of the appropriate individual numbers of killer whales. However, despite occurring in pods, not all animals exposed to similar sound levels will respond in the exact same manner. The BRFs take into account individual responses, and were developed from data that included real exposures of wild killer whales to Naval sonar sources. Further, Navy training and testing activities predominantly occur in portions of the NWTT Study Area inland waters where Southern Resident killer whales rarely occur (*e.g.,* Hood Canal, Dabob Bay, Bremerton, and Keyport). Also, the density is low overall for Southern Resident killer whales, so it is much less likely that a pod will be encountered. Also while Southern Resident killer whales travel in pods, individuals are spread out over a fairly large area and while more than one individual might be taken sometimes if a Navy activity is encountered, it is far less likely that an entire pod would be exposed at levels resulting in take. Please refer to the response to Comment 74 for further discussion of the implication of the 51 authorized takes of Southern Resident killer whales.

We also note that the commenter is incorrect that the mitigation areas in the rule fail to include the whale's offshore habitat. The proposed included mitigation that overlaps with the proposed ESA Southern Resident killer whale critical habitat (in offshore waters), including in the Marine Species Coastal Mitigation Area and the Olympic Coast National Marine Sanctuary Mitigation Area, and the mitigation in those areas has been expanded in the final rule. Please see the Mitigation Measures section for a full description of the mitigation required in these areas.

Regarding the idea that NMFS has grossly overstated the effectiveness of the Navy's mitigation in preventing mortalities, we note that no mortality was modeled, even without consideration of mitigation. Nonetheless, this final rule includes extensive mitigation for Southern Resident killer whales as discussed in the Mitigation Measures section and in the response to Comment 74. Please refer to the Mitigation Measures section of this final rule for a full discussion.

Regarding Command authority, requirements for naval units to obtain approval from the appropriate designated Command authority prior to conducting active sonar pierside maintenance or testing with hull-mounted mid-frequency active sonar will elevate the situational and environmental awareness of respective Command authorities during the event planning process. Requiring designated Command authority approval provides an increased level of assurance that mid-frequency active sonar is a required element for each event. Such authorizations are typically based on the unique characteristics of the area from a military readiness perspective, taking into account the importance of the area for marine species and the need to mitigate potential impacts on Southern Resident killer whales (and other marine mammals, such as gray whales) to the maximum extent practicable. Additionally, the Navy has reported to NMFS that, where included in past NWTT authorizations, the requirement for Navy personnel to gain permission from the appropriate command

authority to conduct activities in a particular mitigation area has resulted in the activities not being conducted in the designated mitigation areas.

Please refer to Comment 77 for a full explanation of the higher take numbers for Washington Inland Waters harbor porpoises and Hood Canal harbor seals in comparison to Southern Resident killer whales.

Other Comments

Comment 85: A commenter questioned how many incidental injuries and deaths would it take before NOAA and the Navy recognize the dire situation in which they are putting marine mammals. The commenter further questioned what would it take for NOAA to decline the Navy's request for yet another permit in which hundreds and thousands of animals are slated to be hurt or die.

Response: Through the MMPA, Congress has determined that an applicant, including a federal agency like the Navy, can request and receive marine mammal incidental take authorization provided all statutory findings are made (and all other legal requirements are met). For the Navy's application, NMFS has determined, among other things, that the estimated take will have a negligible impact on each of the affected species or stocks and has included the required mitigation, monitoring, and reporting measures. Therefore it is appropriate to authorize the incidental take. As discussed elsewhere in this section and the Mitigation Measures section of the rule, the final rule includes extensive mitigation measures to reduce impacts to the least practicable level. We note that the commenter overstates the scale of authorized injury and mortality and, further, that the rule includes a robust suite of mitigation measures to lessen the probability and severity of impacts on marine mammals.

Comment 86: A commenter stated that the Navy is entitled to consult with the Office of National Marine Sanctuaries to gain access to National Marine Sanctuary waters, in this case the Olympic Coast National Marine Sanctuary. The commenter asserted that the authority to do so does not, however, justify its position in designing the NWTT Study Area to include an offshore portion of these waters. The meaning of the word ''sanctuary'' has been compromised beyond recognition by federal government agencies, but that does not mean the Navy should continue to disregard the intent of the government in establishing these waters to protect marine animal and plant life. The commenter stated that there are no circumstances under which it should be permissible to carry out military training exercises in a designated federal marine sanctuary. Another commenter stated that the Sanctuary would continue to be unacceptably damaged by the Navy's training activities and that the activities cited by the Navy would cause long-term damage to the Sanctuary ecosystem which NOAA is supposed to protect as its administrator. Another commenter stated that the Navy needs to clear out of the Olympic Coast National Marine Sanctuary, permanently.

Response: Regulations for the Olympic Coast National Marine Sanctuary at 15 CFR part 922, subpart O specifically address the conduct of Department of Defense military activities in the sanctuary, though we disagree with one commenter's suggestion that the Navy was intentionally targeting the Sanctuary. In addition, both NMFS and the Navy consulted with NOAA's Office of National Marine Sanctuaries under section 304(d) of the National Marine Sanctuaries Act regarding their actions that had the potential to injure sanctuary resources in the Olympic Coast National Marine Sanctuary. We disagree with the commenter's assertion that the Navy's activities will cause long-term damage to the Sanctuary ecosystem and refer the reader to the documents associated with the consultation, which may be found at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.* Comments about the Navy's activities generally in national marine sanctuaries are beyond the scope of this rule.

Comment 87: A commenter stated that NMFS has a federal trust responsibility to Indian Tribes and therefore a heightened duty to apply the MMPA with special care and to protect and preserve marine species and areas of interest and concern for those Tribes to which the federal trust responsibility applies. Therefore, when faced with several alternatives for mitigation, for example, a commenter stated in a related comment that NMFS ''must choose the alternative that is in the best interests of the Indian tribe.''

A commenter stated that the trust responsibility serves several purposes in this context. First, it requires NMFS to be especially cognizant of Tribes' needs as they pertain to their cultural ways of life and engage in meaningful government-to-government consultation concerning the proposed rule. Second, it requires NMFS to ensure that its application of the MMPA incidental take provisions avoids harm to Tribes' cultural ways of life, including subsistence, that are dependent upon culturally important species, places, and ecosystems and protects the species necessary for the Tribes' well-being and survival.

The commenter stated that NMFS' obligation to Indian Tribes applies to all Tribes affected by the Navy's NWTT activities, including the ten federally recognized member Tribes of the InterTribal Sinkyone Wilderness Council, whose territories are situated within and offshore from Northern California and who maintain important cultural connections with their traditional coastal ecosystems and migrating marine mammals. The Sinkyone Council's member Tribes are: Cahto Tribe of Laytonville Rancheria; Coyote Valley Band of Pomo Indians; Hopland Band of Pomo Indians; Pinoleville Pomo Nation; Potter Valley Tribe; Redwood Valley Band of Pomo Indians; Robinson Rancheria of Pomo Indians; Round Valley Indian Tribes; Scotts Valley Band of Pomo Indians; and Sherwood Valley Rancheria of Pomo Indians. The commenter noted that the ten Northern California Tribes are in formal government-to-government consultation with the Navy regarding Tribal opposition to the Navy's training and testing activities, and the NWTT's impacts to marine mammals and the Tribes' cultural ways of life.

Response: NMFS is fully aware of and sensitive to its federal trust responsibilities to all Indian Tribes. Consistent with federal directives on consultation and coordination with Indian Tribal governments, NMFS has engaged in government-to-government discussions with the Northern California Tribes of the InterTribal Sinkyone Wilderness Council, and is discussing concerns directly with the member Tribes and Council staff. The Navy is also engaged in government-to-government consultation with the 10 Northern California Tribes of the InterTribal Sinkyone Wilderness Council (as well as other Tribes) on its training and testing activities, including impacts on marine mammals.

Also, as part of the MMPA rulemaking process, NMFS sought information on how the Navy's activities could affect Alaskan Natives' subsistence use in southeast Alaska. NMFS has added a mitigation measure in this final rule to minimize potential impacts on subsistence hunters from four Alaskan Native communities that are also federally recognized Tribes. See the Subsistence Harvest of Marine Mammals section for more information.

Comment 88: A commenter stated that NMFS proposes to authorize take of multiple island-associated populations, most of unknown population size and many presumably with small or limited ranges. To justify the authorization notwithstanding the lack of robust mitigation measures, the commenter stated that the agency makes a number of assumptions that are not supported by the best available science.

Response: This comment is not applicable to this rulemaking as there are no ''island-associated populations'' impacted by the Navy's NWTT activities or occurring within the NWTT Study Area.

Comment 89: A commenter questioned whether any ethical considerations have gone into the issuance of these authorizations for the United States government to harass and injure marine mammals for the past 10 years, and another commenter referenced Occupational Safety and Health Administration standards for human noise exposure limits and suggested parallel ''pain thresholds'' for killer whales. The commenter asserted that although the MMPA requires mitigation strategies in order to authorize incidental takings, the Navy is violating this provision by requiring a constant authorization to operate in the same location. The commenter stated that the Navy's activities are never-ending and now the Navy asks for yet another seven-year extension of the same rule that will allow the Navy to test its sonar, explosives, and vessels in the same area of water that will impact the same populations of marine mammals that have been subjected to these same tests and disturbances for a decade. The commenter questioned how the Navy can continue to justify repeating their activities in the same location without producing any new results.

The commenter stated that there appears to be no end to the Navy's testing and no end to the Navy's reluctance to unearth credible evidence of the facts surrounding the takings that have and will occur in the NWTT area. The commenter questioned the factual ground on which NMFS can now grant the Navy continued permission to cause injury and death to protected marine mammals. The commenter stated that in this circumstance, the Navy should be denied authorization because it has failed to show that past test activities do not provide a sufficient basis to achieve its military readiness. In the absence of such a showing, the Navy cannot credibly claim that it has pursued the least practical method. Another commenter noted that proximity to Naval bases for the convenience of sailors and their families, or interesting underwater topography taken as a rationale for continuing exercises does not warrant even one ''take'' of Southern Resident killer whales.

Response: The MMPA provides for the authorization of incidental take caused by activities that will continue in an area. The law directs NMFS to process adequate and complete applications for incidental take authorization, and issue the authorization provided all statutory findings and requirements, as well as all associated legal requirements, are met. The MMPA does not require the Navy to prove anything regarding whether previous activities were sufficient for achieving military readiness, or to justify why they have located their activities where they have (except inasmuch as it is considered in the least practicable adverse impact analysis for geographic mitigation considerations). Likewise, section 101(a)(5)(A) of the MMPA does not include standards or determinations for the agency to consider the ethical and other factors raised by the commenters.

As described in the rule, NMFS is required to evaluate the specified activity presented by the Navy in the context of the standards described in this final rule, and NMFS has described how these standards and requirements have been satisfied throughout this final rule.

Both this rule and the prior rules for training and testing activities in the NWTT Study Area have required monitoring to report and help better understand the impacts of the Navy's activities on marine mammals. The Navy has conducted all monitoring as required, and the associated Monitoring Reports may be viewed at: *https://www.navymarinespeciesmonitoring.us/reporting/pacific/.*

Comment 90: A commenter stated that the Navy provides no factual basis from which a rational determination can be made about species population and their geographical location. Indeed, the commenter asserts that it is pure speculation to conclude that any figure cited by the Navy is a ''small'' number of animals. However, one thing is certain according to the commenter. The Navy has had the opportunity and motivation to seek the needed information, and it has failed to do so. The commenter questioned how many incidental injuries and deaths it would take before the Navy's proposed activities were considered to be too great a loss for the animal species involved. In the absence of any credible facts, NMFS cannot make a rational determination that the Navy's activities will affect only a small number of any species and that the outcome of the activities will not adversely affect geographically diverse animal populations.

Response: The ''small numbers'' determination discussed by the commenter does not apply to military readiness activities, including the Navy's activities in the NWTT Study Area. The National Defense Authorization Act for Fiscal Year 2004 amended section 101(a)(5) of the MMPA for military readiness activities to remove the ''small numbers'' and ''specified geographical region'' provisions, as well as amending the definition of ''harassment'' as applied to a ''military readiness activity.''

Comment 91: A commenter stated that NMFS should operate in full transparency and good faith toward our fellow Washingtonians and reopen the comment period. The comment period should be, at least, 60 days with plenty of notice to the communities impacted, thus allowing them to give testimony. Please give proper notification to the public and to all who made comments on the May 29, 2019, Navy EIS. The Navy should be able to provide those names and addresses. The commenter specifically requested that NMFS include them on its list for notification for public comment. Another commenter stated that NMFS failed to notify the public and other governmental agencies regarding the authorization process. The lack of transparency has not allowed for NEPA-mandated public comment.

Response: NMFS provided full notice to the public in the **Federal Register** on two opportunities to provide information and comments related to this rulemaking: The notice of receipt of the Navy's application for MMPA incidental take authorization (84 FR 38225, August 6, 2019) and the notice of NMFS' proposed incidental take rule (85 FR 33914, June 2, 2020). NMFS provided 30 and 45 days, respectively, for the public to comment and provide input on those documents. These notices and the associated comment periods satisfy the requirements of the MMPA and our implementing regulations. Further, interested persons also had the opportunity to comment through the NEPA process on, among other things, the Notice of Intent to Prepare a Supplemental Environmental Impact Statement for Northwest Training and Testing and the Notice of Availability of the NWTT Draft Supplemental Environmental Impact Statement/Overseas Environmental Impact Statement for both this MMPA

rulemaking and the Navy's activities. Given these opportunities for public input and the need to ensure that the MMPA rulemaking process was completed in the time needed to ensure coverage of the Navy's training and testing activities, NMFS determined that additional time for public comment was not possible. NMFS has practiced full and appropriate transparency under both the MMPA and NEPA.

Changes From the Proposed Rule to the Final Rule

Between publication of the proposed rule and development of the final rule, the Navy has decreased their activity levels for some training activities. As a result, the annual and/or seven-year take estimates for some species have changed (all decreases with the exception of *Kogia,* which increased by 1 annually and over seven years). Additional mitigation measures have also been added, including the identification of a new mitigation area, additional requirements in existing areas, and new procedural measures. Additionally, harbor seal abundance estimates for inland water stocks have been refined.

The Navy has reduced the number of planned Mine Neutralization-Explosive Ordnance Disposal (EOD) (Bin E3) training events from 12 to 6 annually, and 84 to 42 over the seven-year period of the rule. The Navy also reduced the number of Gunnery Exercise (Surface-to-Surface)- Ship (GUNEX [S–S]-Ship) training exercises from 90 to 34 annually, and 504 to 238 over the seven-year period, counting only the explosive events, as noted in Table 3. Additionally, the Navy added bin HF1 to the Submarine Sonar Maintenance training activity. (This change does not increase total HF1 hours, but redistributes them to include use of the source types identified in bin HF1) Finally, the Navy clarified the number of planned Mine Countermeasure and Neutralization Testing events in the offshore area. The final rule reflects 2 events annually, and 6 events over the seven-year period, as one of the 3 annual events noted in the proposed rule does not include acoustic components. This change resulted in decreases in estimated take over seven years for the following species: fin whale, sei whale, minke whale, humpback whale, gray whale, northern right whale dolphin, Pacific white-sided dolphin, Risso's dolphin, *Kogia* whales, Dall's porpoise, harbor porpoise, California sea lion, Steller sea lion, harbor seal, and northern elephant seal. Revised take estimates are reflected in Table 32 and Table 33. This change in activity also resulted in a reduction in HF4 sonar hours associated with Mine Countermeasure and Neutralization testing; however, this reduction is not shown quantitatively.

In addition, the take estimates for some species during both training and testing have been updated, and are reflected in Table 32 (Training) and Table 33 (Testing). For all updated species except *Kogia,* the maximum annual take remained the same, but the seven-year total decreased. For *Kogia* Spp., takes during training activities decreased by 1 both annually, and over the seven-year period of the rule. During testing activities, annual takes by Level B harassment decreased by 1 and annual takes by Level A harassment increased by 1. Over the seven-year period of the rule, takes by Level B harassment during testing activities decreased by 1.

Specifically regarding the harbor seal density estimates, since publication of the proposed rule, additional information and analyses have been used to refine the abundance estimate of the Washington Northern Inland Waters, Hood Canal, and Southern Puget Sound stocks of harbor seal. These changes are discussed in greater detail in the *Group and Species-Specific Analyses* section of this rule, and the updated abundance estimates are used in our analysis and negligible impact determination.

Regarding the additional mitigation measures, a new mitigation area, the Juan de Fuca Eddy Marine Species Mitigation Area has been added. No mine countermeasure and neutralization testing will be conducted in this area, and the Navy will conduct no more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in this new Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined. Please see the *Mitigation Areas* section for additional information on the new Juan de Fuca Eddy Marine Species Mitigation Area.

New mitigation requirements also have been added in the following mitigation areas: The Marine Species Coastal Mitigation Area, the Olympic Coast National Marine Sanctuary Mitigation Area, and the Puget Sound and Strait of Juan de Fuca Mitigation Area. The *Mitigation Areas* section describes the specific additions in these mitigation areas since publication of the proposed rule and discusses additional information about all of the mitigation area requirements.

Additionally, new procedural mitigation requires the Navy to conduct Mine Countermeasures and Neutralization during daylight hours and in Beaufort sea state conditions of 3 or less.

This final rule also includes new discussion of monitoring projects being conducted under the 2020–2027 rule. These planned projects include research on the offshore distribution of Southern Resident killer whales in the Pacific Northwest (ongoing and planned through 2022), and characterizing the distribution of ESA-listed salmonids in the Pacific Northwest (ongoing and planned through 2022). Please see the *Past and Current Monitoring in the NWTT Study Area* section for additional details about these planned projects.

Finally, NMFS has added information discussing the nature of subsistence activities by Alaskan Natives in the NWTT Study Area in the Subsistence Harvest of Marine Mammals section of this final rule. NMFS also added a requirement for the Navy to continue to notify the following Alaskan Native communities of Navy operations that involve restricting access in the Western Behm Canal at least 72 hours in advance through issuance of its Notices to Mariners to minimize potential impact on subsistence hunters: Central Council of the Tlingit and Haida Indian Tribes, Ketchikan Indian Corporation, Organized Village of Saxman, and Metlakatla Indian Community, Annette Island Reserve.

Description of Marine Mammals and Their Habitat in the Area of the Specified Activities

Marine mammal species and their associated stocks that have the potential to occur in the NWTT Study Area are presented in Table 9. The Navy anticipates the take of individuals of 28 [3] marine mammal species by Level A harassment and Level B harassment incidental to training and testing activities from the use of sonar and other transducers and in-water detonations. In addition, the Navy requested authorization for three takes of large whales by serious injury or mortality from vessel strikes over the seven-year period. Currently, the Southern Resident killer whale has critical habitat designated under the Endangered Species Act (ESA) in the NWTT Study Area (described below).

[3] The total number of species was calculated by counting Mesoplodont beaked whales as one species for the reasons explained in the Baird's and Cuvier's beaked whales and Mesoplodon species (California/Oregon/Washington stocks) section. The proposed rule erroneously indicated anticipated take of individuals of 29 marine mammal species.

However, NMFS has recently published two proposed rules, proposing new or revised ESA-designated critical habitat for humpback whales (84 FR 54354; October 9, 2019) and Southern Resident killer whales (84 FR 49214; September 19, 2019).

The NWTT proposed rule included additional information about the species in this rule, all of which remains valid and applicable but has not been reprinted in this final rule, including a subsection entitled *Marine Mammal Hearing* that described the importance of sound to marine mammals and characterized the different groups of marine mammals based on their hearing sensitivity. Therefore, we refer the reader to our **Federal Register** notice of proposed rulemaking (85 FR 33914; June 2, 2020) for more information.

Information on the status, distribution, abundance, population trends, habitat, and ecology of marine mammals in the NWTT Study Area may be found in Chapter 4 of the Navy's rulemaking/LOA application. NMFS has reviewed this information and found it to be accurate and complete. Additional information on the general biology and ecology of marine mammals is included in the 2020 NWTT FSEIS/OEIS. Table 9 incorporates data from the U.S. Pacific and the Alaska Marine Mammal Stock Assessment Reports (SARs) (Carretta *et al.,* 2020; Muto *et al.,* 2020), as well as incorporating the best available science, including monitoring data, from the Navy's marine mammal research efforts. NMFS has also reviewed new scientific literature since publication of the proposed rule, and determined that none of these nor any other new information changes our determination of which species have the potential to be affected by the Navy's activities or the information pertinent to status, distribution, abundance, population trends, habitat, or ecology of the species in this final rulemaking, except as noted below or, in the case of revised harbor seal abundance, in the applicable section of the Analysis and Negligible Impact Determination section.

TABLE 9—MARINE MAMMAL EXPECTED OCCURRENCE WITHIN THE NWTT STUDY AREA

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]	Occurrence [8]		
							Offshore area	Inland waters	Western behm canal
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)									
Family Eschrichtiidae:									
Gray whale	*Eschrichtius robustus*	Eastern North Pacific	-, -, N	26.960 (0.05, 25,849, 2016).	801	139	Seasonal	Seasonal	
		Western North Pacific	E, D, Y	290 (NA, 271, 2016)	0.12	UNK	Rare	Rare	
Family Balaenopteridae (rorquals):									
Blue whale	*Balaenoptera musculus.*	Eastern North Pacific	E, D, Y	1,496 (0.44, 1,050, 2014).	1.2	≥19.4	Seasonal		
Fin whale	*Balaenoptera physalus*	Northeast Pacific	E, D, Y	3,168 (0.26, 2,554, 2013) [4].	5.1	0.4			Rare.
		CA/OR/WA	E, D, Y	9,029 (0.12, 8,127, 2014).	81	≥43.5	Seasonal	Rare	
Humpback whale	*Megaptera novaeangliae.*	Central North Pacific	T/E[5], D, Y	10,103 (0.3, 7,891, 2006).	83	25	Regular	Regular	Regular.
		CA/OR/WA	T/E[5], D, Y	2,900 (0.05, 2,784, 2014).	16.7	≥42.1	Regular	Regular	Regular.
Minke whale	*Balaenoptera acutorostrata.*	Alaska	-, -, N	UNK	UND	0			Rare.
		CA/OR/WA	-, -, N	636 (0.72, 369, 2014)	3.5	≥1.3	Regular	Seasonal	
Sei whale	*Balaenoptera borealis*	Eastern North Pacific	E, D, Y	519 (0.4, 374, 2014)	0.75	≥0.2	Regular		
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)									
Family Physeteridae:									
Sperm whale	*Physeter macrocephalus.*	CA/OR/WA	E, D, Y	1.997 (0.57, 1,270, 2014).	2.5	0.6	Regular		
Family Kogiidae:									
Dwarf sperm whale.	*Kogia sima*	CA/OR/WA	-, -, N	UNK	UND	0	Rare		
Pygmy sperm whale.	*Kogia breviceps*	CA/OR/WA	-, -, N	4,111 (1.12, 1,924, 2014).	19.2	0	Regular		
Family Ziphiidae (beaked whales):									
Baird's beaked whale.	*Berardius bairdii*	CA/OR/WA	-, -, N	2,697 (0.6, 1,633, 2014).	16	0	Regular		
Cuvier's beaked whale.	*Ziphius cavirostris*	CA/OR/WA	-, -, N	3,274 (0.67, 2,059, 2014).	21	<0.1	Regular		
Mesoplodont beaked whales.	*Mesoplodon* species	CA/OR/WA	-, -, N	3,044 (0.54, 1,967, 2014).	20	0.1	Regular		
Family Delphinidae:									
Common bottlenose dolphin.	*Tursiops truncatus*	CA/OR/WA Offshore	-, -, N	1,924 (0.54, 1,255, 2014).	11	≥1.6	Regular		
Killer whale	*Orcinus orca*	Eastern North Pacific Alaska Resident.	-, -, N	2,347 (UNK, 2,347, 2012) [6].	24	1			Regular.
		Eastern North Pacific Northern Resident.	-, -, N	302 (UNK, 302, 2018) [6].	2.2	0.2	Seasonal	Seasonal	
		West Coast Transient	-, -, N	243 (UNK, 243, 2009)	2.4	0	Regular	Regular	Regular.
		Eastern North Pacific Offshore.	-, -, N	300 (0.1, 276, 2012)	2.8	0	Regular		Regular.
		Eastern North Pacific Southern Resident.	E, D, Y	75 (NA, 75, 2018)	0.13	0	Regular	Regular	
Northern right whale dolphin.	*Lissodelphus borealis*	CA/OR/WA	-, -, N	26,556 (0.44, 18,608, 2014).	179	3.8	Regular		
Pacific white-sided dolphin.	*Lagenorhynchus obliquidens.*	North Pacific	-, -, N	26,880 (UNK, NA, 1990).	UND	0			Regular.
		CA/OR/WA	-, -, N	26,814 (0.28, 21,195, 2014).	191	7.5	Regular	Regular	
Risso's dolphin	*Grampus griseus*	CA/OR/WA	-, -, N	6,336 (0.32, 4,817, 2014).	46	≥3.7	Regular	Rare	
Short-beaked common dolphin.	*Delphinus delphis*	CA/OR/WA	-, -, N	969,861 (0.17, 839,325, 2014).	8,393	≥40	Regular	Rare	

TABLE 9—MARINE MAMMAL EXPECTED OCCURRENCE WITHIN THE NWTT STUDY AREA—Continued

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]	Occurrence [8]		
							Offshore area	Inland waters	Western behm canal
Short-finned pilot whale.	*Globicephala macrorhynchus.*	CA/OR/WA	-, -, N	836 (0.79, 466, 2014)	4.5	1.2	Regular	Rare	
Striped dolphin	*Stenella coeruleoalba*	CA/OR/WA	-, -, N	29,211 (0.2, 24,782, 2014).	238	≥0.8	Regular		
Family Phocoenidae (porpoises):									
Dall's porpoise	*Phocoenoides dalli*	Alaska	-, -, N	83,400 (0.097, NA, 1991).	UND	38			Regular.
		CA/OR/WA	-, -, N	25,750 (0.45, 17,954, 2014).	172	0.3	Regular	Regular	
Harbor porpoise	*Phocoena phocoena*	Southeast Alaska	-, -, Y	1,354 (0.12, 1,224, 2012).	12	34			Regular.
		Northern OR/WA Coast.	-, -, N	21,487 (0.44, 15,123, 2011).	151	≥3	Regular		
		Northern CA/Southern OR.	-, -, N	24,195 (0.40, 17,447, 2016).	349	≥0.2	Regular		
		Washington Inland Waters.	-, -, N	11,233 (0.37, 8,308, 2015).	66	≥7.2		Regular	
Order Carnivora—Superfamily Pinnipedia									
Family Otariidae (eared seals and sea lions):									
California sea lion	*Zalophus californianus*	U.S.	-, -, N	257,606 (NA, 233,515, 2014).	14,011	≥321	Seasonal	Regular	
Guadalupe fur seal	*Arctocephalus townsendi.*	Mexico to California	T, D, Y	34,187 (NA, 31,109, 2013).	1,062	≥3.8	Seasonal		
Northern fur seal	*Callorhinus ursinus*	Eastern Pacific	-, D, Y	620,660 (0.2, 525,333, 2016).	11,295	399	Regular		Seasonal.
		California	-, -, N	14,050 (NA, 7,524, 2013).	451	1.8	Regular		
Steller sea lion	*Eumetopias jubatus*	Eastern U.S.	-, -, N	43,201 (NA, 43,201, 2017) [7].	2,592	112	Regular	Seasonal	Regular.
Family Phocidae (earless seals):									
Harbor seal	*Phoca vitulina*	Southeast Alaska (Clarence Strait).	-, -, N	27,659 (UNK, 24,854, 2015).	746	40			Regular.
		OR/WA Coast	-, -, N	UNK	UND	10.6	Regular	Seasonal	
		California	-, -, N	30,968 (0.157, 27,348, 2012).	1,641	43	Regular		
		Washington Northern Inland Waters.	-, -, N	UNK	UND	9.8	Seasonal	Regular	
		Hood Canal	-, -, N	UNK	UND	0.2	Seasonal	Regular	
		Southern Puget Sound	-, -, N	UNK	UND	3.4	Seasonal	Regular	
Northern Elephant seal:	*Mirounga angustirostris.*	California	-, -, N	179,000 (NA, 81,368, 2010).	4,882	8.8	Regular	Regular	Seasonal.

[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 potential biological removal (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: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.* CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable. For the Eastern North Pacific Southern Resident stock of killer whales Nbest/Nmin are based on a direct count of individually identifiable animals. The population size of the U.S. stock of California sea lion was estimated from a 1975–2014 time series of pup counts (Lowry *et al.* 2017), combined with mark-recapture estimates of survival rates (DeLong *et al.* 2017, Laake *et al.* 2018). The population size of the Mexico to California stock of Guadalupe fur seals was estimated from pup count data collected in 2013 and a range of correction factors applied to pup counts to account for uncounted age classes and pre-census pup mortality (García-Aguilar *et al.* 2018). The population size of the California stock of Northern fur seals was estimated from pup counts multiplied by an expansion factor (San Miguel Island) and maximum pup, juvenile, and adult counts (Farrallon Islands) at rookeries. The population size of the Eastern U.S. stock of Steller sea lions was estimated from pup counts and non-pup counts at rookeries in Southeast Alaska, British Columbia, Oregon, and California. The population size of the California stock of Northern Elephant seals was estimated from pup counts at rookeries multiplied by the inverse of the expected ratio of pups to total animals (McCann, 1985; Lowry *et al.,* 2014).

[3] These values, found in NMFS' SARs, represent annual levels of human-caused mortality and serious injury (M/SI) from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual mortality or serious injury (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 SAR reports this stock abundance assessment as provisional and notes that it is an underestimate for the entire stock because it is based on surveys which covered only a small portion of the stock's range.

[5] Humpback whales in the Central North Pacific stock and the CA/OR/WA stock are from three Distinct Population Segments (DPSs) based on animals identified in breeding areas in Hawaii, Mexico, and Central America. Both stocks and all three DPSs co-occur in the NWTT Study Area.

[6] Stock abundance estimate is based on counts of individual animals identified from photo-identification catalogues. Surveys for abundance estimates of these stocks are conducted infrequently.

[7] Stock abundance estimate is the best estimate counts, which have not been corrected to account for animals at sea during abundance surveys.

[8] A "-" indicates the species or stock does not occur in that area.

Note—Unknown (UNK); Undetermined (UND); Not Applicable (NA); California (CA); Oregon (OR); Washington (WA).

Below, we include additional information about the marine mammals in the area of the specified activities that informs our analysis, such as identifying known areas of important habitat or behaviors, or where Unusual Mortality Events (UME) have been designated.

Critical Habitat

Currently, only the distinct population segment (DPS) of Southern Resident killer whale has ESA-designated critical habitat in the NWTT Study Area. NMFS has published two proposed rules, however, proposing new or revised ESA-designated critical habitat for Southern Resident killer whale (84 FR 49214; September 19, 2019) and humpback whales (84 FR 54354; October 9, 2019).

NMFS designated critical habitat for the Southern Resident killer whale DPS on November 29, 2006 (71 FR 69054) in inland waters of Washington State. Based on the natural history of the Southern Resident killer whales and their habitat needs, NMFS identified physical or biological features essential to the conservation of the Southern Resident killer whale DPS: (1) Water quality to support growth and development; (2) prey species of sufficient quantity, quality, and availability to support individual growth, reproduction, and development, as well as overall population growth; and (3) passage conditions to allow for migration, resting, and foraging. ESA-designated critical habitat consists of three areas: (1) The Summer Core Area in Haro Strait and waters around the

San Juan Islands; (2) Puget Sound; and (3) the Strait of Juan de Fuca, which comprise approximately 2,560 square miles (mi^2) (6,630 square kilometers (km^2)) of marine habitat. In designating critical habitat, NMFS considered economic impacts and impacts to national security, and concluded that the benefits of exclusion of 18 military sites, comprising approximately 112 mi^2 (291 km^2), outweighed the benefits of inclusion because of national security impacts.

On January 21, 2014, NMFS received a petition requesting revisions to the Southern Resident killer whale critical habitat designation. The petition requested that NMFS revise critical habitat to include ''inhabited marine waters along the West Coast of the United States that constitute essential foraging and wintering areas,'' specifically the region between Cape Flattery, Washington and Point Reyes, California extending from the coast to a distance of 47.2 mi (76 km) offshore. The petition also requested that NMFS adopt a fourth essential habitat feature in both current and expanded critical habitat relating to in-water sound levels. On September 19, 2019 (84 FR 54354), NMFS published a proposed rule proposing to revise the critical habitat designation for the Southern Resident killer whale DPS by designating six new areas (using the same essential features determined in 2006, and not including the requested essential feature relating to in-water sound levels) along the U.S. West Coast. Specific new areas proposed along the U.S. West Coast include 15,626.6 mi^2 (40,472.7 km^2) of marine waters between the 6.1 m (20 ft) depth contour and the 200 m (656.2 ft) depth contour from the U.S. international border with Canada south to Point Sur, California.

For humpback whales, on September 8, 2016, NMFS revised the listing of humpback whales under the ESA by removing the original, taxonomic-level species listing, and in its place listing four DPSs as endangered and one DPS as threatened (81 FR 62260). NMFS also determined that nine additional DPSs did not warrant listing. This listing of DPSs of humpback whales under the ESA in 2016 triggered the requirement to designate critical habitat, to the maximum extent prudent and determinable, for those DPSs occurring in areas under U.S. jurisdiction—specifically, the Central America, Mexico, and Western North Pacific DPSs.

In the proposed rule to revise the humpback whale listing, NMFS solicited information that could inform a critical habitat designation (80 FR 22304; April 21, 2015), but NMFS did not receive relevant data or information regarding habitats or habitat features in areas within U.S. jurisdiction. In the final rule listing the five DPSs of humpback whales, NMFS concluded that critical habitat was not yet determinable, which had the effect of extending by one year the statutory deadline for designating critical habitat (16 U.S.C. 1533(b)(6)(C)(ii)).

On October 9, 2019, NMFS proposed to designate critical habitat for the endangered Western North Pacific DPS, the endangered Central America DPS, and the threatened Mexico DPS of humpback whales (84 FR 54354). Areas proposed as critical habitat include specific marine areas located off the coasts of California, Oregon, Washington, and Alaska. Based on consideration of national security and economic impacts, NMFS also proposed to exclude multiple areas from the designation for each DPS.

NMFS, in the proposed rule, identified prey species, primarily euphausiids and small pelagic schooling fishes of sufficient quality, abundance, and accessibility within humpback whale feeding areas to support feeding and population growth, as an essential habitat feature. NMFS, through a critical habitat review team (CHRT), also considered inclusion of migratory corridors and passage features, as well as sound and the soundscape, as essential habitat features. NMFS did not propose to include either, however, as the CHRT concluded that the best available science did not allow for identification of any consistently used migratory corridors or definition of any physical, essential migratory or passage conditions for whales transiting between or within habitats of the three DPSs. The best available science also currently does not enable NMFS to identify particular sound levels or to describe a certain soundscape feature that is essential to the conservation of humpback whales.

Biologically Important Areas

Biologically Important Areas (BIAs) include areas of known importance for reproduction, feeding, or migration, or areas where small and resident populations are known to occur (Van Parijs, 2015). Unlike ESA critical habitat, these areas are not formally designated pursuant to any statute or law, but are a compilation of the best available science intended to inform impact and mitigation analyses. An interactive map of the BIAs may be found here: *https://cetsound.noaa.gov/biologically-important-area-map.*

BIAs off the West Coast of the United States (including southeastern Alaska) that overlap portions of the NWTT Study Area include the following feeding and migration areas: Northern Puget Sound Feeding Area for gray whales (March–May); Northwest Feeding Area for gray whales (May–November); Northbound Migration Phase A for gray whales (January–July); Northbound Migration Phase B for gray whales (March–July); Southbound Migration for gray whales (October–March); Northern Washington Feeding Area for humpback whales (May–November); Stonewall and Heceta Bank Feeding Area for humpback whales (May–November); and Point St. George Feeding Area for humpback whales (July–November) (Calambokidis *et al.,* 2015).

The NWTT Study Area overlaps with the Northern Puget Sound Feeding Area for gray whales and the Northwest Feeding Area for gray whales. Gray whale migration corridor BIAs (Northbound and Southbound) overlap with the NWTT Study Area, but only in a portion of the Northwest coast of Washington, approximately from Pacific Beach and extending north to the Strait of Juan de Fuca. The offshore Northern Washington Feeding Area for humpback whales is located entirely within the NWTT Study Area boundaries. The Stonewall and Heceta Bank Feeding Area for humpback whales only partially overlaps with the NWTT Study Area, and the Point St. George Feeding Area for humpback whales has extremely limited overlap with the Study Area since they abut approximately 12 nmi from shore which is where the NWTT Study Area boundary begins. To mitigate impacts to marine mammals in these BIAs, the Navy will implement several procedural mitigation measures and mitigation areas (described later in the Mitigation Measures section).

National Marine Sanctuaries

Under Title III of the Marine Protection, Research, and Sanctuaries Act of 1972 (also known as the National Marine Sanctuaries Act (NMSA)), NOAA can establish as national marine sanctuaries (NMS), areas of the marine environment with special conservation, recreational, ecological, historical, cultural, archaeological, scientific, educational, or aesthetic qualities. Sanctuary regulations prohibit or regulate activities that could destroy, cause the loss of, or injure sanctuary resources pursuant to the regulations for that sanctuary and other applicable law (15 CFR part 922). NMSs are managed on a site-specific basis, and each

sanctuary has site-specific regulations. Most, but not all, sanctuaries have site-specific regulatory exemptions from the prohibitions for certain military activities. Separately, section 304(d) of the NMSA requires Federal agencies to consult with the Office of National Marine Sanctuaries whenever their activities are likely to destroy, cause the loss of, or injure a sanctuary resource. One NMS, the Olympic Coast NMS managed by the Office of National Marine Sanctuaries, is located within the offshore portion of the NWTT Study Area (for a map of the location of this NMS see Chapter 6 of the 2020 NWTT FSEIS/OEIS, Figure 6.1–1). Additionally, a portion of the Quinault Range Site overlaps with the southern end of the Sanctuary.

The Olympic Coast NMS includes 3,188 mi^2 of marine waters and submerged lands off the Olympic Peninsula coastline. The sanctuary extends 25–50 mi. (40.2–80.5 km) seaward, covering much of the continental shelf and portions of three major submarine canyons. The boundaries of the sanctuary as defined in the Olympic Coast NMS regulations (15 CFR part 922, subpart O) extend from Koitlah Point, due north to the United States/Canada international boundary, and seaward to the 100-fathom isobath (approximately 180 m in depth). The seaward boundary of the sanctuary follows the 100-fathom isobath south to a point due west of the Copalis River, and cuts across the tops of Nitinat, Juan de Fuca, and the Quinault Canyons. The shoreward boundary of the sanctuary is at the mean lower low-water line when adjacent to American Indian lands and state lands, and includes the intertidal areas to the mean higher high-water line when adjacent to federally managed lands. When adjacent to rivers and streams, the sanctuary boundary cuts across the mouths but does not extend up river or up stream. The Olympic Coast NMS includes many types of productive marine habitats including kelp forests, subtidal reefs, rocky and sand intertidal zones, submarine canyons, rocky deep-sea habitat, and plankton-rich upwelling zones. These habitats support the Sanctuary's rich biodiversity which includes 29 species of marine mammals that reside in or migrate through the Sanctuary (Office of National Marine Sanctuaries, 2008). Additional information on the Olympic Coast NMS can be found at *https://olympiccoast.noaa.gov.*

Mitigation measures in the Olympic Coast NMS include limits on the use of MF1 mid-frequency active sonar during testing and training and prohibition of explosive Mine Countermeasure and Neutralization Testing activities and non-explosive bombing training activities. See the *Mitigation Areas* section of this final rule for additional discussion of mitigation measures required in the Olympic Coast National Marine Sanctuary.

Unusual Mortality Events (UMEs)

An UME is defined under Section 410(6) of the MMPA as a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response. Three UMEs with ongoing or recently closed investigations in the NWTT Study Area that inform our analysis are discussed below. The California sea lion UME in California was closed on May 6, 2020. The Guadalupe fur seal UME in California and the gray whale UME along the west coast of North America are active and involve ongoing investigations.

California Sea Lion UME

From January 2013 through September 2016, a greater than expected number of young malnourished California sea lions (*Zalophus californianus*) stranded along the coast of California. Sea lions stranding from an early age (6–8 months old) through two years of age (hereafter referred to as juveniles) were consistently underweight without other disease processes detected. Of the 8,122 stranded juveniles attributed to the UME, 93 percent stranded alive (n=7,587, with 3,418 of these released after rehabilitation) and 7 percent (n=531) stranded dead. Several factors are hypothesized to have impacted the ability of nursing females and young sea lions to acquire adequate nutrition for successful pup rearing and juvenile growth. In late 2012, decreased anchovy and sardine recruitment (CalCOFI data, July 2013) may have led to nutritionally stressed adult females. Biotoxins were present at various times throughout the UME, and while they were not detected in the stranded juvenile sea lions (whose stomachs were empty at the time of stranding), biotoxins may have impacted the adult females' ability to support their dependent pups by affecting their cognitive function (*e.g.,* navigation, behavior towards their offspring). Therefore, the role of biotoxins in this UME, via its possible impact on adult females' ability to support their pups, is unclear. The proposed primary cause of the UME was malnutrition of sea lion pups and yearlings due to ecological factors. These factors included shifts in distribution, abundance, and/or quality of sea lion prey items around the Channel Island rookeries during critical sea lion life history events (nursing by adult females, and transitioning from milk to prey by young sea lions). These prey shifts were most likely driven by unusual oceanographic conditions at the time due to the ''Warm Water Blob'' and El Niño. This investigation closed on May 6, 2020. Please refer to: *https://www.fisheries.noaa.gov/national/marine-life-distress/2013-2017-california-sea-lion-unusual-mortality-event-california* for more information on this UME.

Guadalupe Fur Seal UME

Increased strandings of Guadalupe fur seals began along the entire coast of California in January 2015 and were eight times higher than the historical average (approximately 10 seals/yr). Strandings have continued since 2015 and remained well above average through 2019. Numbers by year are as follows: 2015 (98), 2016 (76), 2017 (62), 2018 (45), 2019 (116), 2020 (95 as of October 4, 2020). The total number of Guadalupe fur seals stranding in California from January 1, 2015, through October 4, 2020, in the UME is 492. Additionally, strandings of Guadalupe fur seals became elevated in the spring of 2019 in Washington and Oregon; subsequently, strandings for seals in these two states have been added to the UME starting from January 1, 2019. The current total number of strandings in Washington and Oregon is 132 seals, including 91 (46 in Oregon; 45 in Washington) in 2019 and 41 (30 in Oregon; 11 in Washington) in 2020 as of October 4, 2020. Strandings are seasonal and generally peak in April through July of each year. The Guadalupe fur seal strandings have been mostly weaned pups and juveniles (1–2 years old) with both live and dead strandings occurring. Current findings from the majority of stranded animals include primary malnutrition with secondary bacterial and parasitic infections. When the 2013–2016 California sea lion UME was active, it was occurring in the same area as the California portion of this UME. This investigation is ongoing. Please refer to: *https://www.fisheries.noaa.gov/national/marine-life-distress/2015-2020-guadalupe-fur-seal-unusual-mortality-event-california* for more information on this UME.

Gray Whale UME

Since January 1, 2019, elevated gray whale strandings have occurred along the west coast of North America, from Mexico to Canada. As of October 4, 2020, there have been a total of 384 strandings along the coasts of the United

States, Canada, and Mexico, with 200 of those strandings occurring along the U.S. coast. Of the strandings on the U.S. coast, 92 have occurred in Alaska, 40 in Washington, 9 in Oregon, and 53 in California. Partial necropsy examinations conducted on a subset of stranded whales have shown evidence of poor to thin body condition in some of the whales. Additional findings have included human interactions (entanglements or vessel strikes) and pre-mortem killer whale predation in several whales. As part of the UME investigation process, NOAA has assembled an independent team of scientists to coordinate with the Working Group on Marine Mammal Unusual Mortality Events to review the data collected, sample stranded whales, consider possible causal-linkages between the mortality event and recent ocean and ecosystem perturbations, and determine the next steps for the investigation. Please refer to: *https://www.fisheries.noaa.gov/national/marine-life-distress/2019-2020-gray-whale-unusual-mortality-event-along-west-coast-and* for more information on this UME.

Species Not Included in the Analysis

The species carried forward for analysis (and described in Table 9) are those likely to be found in the NWTT Study Area based on the most recent data available, and do not include species that may have once inhabited or transited the area but have not been sighted in recent years (*e.g.,* species which were extirpated from factors such as 19th and 20th century commercial exploitation). Several species that may be present in the northwest Pacific Ocean have an extremely low probability of presence in the NWTT Study Area. These species are considered extralimital (not anticipated to occur in the Study Area) or rare (occur in the Study Area sporadically, but sightings are rare). These species/stocks include the Eastern North Pacific stock of Bryde's whale (*Balaenoptera edeni*), Eastern North Pacific stock of North Pacific right whale (*Eubalaena japonica*), false killer whale (*Pseudorca crassidens*), long-beaked common dolphin (*Delphinus capensis*), Western U.S. stock of Steller sea lion (*Eumetopias jubatus*), and Alaska stock of Cuvier's beaked whale (*Ziphius cavirostris*). These species are unlikely to occur in the NWTT Study Area and the reasons for not including each was explained in further detail in the proposed rulemaking (85 FR 33914; June 2, 2020).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

We provided a detailed discussion of the potential effects of the specified activities on marine mammals and their habitat in our **Federal Register** notice of proposed rulemaking (85 FR 33914; June 2, 2020). In the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section of the proposed rule, NMFS provided a description of the ways marine mammals may be affected by these activities in the form of, among other things, serious injury or mortality, physical trauma, sensory impairment (permanent and temporary threshold shift and acoustic masking), physiological responses (particularly stress responses), behavioral disturbance, or habitat effects. All of this information remains valid and applicable. Therefore, we do not reprint the information here, but refer the reader to that document.

NMFS has also reviewed new relevant information from the scientific literature since publication of the proposed rule. Summaries of the new key scientific literature since publication of the proposed rule are presented below.

Temporary hearing shifts have been documented in harbor seals and harbor porpoises with onset levels varying as a function of frequency. Harbor seals experienced TTS 1–4 minutes after exposure to a continuous one-sixth-octave noise band centered at 32 kHz at sound pressure levels of 92 to 152 dB re 1 μPa (Kastelein *et al.* 2020a), with the maximum TTS at 32 kHz occurring below ~176 dB re 1 μPa^2s. These seals appeared to be equally susceptible to TTS caused by sounds in the 2.5–32 kHz range, but experienced TTS at 45 kHz occurring above ~176 dB re 1 μPa^2s (Kastelein *et al.* 2020a).

Harbor porpoises also experience variable temporary hearing shifts as a function of frequency. Kastelein *et al.* (2020b) documented TTS in one porpoise due to a one-sixth-octave noise band centered at 63 kHz from 154–181 dB re 1 μPa^2s 1–4 minutes after exposure, and to another porpoise exposed 1–4 minutes to a 88.4 kHz signal at 192 dB re 1 μPa^2s (no TTS was apparent in either animal at 10 or 125 kHz).

Accomando *et al.* (2020) examined the directional dependence of hearing thresholds for 2, 10, 20, and 30 kHz in two adult bottlenose dolphins. They observed that source direction (*i.e.,* the relative angle between the sound source location and the dolphin) impacted hearing thresholds for these frequencies. Sounds projected from directly behind the dolphins resulted in frequency-dependent increases in hearing thresholds of up to 18.5 dB when compared to sounds projected from in front of the dolphins. Sounds projected directly above the dolphins resulted in thresholds that were approximately 8 dB higher than those obtained when sounds were projected below the dolphins. These findings suggest that dolphins may receive lower source levels when they are oriented 180 degrees away from the sound source, and that dolphins are less sensitive to sound projected from above (leading to some spatial release from masking). Directional or spatial hearing also allows animals to locate sound sources. This study indicates dolphins can detect source direction at lower frequencies than previously thought, allowing them to successfully avoid or approach biologically significant or anthropogenic sound sources at these frequencies.

Houser *et al.* (2020) measured cortisol, aldosterone, and epinephrine levels in the blood samples of 30 bottlenose dolphins before and after exposure to simulated U.S. Navy mid-frequency sonar from 115–185 dB re: 1 μPa. They collected blood samples approximately one week prior to, immediately following, and approximately one week after exposures and analyzed for hormones via radioimmunoassay. Aldosterone levels were below the detection limits in all samples. While the observed severity of behavioral responses scaled (increased) with SPL, levels of cortisol and epinephrine did not show consistent relationships with received SPL. The authors note that it is still unclear whether intermittent, high-level acoustic stimuli elicit endocrine responses consistent with a stress response, and that additional research is needed to determine the relationship between behavioral responses and physiological responses.

In an effort to compare behavioral responses to continuous active sonar (CAS) and pulsed (intermittent) active sonar (PAS), Isojunno *et al.* (2020) conducted at-sea experiments on 16 sperm whales equipped with animal-attached sound- and movement-recording tags in Norway. They examined changes in foraging effort and proxies for foraging success and cost during sonar and control exposures after accounting for baseline variation. They observed no reduction in time spent foraging during exposures to medium-level PAS transmitted at the same peak amplitude as CAS, however they observed similar reductions in foraging during CAS and PAS when they were received at similar energy levels (SELs).

The authors note that these results support the hypothesis that sound energy (SEL) is the main cause of behavioral responses rather than sound amplitude (SPL), and that exposure context and measurements of cumulative sound energy are important considerations for future research and noise impact assessments.

Frankel and Stein (2020) used shoreline theodolite tracking to examine potential behavioral responses of southbound migrating eastern gray whales to a high-frequency active sonar system transmitted by a vessel located off the coast of California. The sonar transducer deployed from the vessel transmitted 21–25 kHz sweeps for half of each day (experimental period), and no sound the other half of the day (control period). In contrast to low-frequency active sonar tests conducted in the same area (Clark *et al.,* 1999; Tyack and Clark, 1998), no overt behavioral responses or deflections were observed in field or visual data. However, statistical analysis of the tracking data indicated that during experimental periods at received levels of approximately 148 dB re: 1 μPa2 (134 dB re: 1 μPa2 s) and less than 2 km from the transmitting vessel, gray whales deflected their migration paths inshore from the vessel. The authors indicate that these data suggest the functional hearing sensitivity of gray whales extends to at least 21 kHz. These findings agree with the predicted mysticete hearing curve and BRFs used in the analysis to estimate take by Level A harassment (PTS) and Level B harassment (behavioral response) for this rule (see the Technical Report *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)*).

In February 2020, a study (Simonis *et al.,* 2020) was published titled ''Co-occurrence of beaked whale strandings and naval sonar in the Mariana Islands, Western Pacific.'' In summary, the authors compiled the publicly available information regarding Navy training exercises from 2006–2019 (from press releases, *etc.*), as well as the passive acoustic monitoring data indicating sonar use that they collected at two specific locations on HARP recorders over a shorter amount of time, and compared it to the dates of beaked whale strandings. Using this data, they reported that six of the 10 Cuvier's beaked whales, from four of eight events, stranded during or within six days of a naval ASW exercise using sonar. In a Note to the article, the authors acknowledged additional information provided by the Navy while the article was in press that one of the strandings occurred a day prior to sonar transmissions and so should not be considered coincident with sonar. The authors' analysis examined the probability that three of eight random days would fall during, or within six days after, a naval event (utilizing the Navy training events and sonar detections of which the authors were aware). Their test results indicated that the probability that three of eight stranding events were randomly associated with naval sonar was one percent.

The authors did not have access to the Navy's classified data (in the Note added to the article, Simonis *et al.* noted that the Navy was working with NMFS to make the broader classified dataset available for further statistical analysis). Later reporting by the Navy indicated there were more than three times as many sonar days in the Marianas during the designated time period than Simonis *et al.* (2020) reported. Primarily for this reason, the Navy tasked the Center for Naval Analysis (CNA) with repeating the statistical examination of Simonis *et al.* using the full classified sonar record, including ship movement information to document the precise times and locations of Navy sonar use throughout the time period of consideration (2007–2019).

The results of the Simonis *et al.* (2020) paper and the CNA analysis both suggest (the latter to a notably lesser degree) that it is more probable than not that there was some form of non-random relationship between sonar days and strandings in the Marianas during this period of time; however, the results of the Navy analysis (using the full dataset) allow, statistically, that the strandings and sonar use may not be related.

Varghese *et al.* (2020) analyzed group vocal periods from Cuvier's beaked whales during multibeam echosounder activity recorded in the Southern California Antisubmarine Warfare Range, and failed to find any clear evidence of behavioral response due to the echosounder survey. The whales did not leave the range or cease foraging.

De Soto *et al.* (2020) hypothesized that the high degree of vocal synchrony in beaked whales during their deep foraging dives, coupled with their silent, low-angled ascents, have evolved as an anti-predator response to killer whales. Since killer whales do not dive deep when foraging and so may be waiting at the surface for animals to finish a dive, these authors speculated that by diving in spatial and vocal cohesion with all members of their group, and by surfacing silently and up to a kilometer away from where they were vocally active during the dive, they minimize the ability of killer whales to locate them when at the surface. This may lead to a trade-off for the larger, more fit animals that could conduct longer foraging dives, such that all members of the group remain together and are better protected by this behavior. The authors further speculate that this may explain the long, slow, silent, and shallow ascents that beaked whales make when sonar occurs during a deep foraging dive. However, these hypotheses are based only on the dive behavior of tagged beaked whales, with no observations of predation attempts by killer whales, and need to be tested further to be validated.

Having considered the new information, along with information provided in public comments on the proposed rule, we have determined that there is no new information that substantively affects our analysis of potential impacts on marine mammals and their habitat that appeared in the proposed rule, all of which remains applicable and valid for our assessment of the effects of the Navy's activities during the seven-year period of this rule.

Estimated Take of Marine Mammals

This section indicates the number of takes that NMFS is authorizing, which is based on the amount of take that NMFS anticipates could occur or the maximum amount that is reasonably likely to occur, depending on the type of take and the methods used to estimate it, as described in detail below. NMFS coordinated closely with the Navy in the development of their incidental take application, and agrees that the methods the Navy has put forth described herein to estimate take (including the model, thresholds, and density estimates), and the resulting numbers are based on the best available science and appropriate for authorization. Nonetheless, since publication of the proposed rule, the Navy has adjusted their planned activity by reducing the number of times Mine Countermeasure and Neutralization testing could occur over the seven-year authorization. This change in action resulted in decreases in estimated take over seven years for the following species: fin whale, sei whale, minke whale, humpback whale, gray whale, northern right whale dolphin, Pacific white-sided dolphin, Risso's dolphin, *Kogia* whales, Dall's porpoise, harbor porpoise, California sea lion, Steller sea lion, harbor seal, and northern elephant seal. These changes also resulted in a reduction in HF4 sonar hours associated with Mine Countermeasure and

Neutralization testing; however, this reduction is not shown quantitatively.

Takes are predominantly in the form of harassment, but a small number of mortalities are also possible. For a 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 such behavioral patterns are abandoned or significantly altered (Level B Harassment).

Authorized takes will primarily be in the form of Level B harassment, as use of the acoustic and explosive sources (*i.e.,* sonar and explosives) is more likely to result in behavioral disturbance (rising to the level of a take as described above) or temporary threshold shift (TTS) for marine mammals than other forms of take. There is also the potential for Level A harassment, however, in the form of auditory injury, to result from exposure to the sound sources utilized in training and testing activities. No Level A harassment from tissue damage is anticipated or authorized. Lastly, no more than three serious injuries or mortalities total (over the seven-year period) of large whales could potentially occur through vessel collisions. Although we analyze the impacts of these potential serious injuries or mortalities that are authorized, the planned mitigation and monitoring measures are expected to minimize the likelihood (*i.e.,* further lower the already low probability) that ship strike (and the associated serious injury or mortality) would occur.

The Navy has not requested, and NMFS does not anticipate or authorize, incidental take by mortality of beaked whales or any other species as a result of sonar use. As discussed in the proposed rule, there are a few cases where active naval sonar (in the United States or, largely, elsewhere) has either potentially contributed to or been more definitively causally linked with marine mammal mass strandings. There are a suite of factors that have been associated with these specific cases of strandings (steep bathymetry, multiple hull-mounted platforms using sonar simultaneously, constricted channels, strong surface ducts, *etc.*) that are not present together in the NWTT Study Area and during the specified activities. The number of incidences of strandings resulting from exposure to active sonar are few worldwide, there are no major training exercises utilizing multiple-hull-mounted sonar in the NWTT Study Area, the overall amount of active sonar use is low relative to other Navy Study Areas, and there have not been any documented mass strandings of any cetacean species in the NWTT Study Area. Accordingly, mortality is not anticipated or authorized.

Generally speaking, for acoustic impacts NMFS estimates the amount and type of harassment by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be taken by behavioral disturbance (in this case, as defined in the military readiness definition of Level B harassment included above) or incur some degree of temporary or permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day or event; (3) the density or occurrence of marine mammals within these ensonified areas; and (4) the number of days of activities or events. Below, we describe these components in more detail and present the take estimates.

Acoustic Thresholds

Using the best available science, NMFS, in coordination with the Navy, has established acoustic thresholds that identify the most appropriate received level of underwater sound above which marine mammals exposed to these sound sources could be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered, or to incur TTS (equated to Level B harassment) or PTS of some degree (equated to Level A harassment). Thresholds have also been developed to identify the pressure levels above which animals may incur non-auditory injury from exposure to pressure waves from explosive detonation.

Despite the quickly evolving science, there are still challenges in quantifying expected behavioral responses that qualify as take by Level B harassment, especially where the goal is to use one or two predictable indicators (*e.g.,* received level and distance) to predict responses that are also driven by additional factors that cannot be easily incorporated into the thresholds (*e.g.,* context). So, while the thresholds that identify Level B harassment by behavioral disturbance (referred to as ''behavioral harassment thresholds'') have been refined to better consider the best available science (*e.g.,* incorporating both received level and distance), they also still have some built-in conservative factors to address the challenge noted. For example, while duration of observed responses in the data are now considered in the thresholds, some of the responses that are informing take thresholds are of a very short duration, such that it is possible some of these responses might not always rise to the level of disrupting behavior patterns to a point where they are abandoned or significantly altered. We describe the application of this Level B harassment threshold as identifying the maximum number of instances in which marine mammals could be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered. In summary, we believe these thresholds are the most appropriate method for predicting Level B harassment by behavioral disturbance given the best available science and the associated uncertainty.

Hearing Impairment (TTS/PTS) and Tissue Damage and Mortality

NMFS' Acoustic Technical Guidance (NMFS, 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). The Acoustic Technical Guidance also identifies criteria to predict TTS, which is not considered injury and falls into the Level B harassment category. The Navy's planned activity includes the use of non-impulsive (sonar) and impulsive (explosives) sources.

These thresholds (Tables 10 and 11) were developed by compiling and synthesizing the best available science and soliciting input multiple times from both the public and peer reviewers. The references, analysis, and methodology used in the development of the thresholds are described in the Acoustic Technical Guidance, which may be accessed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 10—ACOUSTIC THRESHOLDS IDENTIFYING THE ONSET OF TTS AND PTS FOR NON-IMPULSIVE SOUND SOURCES BY FUNCTIONAL HEARING GROUPS

Functional hearing group	Non-impulsive	
	TTS threshold SEL (weighted)	PTS threshold SEL (weighted)
Low-Frequency Cetaceans	179	199
Mid-Frequency Cetaceans	178	198
High-Frequency Cetaceans	153	173
Phocid Pinnipeds (Underwater)	181	201
Otarid Pinnipeds (Underwater)	199	219

Note: SEL thresholds in dB re: 1 $\mu Pa^2 s$.

Based on the best available science, the Navy (in coordination with NMFS) used the acoustic and pressure thresholds indicated in Table 11 to predict the onset of TTS, PTS, tissue damage, and mortality for explosives (impulsive) and other impulsive sound sources.

TABLE 11—ONSET OF TTS, PTS, TISSUE DAMAGE, AND MORTALITY THRESHOLDS FOR MARINE MAMMALS FOR EXPLOSIVES

Functional hearing group	Species	Onset TTS [1]	Onset PTS	Mean onset slight GI tract injury	Mean onset slight lung injury	Mean onset mortality
Low-frequency cetaceans.	All mysticetes	168 dB SEL (weighted)or 213 dB Peak SPL.	183 dB SEL (weighted)or 219 dB Peak SPL.	237 dB Peak SPL	Equation 1	Equation 2.
Mid-frequency cetaceans.	Most delphinids, medium and large toothed whales.	170 dB SEL(weighted) or 224 dB Peak SPL.	185 dB SEL (weighted)or 230 dB Peak SPL.	237 dB Peak SPL		
High-frequency cetaceans.	Porpoises and *Kogia spp.*.	140 dB SEL (weighted)or 196 dB Peak SPL.	155 dB SEL (weighted) or 202 dB Peak SPL.	237 dB Peak SPL		
Phocidae	Harbor seal, Hawaiian monk seal, Northern elephant seal.	170 dB SEL (weighted)or 212 dB Peak SPL.	185 dB SEL (weighted)or 218 dB Peak SPL.	237 dB Peak SPL		
Otariidae	California sea lion, Guadalupe fur seal, Northern fur seal.	188 dB SEL (weighted) or 226 dB Peak SPL.	203 dB SEL (weighted) or 232 dB Peak SPL.	237 dB Peak SPL		

Notes: (1) Equation 1: $47.5M^{1/3}(1+[D_{Rm}/10.1])^{1/6}$ Pa-sec (2) Equation 2: $103M^{1/3}(1+[D_{Rm}/10.1])^{1/6}$ Pa-sec (3) M = mass of the animals in kg (4) D_{Rm} = depth of the receiver (animal) in meters (5) SPL = sound pressure level.
[1] Peak thresholds are unweighted.

The criteria used to assess the onset of TTS and PTS due to exposure to sonars (non-impulsive, see Table 10 above) are discussed further in the Navy's rulemaking/LOA application (see Hearing Loss from Sonar and Other Transducers in Chapter 6, Section 6.4.2.1, Methods for Analyzing Impacts from Sonars and Other Transducers). Refer to the *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis* (Phase III) report (U.S. Department of the Navy, 2017c) for detailed information on how the criteria and thresholds were derived. Tables 30 indicates the range to effects for tissue damage for different explosive types. Non-auditory injury (*i.e.,* other than PTS) and mortality from sonar and other transducers is not reasonably likely to result for the reasons explained in the proposed rule under the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section—*Acoustically Mediated Bubble Growth and other Pressure-related Injury* and the additional discussion in this final rule and is therefore not considered further in this analysis.

The mitigation measures associated with explosives are expected to be effective in preventing tissue damage to any potentially affected species, and no species are anticipated to incur tissue damage during the period of this rule. Specifically, the Navy will implement mitigation measures (described in the Mitigation Measures section) during explosive activities, including delaying detonations when a marine mammal is observed in the mitigation zone. Nearly all explosive events will occur during daylight hours to improve the sightability of marine mammals and thereby improve mitigation effectiveness. Observing for marine mammals during the explosive activities will include visual and passive acoustic detection methods (when they are available and part of the activity) before the activity begins, in order to cover the mitigation zones that can range from 500 yd (457 m) to 2,500 yd (2,286 m) depending on the source (*e.g.,* explosive sonobuoy, explosive torpedo, explosive bombs; see Tables 38–44).

Level B Harassment by Behavioral Disturbance

Though significantly driven by received level, the onset of Level B harassment by behavioral disturbance from anthropogenic noise exposure is

also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Ellison *et al.,* 2011; Southall *et al.,* 2007). Based on what the available science indicates and the practical need to use thresholds based on a factor, or factors, that are both predictable and measurable for most activities, NMFS uses generalized acoustic thresholds based primarily on received level (and distance in some cases) to estimate the onset of Level B harassment by behavioral disturbance.

Sonar

As noted above, the Navy coordinated with NMFS to develop, and propose for use in this rule, thresholds specific to their military readiness activities utilizing active sonar that identify at what received level and distance Level B harassment by behavioral disturbance would be expected to result. These thresholds are referred to as ''behavioral harassment thresholds'' throughout the rest of the rule. These behavioral harassment thresholds consist of BRFs and associated cutoff distances, and are also referred to, together, as ''the criteria.'' These criteria are used to estimate the number of animals that may exhibit a behavioral response that qualifies as a take when exposed to sonar and other transducers. The way the criteria were derived is discussed in detail in the *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)* report (U.S. Department of the Navy, 2017c). Developing these behavioral harassment criteria involved multiple steps. All peer-reviewed published behavioral response studies conducted both in the field and on captive animals were examined in order to understand the breadth of behavioral responses of marine mammals to sonar and other transducers. NMFS has carefully reviewed the Navy's criteria, *i.e.,* BRFs and cutoff distances for these species, and agrees that they are the best available science and the appropriate method to use at this time for determining impacts to marine mammals from sonar and other transducers and for calculating take and to support the determinations made in this rule. The Navy and NMFS will continue to evaluate the information as new science becomes available. The criteria have been rigorously vetted within the Navy community, among scientists during expert elicitation, and then reviewed by the public before being applied. It is not necessary or possible to revise and update the criteria and risk functions every time a new paper is published. The Navy and NMFS consider new information as it becomes available for updates to the criteria in the future, when the next round of updated criteria will be developed. Thus far, no new information has been published or otherwise conveyed that would fundamentally change the assessment of impacts or conclusions of the 2020 NWTT FSEIS/OEIS or this rule.

As discussed above, marine mammal responses to sound (some of which are considered disturbances that qualify as a take) are highly variable and context specific, *i.e.,* they are affected by differences in acoustic conditions; differences between species and populations; differences in gender, age, reproductive status, or social behavior; and other prior experience of the individuals. This means that there is support for considering alternative approaches for estimating Level B harassment by behavioral disturbance. Although the statutory definition of Level B harassment for military readiness activities means that a natural behavioral pattern of a marine mammal is significantly altered or abandoned, the current state of science for determining those thresholds is somewhat unsettled.

In its analysis of impacts associated with sonar acoustic sources (which was coordinated with NMFS), the Navy used an updated conservative approach that likely overestimates the number of takes by Level B harassment due to behavioral disturbance and response. Many of the behavioral responses identified using the Navy's quantitative analysis are most likely to be of moderate severity as described in the Southall *et al.* (2007) behavioral response severity scale. These ''moderate'' severity responses were considered significant if they were sustained for the duration of the exposure or longer. Within the Navy's quantitative analysis, many reactions are predicted from exposure to sound that may exceed an animal's threshold for Level B harassment by behavioral disturbance for only a single exposure (a few seconds) to several minutes, and it is likely that some of the resulting estimated behavioral responses that are counted as Level B harassment would not constitute significant alteration or abandonment of the natural behavioral patterns. The Navy and NMFS have used the best available science to address the challenging differentiation between significant and non-significant behavioral reactions (*i.e.,* whether the behavior has been abandoned or significantly altered such that it qualifies as harassment), but have erred on the cautious side where uncertainty exists (*e.g.,* counting these lower duration reactions as take), which likely results in some degree of overestimation of Level B harassment by behavioral disturbance. We consider application of these behavioral harassment thresholds, therefore, as identifying the maximum number of instances in which marine mammals could be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered (*i.e.,* Level B harassment). Because this is the most appropriate method for estimating Level B harassment given the best available science and uncertainty on the topic, it is these numbers of Level B harassment by behavioral disturbance that are analyzed in the Analysis and Negligible Impact Determination section and are authorized.

In the Navy's acoustic impact analyses during Phase II (the previous phase of Navy testing and training, 2015–2020; see also Navy's *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis Technical Report,* 2012), the likelihood of Level B harassment by behavioral disturbance in response to sonar and other transducers was based on a probabilistic function (BRF), that related the likelihood (*i.e.,* probability) of a behavioral response (at the level of a Level B harassment) to the received SPL. The BRF was used to estimate the percentage of an exposed population that is likely to exhibit Level B harassment due to altered behaviors or behavioral disturbance at a given received SPL. This BRF relied on the assumption that sound poses a negligible risk to marine mammals if they are exposed to SPL below a certain ''basement'' value. Above the basement exposure SPL, the probability of a response increased with increasing SPL. Two BRFs were used in Navy acoustic impact analyses: BRF1 for mysticetes and BRF2 for other species. BRFs were not used for beaked whales during Phase II analyses. Instead, a step function at an SPL of 140 dB re: 1 μPa was used for beaked whales as the threshold to predict Level B harassment by behavioral disturbance.

Developing the criteria for Level B harassment by behavioral disturbance for Phase III (the current phase of Navy training and testing activities) involved multiple steps: all available behavioral response studies conducted both in the field and on captive animals were examined to understand the breadth of behavioral responses of marine mammals to sonar and other transducers (see also Navy's *Criteria and Thresholds*

for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III) Technical Report, 2017). Six behavioral response field studies with observations of 14 different marine mammal species reactions to sonar or sonar-like signals and 6 captive animal behavioral studies with observations of 8 different species reactions to sonar or sonar-like signals were used to provide a robust data set for the derivation of the Navy's Phase III marine mammal behavioral response criteria. All behavioral response research that has been published since the derivation of the Navy's Phase III criteria (c.a. December 2016) has been examined and is consistent with the current BRFs. Marine mammal species were placed into behavioral criteria groups based on their known or presumed behavioral sensitivities to sound. In most cases these divisions were driven by taxonomic classifications (*e.g.,* mysticetes, pinnipeds). The data from the behavioral studies were analyzed by looking for significant responses, or lack thereof, for each experimental session. The resulting four Bayesian Biphasic Dose Response Functions (referred to as the BRFs) that were developed for odontocetes, pinnipeds, mysticetes, and beaked whales predict the probability of a behavioral response qualifying as Level B harassment given exposure to certain received levels of sound. These BRFs are then used in combination with the cutoff distances described below to estimate the number of takes by Level B harassment.

The Navy used cutoff distances beyond which the potential of significant behavioral responses (and therefore Level B harassment) is considered to be unlikely (see Table 12 below). This was determined by examining all available published field observations of behavioral reactions to sonar or sonar-like signals that included the distance between the sound source and the marine mammal. The longest distance, rounded up to the nearest 5-km increment, was chosen as the cutoff distance for each behavioral criteria group (*i.e.* odontocetes, mysticetes, pinnipeds, and beaked whales). For animals within the cutoff distance, a BRF based on a received SPL as presented in Chapter 6, Section 6.4.2.1 (Methods for Analyzing Impacts from Sonars and other Transducers) of the Navy's rulemaking/LOA application was used to predict the probability of a potential significant behavioral response. For training and testing events that contain multiple platforms or tactical sonar sources that exceed 215 dB re: 1 μPa at 1 m, this cutoff distance is substantially increased (*i.e.,* doubled) from values derived from the literature. The use of multiple platforms and intense sound sources are factors that probably increase responsiveness in marine mammals overall (however, we note that helicopter dipping sonars were considered in the intense sound source group, despite lower source levels, because of data indicating that marine mammals are sometimes more responsive to the less predictable employment of this source). There are currently few behavioral observations under these circumstances; therefore, the Navy conservatively predicted significant behavioral responses that will rise to Level B harassment at farther ranges as shown in Table 12, versus less intense events.

TABLE 12—CUTOFF DISTANCES FOR MODERATE SOURCE LEVEL, SINGLE PLATFORM TRAINING AND TESTING EVENTS AND FOR ALL OTHER EVENTS WITH MULTIPLE PLATFORMS OR SONAR WITH SOURCE LEVELS AT OR EXCEEDING 215 dB RE: 1 μPa AT 1 m

Criteria group	Moderate SL/ single platform cutoff distance (km)	High SL/multi-platform cutoff distance (km)
Odontocetes	10	20
Pinnipeds	5	10
Mysticetes	10	20
Beaked Whales	25	50
Harbor Porpoise	20	40

Notes: dB re: 1 μPa at 1 m = decibels referenced to 1 micropascal at 1 meter, km = kilometer, SL = source level.

The range to received sound levels in 6-dB steps from five representative sonar bins and the percentage of animals that may be taken by Level B harassment at the received level and distance indicated under each BRF are shown in Tables 13 through 17. Cells are shaded if the mean range value for the specified received level exceeds the distance cutoff range for a particular hearing group and therefore are not included in the estimated take. See Chapter 6, Section 6.4.2.1 (Methods for Analyzing Impacts from Sonars and Other Transducers) of the Navy's rulemaking/LOA application for further details on the derivation and use of the BRFs, thresholds, and the cutoff distances to identify takes by Level B harassment, which were coordinated with NMFS. Table 13 illustrates the maximum likely percentage of exposed individuals taken at the indicated received level and associated range (in which marine mammals would be reasonably expected to experience a disruption in behavioral patterns to a point where they are abandoned or significantly altered) for low-frequency active sonar (LFAS). As noted previously, NMFS carefully reviewed, and contributed to, the Navy's behavioral harassment thresholds (*i.e.,* the BRFs and the cutoff distances) for the species, and agrees that these methods represent the best available science at this time for determining impacts to marine mammals from sonar and other transducers.

TABLE 13—RANGES TO ESTIMATED LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR SONAR BIN LF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Received level (dB re: 1 μPa)	Average range (m) with minimum and maximum values in parentheses	Probability of behavioral response for sonar bin LF4				
		Odontocete (%)	Mysticete (%)	Pinniped (%)	Beaked whale (%)	Harbor porpoise (%)
196	1 (0–1)	100	100	100	100	100
190	3 (0–3)	100	98	99	100	100
184	6 (0–8)	99	88	98	100	100
178	13 (0–30)	97	59	92	100	100
172	29 (0–230)	91	30	76	99	100
166	64 (0–100)	78	20	48	97	100
160	148 (0–310)	58	18	27	93	100
154	366 (230–850)	40	17	18	83	100
148	854 (300–2,025)	29	16	16	66	100
142	1,774 (300–5,025)	25	13	15	45	100
136	3,168 (300–8,525)	23	9	15	28	100
130	5,167 (300–30,525)	20	5	15	18	100
124	7,554 (300–93,775)	17	2	14	14	100
118	10,033 (300–100,000*)	12	1	13	12	0
112	12,700 (300–100,000*)	6	0	9	11	0
106	15,697 (300–100,000*)	3	0	5	11	0
100	17,846 (300–100,000*)	1	0	2	8	0

Notes: dB re: 1 μPa = decibels referenced to 1 micropascal, LF = low-frequency

* Indicates maximum range to which acoustic model was run, a distance of approximately 100 km from the sound source. Cells are shaded if the mean range value for the specified received level exceeds the distance cutoff range for a particular hearing group. Any impacts within the cutoff range for a criteria group are included in the estimated impacts. Cut-off ranges in this table are for activities with high source levels and/or multiple platforms (see Table 12 for behavioral cut-off distances).

Tables 14 through 16 identify the maximum likely percentage of exposed individuals taken at the indicated received level and associated range for mid-frequency active sonar (MFAS).

TABLE 14—RANGES TO ESTIMATED LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR SONAR BIN MF1 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Received level (dB re: 1 μPa)	Average range (m) with minimum and maximum values in parentheses	Probability of Level B harassment by behavioral disturbance for Sonar bin MF1				
		Odontocete (%)	Mysticete (%)	Pinniped (%)	Beaked whale (%)	Harbor porpoise (%)
196	112 (80–170)	100	100	100	100	100
190	262 (80–410)	100	98	99	100	100
184	547 (80–1,025)	99	88	98	100	100
178	1,210 (80–3,775)	97	59	92	100	100
172	2,508 (80–7,525)	91	30	76	99	100
166	4,164 (80–16,025)	78	20	48	97	100
160	6,583 (80–28,775)	58	18	27	93	100
154	10,410 (80–47,025)	40	17	18	83	100
148	16,507 (80–63,525)	29	16	16	66	100
142	21,111 (80–94,025)	25	13	15	45	100
136	26,182 (80–100,000 *)	23	9	15	28	100
130	31,842 (80–100,000 *)	20	5	15	18	100
124	34,195 (80–100,000 *)	17	2	14	14	100
118	36,557 (80–100,000 *)	12	1	13	12	0
112	38,166 (80–100,000 *)	6	0	9	11	0
106	39,571 (80–100,000 *)	3	0	5	11	0
100	41,303 (80–100,000 *)	1	0	2	8	0

Notes: dB re: 1 μPa = decibels referenced to 1 micropascal, MF = mid-frequency.

*Indicates maximum range to which acoustic model was run, a distance of approximately 100 km from the sound source. Cells are shaded if the mean range value for the specified received level exceeds the distance cutoff range for a particular hearing group. Any impacts within the cutoff range for a criteria group are included in the estimated impacts. Cut-off ranges in this table are for activities with high source levels and/or multiple platforms (see Table 12 for behavioral cut-off distances).

TABLE 15—RANGES TO ESTIMATED TAKES BY LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR SONAR BIN MF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Received level (dB re: 1 μPa)	Average range (m) with minimum and maximum values in parentheses	Probability of Level B harassment by behavioral disturbance for Sonar bin MF4				
		Odontocete	Mysticete	Pinniped	Beaked whale	Harbor porpoise
196	8 (0–8)	100	100	100	100	100
190	16 (0–20)	100	98	99	100	100
184	34 (0–40)	99	88	98	100	100
178	68 (0–85)	97	59	92	100	100
172	155 (120–300)	91	30	76	99	100
166	501 (290–975)	78	20	48	97	100
160	1,061 (480–2,275)	58	18	27	93	100
154	1,882 (525–4,025)	40	17	18	83	100
148	2,885 (525–7,525)	29	16	16	66	100
142	4,425 (525–14,275)	25	13	15	45	100
136	9,902 (525–48,275)	23	9	15	28	100
130	20,234 (525–56,025)	20	5	15	18	100
124	23,684 (525–91,775)	17	2	14	14	100
118	28,727 (525–100,000*)	12	1	13	12	0
112	37,817 (525–100,000*)	6	0	9	11	0
106	42,513 (525–100,000*)	3	0	5	11	0
100	43,367 (525–100,000*)	1	0	2	8	0

Notes: dB re: 1 μPa = decibels referenced to 1 micropascal, MF = mid-frequency.

*Indicates maximum range to which acoustic model was run, a distance of approximately 100 km from the sound source. Cells are shaded if the mean range value for the specified received level exceeds the distance cutoff range for a particular hearing group. Any impacts within the cutoff range for a criteria group are included in the estimated impacts. Cut-off ranges in this table are for activities with high source levels and/or multiple platforms (see Table 12 for behavioral cut-off distances).

TABLE 16—RANGES TO ESTIMATED LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR SONAR BIN MF5 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Received level (dB re: 1 μPa)	Average range (m) with minimum and maximum values in parentheses	Probability of Level B harassment by behavioral disturbance for Sonar bin MF5				
		Odontocete	Mysticete	Pinniped	Beaked whale	Harbor porpoise
196	0 (0–0)	100	100	100	100	100
190	1 (0–3)	100	98	99	100	100
184	5 (0–7)	99	88	98	100	100
178	14 (0–18)	97	59	92	100	100
172	29 (0–35)	91	30	76	99	100
166	58 (0–70)	78	20	48	97	100
160	127 (0–280)	58	18	27	93	100
154	375 (0–1,000)	40	17	18	83	100
148	799 (490–1,775)	29	16	16	66	100
142	1,677 (600–3,525)	25	13	15	45	100
136	2,877 (675–7,275)	23	9	15	28	100
130	4,512 (700–12,775)	20	5	15	18	100
124	6,133 (700–19,275)	17	2	14	14	100
118	7,880 (700–26,275)	12	1	13	12	0
112	9,673 (700–33,525)	6	0	9	11	0
106	12,095 (700–45,275)	3	0	5	11	0
100	18,664 (700–48,775)	1	0	2	8	0

Notes: dB re: 1 μPa = decibels referenced to 1 micropascal, MF = mid-frequency.

*Cells are shaded if the mean range value for the specified received level exceeds the distance cutoff range for a particular hearing group. Any impacts within the cutoff range for a criteria group are included in the estimated impacts. Cut-off ranges in this table are for activities with high source levels and/or multiple platforms (see Table 12 for behavioral cut-off distances).

TABLE 17—RANGES TO ESTIMATED TAKE BY LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR SONAR BIN HF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Received level (dB re: 1 μPa)	Average range (m) with minimum and maximum values in parentheses	Probability of Level B harassment by behavioral disturbance for Sonar bin HF4				
		Odontocete	Mysticete	Pinniped	Beaked whale	Harbor porpoise
196	4 (0–7)	100	100	100	100	100
190	10 (0–16)	100	98	99	100	100
184	20 (0–40)	99	88	98	100	100
178	42 (0–85)	97	59	92	100	100
172	87 (0–270)	91	30	76	99	100
166	177 (0–650)	78	20	48	97	100
160	338 (25–825)	58	18	27	93	100
154	577 (55–1,275)	40	17	18	83	100
148	846 (60–1,775)	29	16	16	66	100
142	1,177 (60–2,275)	25	13	15	45	100
136	1,508 (60–3,025)	23	9	15	28	100
130	1,860 (60–3,525)	20	5	15	18	100
124	2,202 (60–4,275)	17	2	14	14	100
118	2,536 (60–4,775)	12	1	13	12	0
112	2,850 (60–5,275)	6	0	9	11	0
106	3,166 (60–6,025)	3	0	5	11	0
100	3,470 (60–6,775)	1	0	2	8	0

Notes: dB re: 1 μPa = decibels referenced to 1 micropascal, MF = mid-frequency.

Explosives

Phase III explosive thresholds for Level B harassment by behavioral disturbance for marine mammals is the hearing groups' TTS threshold minus 5 dB (see Table 18 below and Table 11 for the TTS thresholds for explosives) for events that contain multiple impulses from explosives underwater. This was the same approach as taken in Phase II for explosive analysis. See the *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)* report (U.S. Department of the Navy, 2017c) for detailed information on how the criteria and thresholds were derived. NMFS continues to concur that this approach represents the best available science for determining impacts to marine mammals from explosives.

TABLE 18—THRESHOLDS FOR LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR EXPLOSIVES FOR MARINE MAMMALS

Medium	Functional hearing group	SEL (weighted)
Underwater	Low-frequency cetaceans	163
Underwater	Mid-frequency cetaceans	165
Underwater	High-frequency cetaceans	135
Underwater	Phocids	165
Underwater	Otariids	183

Note: Weighted SEL thresholds in dB re: 1 $\mu Pa^2 s$ underwater.

Navy's Acoustic Effects Model

The Navy's Acoustic Effects Model calculates sound energy propagation from sonar and other transducers and explosives during naval activities and the sound received by animat dosimeters. Animat dosimeters are virtual representations of marine mammals distributed in the area around the modeled naval activity and each dosimeter records its individual sound ''dose.'' The model bases the distribution of animats over the NWTT Study Area on the density values in the *Navy Marine Species Density Database* and distributes animats in the water column proportional to the known time that species spend at varying depths.

The model accounts for environmental variability of sound propagation in both distance and depth when computing the sound level received by the animats. The model conducts a statistical analysis based on multiple model runs to compute the estimated effects on animals. The number of animats that exceed the thresholds for effects is tallied to provide an estimate of the number of marine mammals that could be affected.

Assumptions in the Navy model intentionally err on the side of overestimation when there are unknowns. Naval activities are modeled as though they would occur regardless of proximity to marine mammals, meaning that no mitigation is considered (*i.e.,* no power down or shut down modeled) and without any avoidance of the activity by the animal. The final step of the quantitative analysis of acoustic effects is to consider the implementation of mitigation and the possibility that marine mammals would avoid continued or repeated sound exposures. For more information on this process, see the discussion in the *Take Requests* subsection below. Many explosions from ordnance such as bombs and missiles actually occur upon impact with above-water targets. However, for this analysis, sources such as these were modeled as exploding underwater, which overestimates the amount of explosive and acoustic energy entering the water.

The model estimates the impacts caused by individual training and testing exercises. During any individual modeled event, impacts to individual animats are considered over 24-hour periods. The animats do not represent actual animals, but rather they represent a distribution of animals based on density and abundance data, which

allows for a statistical analysis of the number of instances that marine mammals may be exposed to sound levels resulting in an effect. Therefore, the model estimates the number of instances in which an effect threshold was exceeded over the course of a year, but does not estimate the number of individual marine mammals that may be impacted over a year (*i.e.,* some marine mammals could be impacted several times, while others would not experience any impact). A detailed explanation of the Navy's Acoustic Effects Model is provided in the technical report *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing* (U.S. Department of the Navy, 2018).

Range to Effects

The following section provides range to effects for sonar and other active acoustic sources as well as explosives to specific acoustic thresholds determined using the Navy Acoustic Effects Model. Marine mammals exposed within these ranges for the shown duration are predicted to experience the associated effect. Range to effects is important information in not only predicting acoustic impacts, but also in verifying the accuracy of model results against real-world situations and determining adequate mitigation ranges to avoid higher level effects, especially physiological effects to marine mammals.

Sonar

The ranges to received sound levels in 6–dB steps from five representative sonar bins and the percentage of the total number of animals that may exhibit a significant behavioral response (and therefore Level B harassment) under each BRF are shown in Tables 13 through 17 above, respectively. See Chapter 6, Section 6.4.2.1 (Methods for Analyzing Impacts from Sonars and Other Transducers) of the Navy's rulemaking/LOA application for additional details on the derivation and use of the BRFs, thresholds, and the cutoff distances that are used to identify Level B harassment by behavioral disturbance. NMFS has reviewed the range distance to effect data provided by the Navy and concurs with the analysis.

The ranges to PTS for five representative sonar systems for an exposure of 30 seconds is shown in Table 19 relative to the marine mammal's functional hearing group. This period (30 seconds) was chosen based on examining the maximum amount of time a marine mammal would realistically be exposed to levels that could cause the onset of PTS based on platform (*e.g.,* ship) speed and a nominal animal swim speed of approximately 1.5 m per second. The ranges provided in the table include the average range to PTS, as well as the range from the minimum to the maximum distance at which PTS is possible for each hearing group.

TABLE 19—RANGE TO PERMANENT THRESHOLD SHIFT (Meters) FOR FIVE REPRESENTATIVE SONAR SYSTEMS OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Hearing group	Approximate range in meters for pts from 30 second exposure [1]				
	Sonar bin HF4	Sonar bin LF4	Sonar bin MF1	Sonar bin MF4	Sonar bin MF5
High-frequency cetaceans	38 (22–85)	0 (0–0)	195 (80–330)	30 (30–40)	9 (8–11)
Low-frequency cetaceans	0 (0–0)	2 (1–3)	67 (60–110)	15 (15–17)	0 (0–0)
Mid-frequency cetaceans	1 (0–3)	0 (0–0)	16 (16–19)	3 (3–3)	0 (0–0)
Otariids	0 (0–0)	0 (0–0)	6 (6–6)	0 (0–0)	0 (0–0)
Phocids	0 (0–0)	0 (0–0)	46 (45–75)	11 (11–12)	0 (0–0)

[1] PTS ranges extend from the sonar or other active acoustic sound source to the indicated distance. The average range to PTS is provided as well as the range from the estimated minimum to the maximum range to PTS in parentheses.

The tables below illustrate the range to TTS for 1, 30, 60, and 120 seconds from five representative sonar systems (see Tables 20 through 24).

TABLE 20—RANGES TO TEMPORARY THRESHOLD SHIFT (Meters) FOR SONAR BIN LF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin LF4			
	1 second	30 seconds	60 seconds	120 seconds
High-frequency cetaceans	0 (0–0)	0 (0–0)	0 (0–0)	1 (0–1)
Low-frequency cetaceans	22 (19–30)	32 (25–230)	41 (30–230)	61 (45–100)
Mid-frequency cetaceans	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)
Otariids	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)
Phocids	2 (1–3)	4 (3–4)	4 (4–5)	7 (6–9)

[1] Ranges to TTS represent the model predictions in different areas and seasons within the NWTT Study Area. The zone in which animals are expected to suffer TTS extends from onset-PTS to the distance indicated. The average range to TTS is provided as well as the range from the estimated minimum to the maximum range to TTS in parentheses.

TABLE 21—RANGES TO TEMPORARY THRESHOLD SHIFT (Meters) FOR SONAR BIN MF1 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin MF1			
	1 second	30 seconds	60 seconds	120 seconds
High-frequency cetaceans	2,466 (80–6,275)	2,466 (80–6,275)	3,140 (80–10,275)	3,740 (80–13,525)
Low-frequency cetaceans	1,054 (80–2,775)	1,054 (80–2,775)	1,480 (80–4,525)	1,888 (80–5,275)
Mid-frequency cetaceans	225 (80–380)	225 (80–380)	331 (80–525)	411 (80–700)

TABLE 21—RANGES TO TEMPORARY THRESHOLD SHIFT (Meters) FOR SONAR BIN MF1 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA—Continued

Hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin MF1			
	1 second	30 seconds	60 seconds	120 seconds
Otariids	67 (60–110)	67 (60–110)	111 (80–170)	143 (80–250)
Phocids	768 (80–2,025)	768 (80–2,025)	1,145 (80–3,275)	1,388 (80–3,775)

[1] Ranges to TTS represent the model predictions in different areas and seasons within the NWTT Study Area. The zone in which animals are expected to suffer TTS extends from onset-PTS to the distance indicated. The average range to TTS is provided as well as the range from the estimated minimum to the maximum range to TTS in parentheses.

Note: Ranges for 1 second and 30 second periods are identical for Bin MF1 because this system nominally pings every 50 seconds; therefore, these periods encompass only a single ping.

TABLE 22—RANGES TO TEMPORARY THRESHOLD SHIFT (Meters) FOR SONAR BIN MF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Hearing group	Approximate TTS ranges (meters)[1]			
	Sonar bin MF4			
	1 second	30 seconds	60 seconds	120 seconds
High-frequency cetaceans	279 (220–600)	647 (420–1,275)	878 (500–1,525)	1,205 (525–2,275)
Low-frequency cetaceans	87 (85–110)	176 (130–320)	265 (190–575)	477 (290–975)
Mid-frequency cetaceans	22 (22–25)	35 (35–45)	50 (45–55)	71 (70–85)
Otariids	8 (8–8)	15 (15–17)	19 (19–23)	25 (25–30)
Phocids	66 (65–80)	116 (110–200)	173 (150–300)	303 (240–675)

[1] Ranges to TTS represent the model predictions in different areas and seasons within the NWTT Study Area. The zone in which animals are expected to suffer TTS extends from onset-PTS to the distance indicated. The average range to TTS is provided as well as the range from the estimated minimum to the maximum range to TTS in parentheses.

TABLE 23—RANGES TO TEMPORARY THRESHOLD SHIFT (Meters) FOR SONAR BIN MF5 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Hearing group	Approximate TTS ranges (meters) [1]			
	Sonar nin MF5			
	1 second	30 seconds	60 seconds	120 seconds
High-frequency cetaceans	115 (110–180)	115 (110–180)	174 (150–390)	292 (210–825)
Low-frequency cetaceans	11 (10–13)	11 (10–13)	17 (16–19)	24 (23–25)
Mid-frequency cetaceans	6 (0–9)	6 (0–9)	12 (11–14)	18 (17–22)
Otariids	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)
Phocids	9 (8–11)	9 (8–11)	15 (14–17)	22 (21–25)

[1] Ranges to TTS represent the model predictions in different areas and seasons within the NWTT Study Area. The zone in which animals are expected to suffer TTS extends from onset-PTS to the distance indicated. The average range to TTS is provided as well as the range from the estimated minimum to the maximum range to TTS in parentheses.

TABLE 24—RANGES TO TEMPORARY THRESHOLD SHIFT (Meters) FOR SONAR BIN HF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin HF4			
	1 second	30 seconds	60 seconds	120 seconds
High-frequency cetaceans	236 (60–675)	387 (60–875)	503 (60–1,025)	637 (60–1,275)
Low-frequency cetaceans	2 (0–3)	3 (1–6)	5 (3–8)	8 (5–12)
Mid-frequency cetaceans	12 (7–20)	21 (12–40)	29 (17–60)	43 (24–90)
Otariids	0 (0–0)	0 (0–0)	0 (0–0)	1 (0–1)
Phocids	3 (0–5)	6 (4–10)	9 (5–15)	14 (8–25)

[1] Ranges to TTS represent the model predictions in different areas and seasons within the NWTT Study Area. The zone in which animals are expected to suffer TTS extends from onset-PTS to the distance indicated. The average range to TTS is provided as well as the range from the estimated minimum to the maximum range to TTS in parentheses.

Explosives

The following section provides the range (distance) over which specific physiological or behavioral effects are expected to occur based on the explosive criteria (see Chapter 6, Section 6.5.2 (Impacts from Explosives) of the Navy's rulemaking/LOA application and the *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)* report (U.S. Department of the Navy, 2017c)) and the explosive propagation calculations from the Navy Acoustic Effects Model (see Chapter 6, Section 6.5.2.2 (Impact Ranges for Explosives) of the Navy's rulemaking/LOA application). The range to effects are shown for a range of explosive bins, from E1 (up to 0.25 lb net explosive weight) to E11 (greater than 500 lb to 650 lb net explosive weight) (Tables 25 through 31). Ranges are determined by modeling the distance that noise from

an explosion would need to propagate to reach exposure level thresholds specific to a hearing group that would cause behavioral response (to the degree of Level B harassment), TTS, PTS, and non-auditory injury. Ranges are provided for a representative source depth and cluster size for each bin. For events with multiple explosions, sound from successive explosions can be expected to accumulate and increase the range to the onset of an impact based on SEL thresholds. Ranges to non-auditory injury and mortality are shown in Tables 30 and 31, respectively. NMFS has reviewed the range distance to effect data provided by the Navy and concurs with the analysis. For additional information on how ranges to impacts from explosions were estimated, see the technical report *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing* (U.S. Navy, 2018).

Table 25 shows the minimum, average, and maximum ranges to onset of auditory and likely behavioral effects that rise to the level of Level B harassment for high-frequency cetaceans based on the developed thresholds.

TABLE 25—SEL-BASED RANGES (METERS) TO ONSET PTS, ONSET TTS, AND LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR HIGH-FREQUENCY CETACEANS

Range to effects for explosives: high-frequency cetaceans [1]					
Bin	Source depth (m)	Cluster size	PTS	TTS	Behavioral disturbance
E1	0.1	1	361 (350–370)	1,108 (1,000–1,275)	1,515 (1,025–2,025)
		18	1,002 (925–1,025)	2,404 (1,275–4,025)	3,053 (1,275–5,025)
E2	0.1	1	439 (420–450)	1,280 (1,025–1,775)	1,729 (1,025–2,525)
		5	826 (775–875)	1,953 (1,275–3,025)	2,560(1,275–4,275)
E3	10	1	1,647(160–3,525)	2,942 (160–10,275)	3,232 (160–12,275)
		12	3,140 (160–9,525)	3,804 (160–17,525)	3,944 (160–21,775)
	18.25	1	684 (550–1,000)	2,583 (1,025–5,025)	4,217 (1,525–7,525)
		12	1,774 (1,025–3,775)	5,643 (1,775–10,025)	7,220 (2,025–13,275)
E4	10	2	1,390 (950–3,025)	5,250 (2,275–8,275)	7,004 (2,775–11,275)
	30	2	1,437 (925–2,775)	4,481 (1,525–7,775)	5,872 (2,775–10,525)
	70	2	1,304 (925–2,275)	3,845 (2,525–7,775)	5,272 (3,525–9,525)
	90	2	1,534 (900–2,525)	5,115 (2,525–7,525)	6,840 (3,275–10,275)
E5	0.1	1	940 (850–1,025)	2,159 (1,275–3,275)	2,762 (1,275–4,275)
		20	1,930 (1,275–2,775)	4,281 (1,775–6,525)	5,176 (2,025–7,775)
E7	10	1	2,536 (1,275–3,775)	6,817 (2,775–11,025)	8,963 (3,525–14,275)
	30	1	1,916 (1,025–4,275)	5,784 (2,775–10,525)	7,346 (2,775–12,025)
E8	45.75	1	1,938 (1,275–4,025)	4,919 (1,775–11,275)	5,965 (2,025–15,525)
E10	0.1	1	1,829 (1,025–2,775)	4,166 (1,775–6,025)	5,023 (2,025–7,525)
E11	91.4	1	3,245 (2,025–6,775)	6,459 (2,525–15,275)	7,632 (2,775–19,025)
	200	1	3,745 (3,025–5,025)	7,116 (4,275–11,275)	8,727 (5,025–15,025)

[1] Average distance (m) to PTS, TTS, and behavioral disturbance thresholds are depicted above the minimum and maximum distances which are in parentheses. Values depict the range produced by SEL hearing threshold criteria levels.

Table 26 shows the minimum, average, and maximum ranges to onset of auditory and likely behavioral effects that rise to the level of Level B harassment for low-frequency cetaceans based on the developed thresholds.

TABLE 26—SEL-BASED RANGES (Meters) TO ONSET PTS, ONSET TTS, AND LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR LOW-FREQUENCY CETACEANS

Range to effects for explosives: low-frequency cetaceans [1]					
Bin	Source depth (m)	Cluster size	PTS	TTS	Behavioral disturbance
E1	0.1	1	52 (50–55)	221 (120–250)	354 (160–420)
		18	177 (110–200)	656 (230–875)	836 (280–1,025)
E2	0.1	1	66 (55–70)	276 (140–320)	432 (180–525)
		5	128 (90–140)	512 (200–650)	735 (250–975)
E3	10	1	330 (160–550)	1,583 (160–4,025)	2,085 (160–7,525)
		12	1,177 (160–2,775)	2,546 (160–11,775)	2,954 (160–17,025)
18.25		1	198 (180–220)	1,019 (490–2,275)	1,715 (625–4,025)
		12	646 (390–1,025)	3,723 (800–9,025)	6,399 (1,025–46,525)
E4	10	2	462 (400–600)	3,743 (2,025–7,025)	6,292 (2,525–13,275)
	30	2	527 (330–950)	3,253 (1,775–4,775)	5,540 (2,275–8,275)
	70	2	490 (380–775)	3,026 (1,525–4,775)	5,274 (2,275–7,775)
	90	2	401 (360–500)	3,041 (1,275–4,525)	5,399 (1,775–9,275)
E5	0.1	1	174 (100–260)	633 (220–850)	865 (270–1,275)
		20	550 (200–700)	1,352 (420–2,275)	2,036 (700–4,275)
E7	10	1	1,375 (875–2,525)	7,724 (3,025–15,025)	11,787 (4,525–25,275)
	30	1	1,334 (675–2,025)	7,258 (2,775–11,025)	11,644 (4,525–24,275)
E8	45.75	1	1,227 575–2,525)	3,921 (1,025–17,275)	7,961(1,275–48,525)
E10	0.1	1	546 (200–700)	1,522 (440–5,275)	3,234 (850–30,525)
E11	91.4	1	2,537 (950–5,525)	11,249 (1,775–50,775)	37,926 (6,025–94,775)

TABLE 26—SEL-BASED RANGES (Meters) TO ONSET PTS, ONSET TTS, AND LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR LOW-FREQUENCY CETACEANS—Continued

Range to effects for explosives: low-frequency cetaceans [1]					
Bin	Source depth (m)	Cluster size	PTS	TTS	Behavioral disturbance
	200	1	2,541 (1,525–4,775)	7,407 (2,275–43,275)	42,916 (6,275–51,275)

[1] Average distance (m) to PTS, TTS, and behavioral disturbance thresholds are depicted above the minimum and maximum distances which are in parentheses. Values depict the range produced by SEL hearing threshold criteria levels.

Table 27 shows the minimum, average, and maximum ranges to onset of auditory and likely behavioral effects that rise to the level of Level B harassment for mid-frequency cetaceans based on the developed thresholds.

TABLE 27—SEL-BASED RANGES (Meters) TO ONSET PTS, ONSET TTS, AND LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR MID-FREQUENCY CETACEANS

Range to effects for explosives: Mid-frequency cetaceans [1]					
Bin	Source depth (m)	Cluster size	PTS	TTS	Behavioral disturbance
E1	0.1	1	25 (25–25)	118 (110–120)	203 (190–210)
		18	96 (90–100)	430 (410–440)	676 (600–700)
E2	0.1	1	30 (30–30)	146 (140–150)	246 (230–250)
		5	64 (60–65)	298 (290–300)	493 (470–500)
E3	10	1	61 (50–100)	512 (160–750)	928 (160–2,025)
		12	300 (160–625)	1,604 (160–3,525)	2,085 (160–5,525)
	18.25	1	40 (35–40)	199 (180–280)	368 (310–800)
		12	127 (120–130)	709 (575–1,000)	1,122 (875–2,525)
E4	10	2	73 (70–75)	445 (400–575)	765 (600–1,275)
	30	2	71 (65–90)	554 (320–1,025)	850 (525–1,775)
	70	2	63 (60–85)	382 (320–675)	815 (525–1,275)
	90	2	59 (55–85)	411 (310–900)	870 (525–1,275)
E5	0.1	1	79 (75–80)	360 (350–370)	575 (525–600)
		20	295 (280–300)	979 (800–1,275)	1,442 (925–1,775)
E7	10	1	121 (110–130)	742 (575–1,275)	1,272 (875–2,275)
	30	1	111 (100–130)	826 (500–1,775)	1,327 (925–2,275)
E8	45.75	1	133 (120–170)	817 (575–1,525)	1,298 (925–2,525)
E10	0.1	1	273 (260–280)	956 (775–1,025)	1,370 (900–1,775)
E11	91.4	1	242 (220–310)	1,547 (1,025–3,025)	2,387 (1,275–4,025)
	200	1	209 (200–300)	1,424 (1,025–2,025)	2,354 (1,525–3,775)

[1] Average distance (m) to PTS, TTS, and behavioral disturbance thresholds are depicted above the minimum and maximum distances which are in parentheses. Values depict the range produced by SEL hearing threshold criteria levels.

Table 28 shows the minimum, average, and maximum ranges to onset of auditory and likely behavioral effects that rise to the level of Level B harassment for otariid pinnipeds based on the developed thresholds.

TABLE 28—SEL-BASED RANGES (Meters) TO ONSET PTS, ONSET TTS, AND LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR OTARIIDS

Range to effects for explosives: Otariids [1]					
Bin	Source depth (meters)	Cluster size	Range to PTS (meters)	Range to TTS (meters)	Range to behavioral (meters)
E1	0.1	1	7 (7–8)	34 (30–35)	58 (55–60)
		18	25 (25–25)	124 (120–130)	208 (200–210)
E2	0.1	1	9 (9–10)	43 (40–45)	72 (70–75)
		5	19 (19–20)	88 (85–90)	145 (140–150)
E3	10	1	21 (18–25)	135 (120–210)	250 (160–370)
		12	82 (75–100)	551 (160–875)	954 (160–2,025)
	18.25	1	15 (15–15)	91 (85–95)	155 (150–160)
		12	53 (50–55)	293 (260–430)	528 (420–825)
E4	10	2	30 (30–30)	175 (170–180)	312 (300–350)
	30	2	25 (25–25)	176 (160–250)	400 (290–750)
	70	2	26 (25–35)	148 (140–200)	291 (250–400)
	90	2	26 (25–35)	139 (130–190)	271 (250–360)
E5	0.1	1	25 (24–25)	111 (110–120)	188 (180–190)
		20	93 (90–95)	421 (390–440)	629 (550–725)
E7	10	1	60 (60–60)	318 (300–360)	575 (500–775)

TABLE 28—SEL-BASED RANGES (Meters) TO ONSET PTS, ONSET TTS, AND LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR OTARIIDS—Continued

Range to effects for explosives: Otariids [1]					
Bin	Source depth (meters)	Cluster size	Range to PTS (meters)	Range to TTS (meters)	Range to behavioral (meters)
	30	1	53 (50–65)	376 (290–700)	742 (500–1,025)
E8	45.75	1	55 (55–55)	387 (310–750)	763 (525–1,275)
E10	0.1	1	87 (85–90)	397 (370–410)	599 (525–675)
E11	91.4	1	100 (100–100)	775 (550–1,275)	1,531 (900–3,025)
	200	1	94 (90–100)	554 (525–700)	1,146 (900–1,525)

[1] Average distance (m) to PTS, TTS, and behavioral disturbance thresholds are depicted above the minimum and maximum distances which are in parentheses. Values depict the range produced by SEL hearing threshold criteria levels.

Table 29 shows the minimum, average, and maximum ranges to onset of auditory and likely behavioral effects that rise to the level of Level B harassment for phocid pinnipeds based on the developed thresholds.

TABLE 29—SEL-BASED RANGES (Meters) TO ONSET PTS, ONSET TTS, AND LEVEL B HARASSMENT BY BEHAVIORAL DISTURBANCE FOR PHOCIDS

Range to Effects for Explosives: Phocids [1]					
Bin	Source depth (meters)	Cluster size	Range to PTS (meters)	Range to TTS (meters)	Range to behavioral (meters)
E1	0.1	1	47 (45–50)	219 (210–230)	366 (350–370)
		18	171 (160–180)	764 (725–800)	1,088 (1,025–1,275)
E2	0.1	1	59 (55–60)	273 (260–280)	454 (440–460)
		5	118 (110–120)	547 (525–550)	881 (825–925)
E3	10	1	185 (160–260)	1,144 (160–2,775)	1,655 (160–4,525)
		12	760 (160–1,525)	2,262 (160–8,025)	2,708 (160–12,025)
	18.25	1	112 (110–120)	628 (500–950)	1,138 (875–2,525)
		12	389 (330–625)	2,248 (1,275–4,275)	4,630 (1,275–8,525)
E4	10	2	226 (220–240)	1,622 (950–3,275)	3,087 (1,775–5,775)
	30	2	276 (200–600)	1,451 (1,025–2,275)	2,611 (1,775–4,275)
	70	2	201 (180–280)	1,331 (1,025–1,775)	2,403 (1,525–3,525)
	90	2	188 (170–270)	1,389 (975–2,025)	2,617 (1,775–3,775)
E5	0.1	1	151 (140–160)	685 (650–700)	1,002 (950–1,025)
		20	563 (550–575)	1,838 (1,275–2,275)	2,588 (1,525–3,525)
E7	10	1	405 (370–490)	3,185 (1,775–6,025)	5,314 (2,275–11,025)
	30	1	517 (370–875)	2,740 (1,775–4,275)	4,685 (3,025–7,275)
E8	45.75	1	523 (390–1,025)	2,502 (1,525–6,025)	3,879 (2,025–10,275)
E10	0.1	1	522 (500–525)	1,800 (1,275–2,275)	2,470 (1,525–3,275)
E11	91.4	1	1,063 (675–2,275)	5,043 (2,775–10,525)	7,371 (3,275–18,025)
	200	1	734 (675–850)	5,266 (3,525–9,025)	7,344 (5,025–12,775)

[1] Average distance (m) to PTS, TTS, and behavioral disturbance thresholds are depicted above the minimum and maximum distances which are in parentheses. Values depict the range produced by SEL hearing threshold criteria levels.

Table 30 shows the minimum, average, and maximum ranges due to varying propagation conditions to non-auditory injury as a function of animal mass and explosive bin (*i.e.,* net explosive weight). Ranges to gastrointestinal tract injury typically exceed ranges to slight lung injury; therefore, the maximum range to effect is not mass-dependent. Animals within these water volumes would be expected to receive minor injuries at the outer ranges, increasing to more substantial injuries, and finally mortality as an animal approaches the detonation point.

TABLE 30—RANGES [1] TO 50 PERCENT TO NON-AUDITORY INJURY FOR ALL MARINE MAMMAL HEARING GROUPS

Bin	Range to non-auditory injury (meters) [1]
E1	12 (11–13)
E2	16 (15–16)
E3	25 (25–45)
E4	31 (23–50)
E5	40 (40–40)
E7	104 (80–190)
E8	149 (130–210)
E10	153 (100–400)

TABLE 30—RANGES [1] TO 50 PERCENT TO NON-AUDITORY INJURY FOR ALL MARINE MAMMAL HEARING GROUPS—Continued

Bin	Range to non-auditory injury (meters) [1]
E11	419 (350–725)

[1] Distances in meters (m). Average distance is shown with the minimum and maximum distances due to varying propagation environments in parentheses.

Note: All ranges to non-auditory injury within this table are driven by gastrointestinal tract injury thresholds regardless of animal mass.

Ranges to mortality, based on animal mass, are shown in Table 31 below.

TABLE 31—RANGES [1] TO 50 PERCENT TO MORTALITY RISK FOR ALL MARINE MAMMAL HEARING GROUPS AS A FUNCTION OF ANIMAL MASS

Bin	Range to mortality (meters) for various animal mass intervals (kg) [1]					
	10 kg	250 kg	1,000 kg	5,000 kg	25,000 kg	72,000 kg
E1	3 (2–3)	1 (0–3)	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)
E2	4 (3–5)	2 (1–3)	1 (0–1)	0 (0–0)	0 (0–0)	0 (0–0)
E3	10 (9–20)	5 (3–20)	2 (1–5)	0 (0–3)	0 (0–1)	0 (0–1)
E4	13 (11–19)	7 (4–13)	3 (2–4)	2 (1–3)	1 (1–1)	1 (0–1)
E5	13 (11–15)	7 (4–11)	3 (3–4)	2 (1–3)	1 (1–1)	1 (0–1)
E7	49 (40–80)	27 (15–60)	13 (10–20)	9 (5–12)	4 (4–6)	3 (2–4)
E8	65 (60–75)	34 (22–55)	17 (14–20)	11 (9–13)	6 (5–6)	5 (4–5)
E10	43 (40–50)	25 (16–40)	13 (11–16)	9 (7–11)	5 (4–6)	4 (3–4)
E11	185 (90–230)	90 (30–170)	40 (30–50)	28 (23–30)	15 (13–16)	11 (9–13)

[1] Average distance (m) to mortality is depicted above the minimum and maximum distances, which are in parentheses.

Marine Mammal Density

A quantitative analysis of impacts on a species or stock requires data on their abundance and distribution that may be affected by anthropogenic activities in the potentially impacted area. The most appropriate metric for this type of analysis is density, which is the number of animals present per unit area. Marine species density estimation requires a significant amount of effort to both collect and analyze data to produce a reasonable estimate. Unlike surveys for terrestrial wildlife, many marine species spend much of their time submerged, and are not easily observed. In order to collect enough sighting data to make reasonable density estimates, multiple observations are required, often in areas that are not easily accessible (*e.g.,* far offshore). Ideally, marine mammal species sighting data would be collected for the specific area and time period (*e.g.,* season) of interest and density estimates derived accordingly. However, in many places, poor weather conditions and high sea states prohibit the completion of comprehensive visual surveys.

For most cetacean species, abundance is estimated using line-transect surveys or mark-recapture studies (*e.g.,* Barlow, 2010; Barlow and Forney, 2007; Calambokidis *et al.,* 2008). The result provides one single density estimate value for each species across broad geographic areas. This is the general approach applied in estimating cetacean abundance in NMFS' SARs. Although the single value provides a good average estimate of abundance (total number of individuals) for a specified area, it does not provide information on the species distribution or concentrations within that area, and it does not estimate density for other timeframes or seasons that were not surveyed. More recently, spatial habitat modeling developed by NMFS' Southwest Fisheries Science Center has been used to estimate cetacean densities (Barlow *et al.,* 2009; Becker *et al.,* 2010, 2012a, b, c, 2014, 2016, 2017, 2020; Ferguson *et al.,* 2006a; Forney *et al.,* 2012, 2015; Redfern *et al.,* 2006). These models estimate cetacean density as a continuous function of habitat variables (*e.g.,* sea surface temperature, seafloor depth, *etc.*) and thus allow predictions of cetacean densities on finer spatial scales than traditional line-transect or mark recapture analyses and for areas that have not been surveyed. Within the geographic area that was modeled, densities can be predicted wherever these habitat variables can be measured or estimated.

Ideally, density data would be available for all species throughout the study area year-round, in order to best estimate the impacts of Navy activities on marine species. However, in many places, ship availability, lack of funding, inclement weather conditions, and high sea states prevent the completion of comprehensive year-round surveys. Even with surveys that are completed, poor conditions may result in lower sighting rates for species that would typically be sighted with greater frequency under favorable conditions. Lower sighting rates preclude having an acceptably low uncertainty in the density estimates. A high level of uncertainty, indicating a low level of confidence in the density estimate, is typical for species that are rare or difficult to sight. In areas where survey data are limited or non-existent, known or inferred associations between marine habitat features and the likely presence of specific species are sometimes used to predict densities in the absence of actual animal sightings. Consequently, there is no single source of density data for every area, species, and season because of the fiscal costs, resources, and effort involved in providing enough survey coverage to sufficiently estimate density.

To characterize marine species density for large oceanic regions, the Navy reviews, critically assesses, and prioritizes existing density estimates from multiple sources, requiring the development of a systematic method for selecting the most appropriate density estimate for each combination of

species/stock, area, and season. The selection and compilation of the best available marine species density data resulted in the Navy Marine Species Density Database (NMSDD). The Navy vetted all cetacean densities with NMFS prior to use in the Navy's acoustic analysis for the current NWTT rulemaking process.

A variety of density data and density models are needed in order to develop a density database that encompasses the entirety of the NWTT Study Area. Because this data is collected using different methods with varying amounts of accuracy and uncertainty, the Navy has developed a hierarchy to ensure the most accurate data is used when available. The U.S. Navy Marine Species Density Database Phase III for the Northwest Training and Testing Study Area (U.S. Department of the Navy, 2019), hereafter referred to as the Density Technical Report, describes these models in detail and provides detailed explanations of the models applied to each species density estimate. The list below describes models in order of preference.

1. Spatial density models are preferred and used when available because they provide an estimate with the least amount of uncertainty by deriving estimates for divided segments of the sampling area. These models (see Becker *et al.,* 2016; Forney *et al.,* 2015) predict spatial variability of animal presence as a function of habitat variables (*e.g.,* sea surface temperature, seafloor depth, *etc.*). This model is developed for areas, species, and, when available, specific timeframes (months or seasons) with sufficient survey data; therefore, this model cannot be used for species with low numbers of sightings.

2. Stratified design-based density estimates use line-transect survey data with the sampling area divided (stratified) into sub-regions, and a density is predicted for each sub-region (see Barlow, 2016; Becker *et al.,* 2016; Bradford *et al.,* 2017; Campbell *et al.,* 2014; Jefferson *et al.,* 2014). While geographically stratified density estimates provide a better indication of a species' distribution within the study area, the uncertainty is typically high because each sub-region estimate is based on a smaller stratified segment of the overall survey effort.

3. Design-based density estimations use line-transect survey data from land and aerial surveys designed to cover a specific geographic area (see Carretta *et al.,* 2015). These estimates use the same survey data as stratified design-based estimates, but are not segmented into sub-regions and instead provide one estimate for a large surveyed area.

Although relative environmental suitability (RES) models provide estimates for areas of the oceans that have not been surveyed using information on species occurrence and inferred habitat associations and have been used in past density databases, these models were not used in the current quantitative analysis.

The Navy developed a protocol and database to select the best available data sources based on species, area, and time (season). The resulting Geographic Information System database, used in the NMSDD, includes seasonal density values for every marine mammal species present within the NWTT Study Area. This database is described in the Density Technical Report.

The Navy describes some of the challenges of interpreting the results of the quantitative analysis summarized above and described in the Density Technical Report: ''It is important to consider that even the best estimate of marine species density is really a model representation of the values of concentration where these animals might occur. Each model is limited to the variables and assumptions considered by the original data source provider. No mathematical model representation of any biological population is perfect, and with regards to marine mammal biodiversity, any single model method will not completely explain the actual distribution and abundance of marine mammal species. It is expected that there would be anomalies in the results that need to be evaluated, with independent information for each case, to support if we might accept or reject a model or portions of the model (U.S. Department of the Navy, 2017a).''

The Navy's estimate of abundance (based on density estimates used in the NWTT Study Area) utilizes NMFS' SARs, except for species with high site fidelity/smaller home ranges within the NWTT Study Area, relative to their geographic distribution (*e.g.,* harbor seals). For harbor seals in the inland waters, more up-to-date, site specific population estimates were available. For some species, the stock assessment for a given species may exceed the Navy's density prediction because those species' home range extends beyond the Study Area boundaries. For other species, the stock assessment abundance may be much less than the number of animals in the Navy's modeling given that the NWTT Study Area extends beyond the U.S waters covered by the SAR abundance estimate. The primary source of density estimates are geographically specific survey data and either peer-reviewed line-transect estimates or habitat-based density models that have been extensively validated to provide the most accurate estimates possible.

NMFS coordinated with the Navy in the development of its take estimates and concurs that the Navy's approach for density appropriately utilizes the best available science. Later, in the Analysis and Negligible Impact Determination section, we assess how the estimated take numbers compare to stock abundance in order to better understand the potential number of individuals impacted.

Take Estimation

The 2020 NWTT FSEIS/OEIS considered all training and testing activities planned to occur in the NWTT Study Area that have the potential to result in the MMPA defined take of marine mammals. The Navy determined that the three stressors below could result in the incidental taking of marine mammals. NMFS has reviewed the Navy's data and analysis and determined that it is complete and accurate and agrees that the following stressors have the potential to result in takes by harassment or serious injury/mortality of marine mammals from the Navy's planned activities:

- Acoustics (sonar and other transducers);
- Explosives (explosive shock wave and sound, assumed to encompass the risk due to fragmentation); and
- Vessel strike.

Acoustic and explosive sources have the potential to result in incidental takes of marine mammals by harassment and injury. Vessel strikes have the potential to result in incidental take from injury, serious injury, and/or mortality.

The quantitative analysis process used for the 2020 NWTT FSEIS/OEIS and the Navy's take request in the rulemaking/LOA application to estimate potential exposures to marine mammals resulting from acoustic and explosive stressors is described above and further detailed in the technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing* (U.S. Department of the Navy, 2018). The Navy Acoustic Effects Model (NAEMO) brings together scenario simulations of the Navy's activities, sound propagation modeling, and marine mammal distribution (based on density and group size) by species to model and quantify the exposure of marine mammals above identified thresholds for behavioral harassment, TTS, PTS, non-auditory injury, and mortality.

NAEMO estimates acoustic and explosive effects without taking mitigation into account; therefore, the model overestimates predicted impacts on marine mammals within mitigation zones. To account for mitigation for marine species in the take estimates, the Navy conducts a quantitative assessment of mitigation. The Navy conservatively quantifies the manner in which procedural mitigation is expected to reduce the risk for model-estimated PTS for exposures to sonars and for model-estimated mortality for exposures to explosives, based on species sightability, observation area, visibility, and the ability to exercise positive control over the sound source. See the proposed rule (85 FR 33914; June 2, 2020) for a description of the process for assessing the effectiveness of procedural mitigation measures, along with the process for assessing the potential for animal avoidance. Where the analysis indicates mitigation would effectively reduce risk, the model-estimated PTS takes are considered reduced to TTS and the model-estimated mortalities are considered reduced to injury. For a complete explanation of the process for assessing the effects of mitigation, see the Navy's rulemaking/LOA application (Section 6: Take Estimates for Marine Mammals, and Section 11: Mitigation Measures) and the technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing* (U.S. Department of the Navy, 2018). The extent to which the mitigation areas reduce impacts on the affected species is addressed qualitatively separately in the Analysis and Negligible Impact Determination section.

NMFS coordinated with the Navy in the development of this quantitative method to address the effects of procedural mitigation on acoustic and explosive exposures and takes, and NMFS independently reviewed and concurs with the Navy that it is appropriate to incorporate the quantitative assessment of mitigation into the take estimates based on the best available science.

As a general matter, NMFS does not prescribe the methods for estimating take for any applicant, but we review and ensure that applicants use the best available science, and methodologies that are logical and technically sound. Applicants may use different methods of calculating take (especially when using models) and still get to a result that is representative of the best available science and that allows for a rigorous and accurate evaluation of the effects on the affected populations. There are multiple pieces of the Navy take estimation methods—propagation models, animat movement models, and behavioral thresholds, for example. NMFS evaluates the acceptability of these pieces as they evolve and are used in different rules and impact analyses. Some of the pieces of the Navy's take estimation process have been used in Navy incidental take rules since 2009 and have undergone multiple public comment processes; all of them have undergone extensive internal Navy review, and all of them have undergone comprehensive review by NMFS, which has sometimes resulted in modifications to methods or models.

The Navy uses rigorous review processes (verification, validation, and accreditation processes; peer and public review) to ensure the data and methodology it uses represent the best available science. For instance, the NAEMO model is the result of a NMFS-led Center for Independent Experts (CIE) review of the components used in earlier models. The acoustic propagation component of the NAEMO model (CASS/GRAB) is accredited by the Oceanographic and Atmospheric Master Library (OAML), and many of the environmental variables used in the NAEMO model come from approved OAML databases and are based on in-situ data collection. The animal density components of the NAEMO model are base products of the NMSDD, which includes animal density components that have been validated and reviewed by a variety of scientists from NMFS Science Centers and academic institutions. Several components of the model, for example the Duke University habitat-based density models, have been published in peer reviewed literature. Others like the Atlantic Marine Assessment Program for Protected Species, which was conducted by NMFS Science Centers, have undergone quality assurance and quality control (QA/QC) processes. Finally, the NAEMO model simulation components underwent QA/QC review and validation for model parts such as the scenario builder, acoustic builder, scenario simulator, *etc.,* conducted by qualified statisticians and modelers to ensure accuracy. Other models and methodologies have gone through similar review processes.

In summary, we believe the Navy's methods, including the underlying NAEMO modeling and the method for incorporating mitigation and avoidance, are the most appropriate methods for predicting non-auditory injury, PTS, TTS, and behavioral disturbance. But even with the consideration of mitigation and avoidance, given some of the more conservative components of the methodology (*e.g.,* the thresholds do not consider ear recovery between pulses), we would describe the application of these methods as identifying the maximum number of instances in which marine mammals would be reasonably expected to be taken through non-auditory injury, PTS, TTS, or behavioral disturbance.

Summary of Estimated Take by Harassment From Training and Testing Activities

Based on the methods discussed in the previous sections and the Navy's model and quantitative assessment of mitigation, the Navy provided its take estimate and request for authorization of takes incidental to the use of acoustic and explosive sources for training and testing activities both annually (based on the maximum number of activities that could occur per 12-month period) and over the seven-year period covered by the Navy's rulemaking/LOA application. The following species/stocks present in the NWTT Study Area were modeled by the Navy and estimated to have 0 takes of any type from any activity source: Eastern North Pacific Northern Resident stock of killer whales, Western North Pacific stock of gray whales, and California stock of harbor seals. NMFS has reviewed the Navy's data, methodology, and analysis and determined that it is complete and accurate. NMFS agrees that the estimates for incidental takes by harassment from all sources requested for authorization are the maximum number of instances in which marine mammals are reasonably expected to be taken.

For training and testing activities, Tables 32 and 33 summarize the Navy's take estimate and request and include the maximum amount of Level A harassment and Level B harassment for the seven-year period that NMFS concurs is reasonably expected to occur by species and stock. Note that take by Level B harassment includes both behavioral disturbance and TTS. Tables 6–14–41 (sonar and other transducers) and 6–56–71 (explosives) in Section 6 of the Navy's rulemaking/LOA application provide the comparative amounts of TTS and behavioral disturbance for each species and stock annually, noting that if a modeled marine mammal was ''taken'' through exposure to both TTS and behavioral disturbance in the model, it was recorded as a TTS.

TABLE 32—ANNUAL AND SEVEN-YEAR TOTAL SPECIES-SPECIFIC TAKE ESTIMATES AUTHORIZED FROM ACOUSTIC AND EXPLOSIVE SOUND SOURCE EFFECTS FOR ALL TRAINING ACTIVITIES IN THE NWTT STUDY AREA

Species	Stock	Annual		7-Year total [1]	
		Level B	Level A	Level B	Level A
Order Cetacea Suborder Mysticeti (baleen whales)					
Family Balaenopteridae (rorquals):					
Blue whale *	Eastern North Pacific	2	0	11	0
Fin whale *	Northeast Pacific	0	0	0	0
	California, Oregon, Washington	54	0	377	0
Sei whale *	Eastern North Pacific	30	0	206	0
Minke whale	Alaska	0	0	0	0
	California, Oregon, Washington	110	0	767	0
Humpback whale	Central North Pacific	5	0	31	0
	California, Oregon, Washington †	4	0	[2] 28	0
Family Eschrichtiidae (gray whale):					
Gray whale	Eastern North Pacific	2	0	10	0
	Western North Pacific †	0	0	0	0
Suborder Odontoceti (toothed whales)					
Family Delphinidae (dolphins):					
Bottlenose dolphin	California, Oregon, & Washington, Offshore	5	0	33	0
Killer whale	Alaska Resident	0	0	0	0
	Eastern North Pacific Offshore	68	0	[2] 476	0
	Northern Resident	0	0	0	0
	West Coast Transient	78	0	538	0
	Southern Resident †	3	0	15	0
Northern right whale dolphin	California, Oregon, Washington	7,941	0	55,493	0
Pacific white-sided dolphin	North Pacific	0	0	0	0
	California, Oregon, Washington	5,284	0	36,788	0
Risso's dolphin	California, Oregon, Washington	2,286	0	15,972	0
Short-beaked common dolphin	California, Oregon, Washington	1,165	0	8,124	0
Short-finned pilot whale	California, Oregon, Washington	57	0	398	0
Striped dolphin	California, Oregon, Washington	439	0	3,059	0
Family Kogiidae (Kogia spp.):					
Kogia whales	California, Oregon, Washington	[3] 382	0	[3] 2,665	0
Family Phocoenidae (porpoises):					
Dall's porpoise	Alaska	0	0	0	0
	California, Oregon, Washington	13,299	8	92,793	48
Harbor porpoise	Southeast Alaska	0	0	0	0
	Northern Oregon/Washington Coast	299	0	2,092	0
	Northern California/Southern Oregon	21	0	145	0
	Washington Inland Waters	12,315	43	79,934	291
Family Physeteridae (sperm whale):					
Sperm whale *	California, Oregon, Washington	512	0	3,574	0
Family Ziphiidae (beaked whales):					
Baird's beaked whale	California, Oregon, Washington	556	0	3,875	0
Cuvier's beaked whale	California, Oregon, Washington	1,462	0	10,209	0
Mesoplodon spp	California, Oregon, Washington	652	0	4,549	0
Suborder Pinnipedia					
Family Otariidae (sea lions and fur seals):					
California sea lion	U.S. Stock	3,624	0	25,243	0
Steller sea lion	Eastern U.S.	108	0	743	0
Guadalupe fur seal *	Mexico	608	0	4,247	0
Northern fur seal	Eastern Pacific	2,134	0	14,911	0
	California	43	0	300	0
Family Phocidae (true seals):					
Harbor seal	Southeast Alaska—Clarence Strait	0	0	0	0
	Oregon/Washington Coastal	0	0	0	0
	Washington Northern Inland Waters	669	5	3,938	35
	Hood Canal	2,686	1	18,662	5
	Southern Puget Sound	1,090	1	6,657	6
Northern elephant seal	California	1,909	1	13,324	1

* ESA-listed species (all stocks) within the NWTT Study Area. † Only designated populations are ESA-listed.

[1] The seven-year totals may be less than the annual totals times seven, given that not all activities occur every year, some activities occur multiple times within a year, and some activities only occur a few times over the course of a seven-year period.

[2] The proposed rule incorrectly indicated 32 takes by Level B harassment of the CA/OR/WA stock of humpback whale, and 478 takes by Level B harassment of the Eastern North Pacific Offshore stock of killer whale over the seven-year period of the rule. Given that the annual take estimate is calculated based on the maximum amount of activity that could occur within a one-year period, the seven-year take estimate would, at most, be seven times the annual take estimate. (However, we note that in some cases, the seven-year take estimate is less than seven times the annual take estimate, as some activities have restrictions on the number of activities over the seven-year period.)

[3] For *Kogia* Spp., the proposed rule indicated 381 annual takes by Level B harassment, and 2,664 takes by Level B harassment over the seven-year period of the rule. These updated take estimates reflect clarifications due to rounding errors in the proposed rule.

TABLE 33—ANNUAL AND SEVEN-YEAR TOTAL SPECIES-SPECIFIC TAKE ESTIMATES AUTHORIZED FROM ACOUSTIC AND EXPLOSIVE SOUND SOURCE EFFECTS FOR ALL TESTING ACTIVITIES IN THE NWTT STUDY AREA

Species	Stock	Annual		7-Year total	
		Level B	Level A	Level B	Level A
Order Cetacea Suborder Mysticeti (baleen whales)					
Family Balaenopteridae (rorquals):					
Blue whale *	Eastern North Pacific	8	0	38	0
Fin whale *	Northeast Pacific	2	0	10	0
	California, Oregon, Washington	81	0	[1] 389	0
Sei whale *	Eastern North Pacific	53	0	[1] 257	0
Minke whale	Alaska	2	0	9	0
	California, Oregon, Washington	192	0	[1] 913	0
Humpback whale *	Central North Pacific	110	0	[1] 577	0
	California, Oregon, Washington	89	0	[1] 456	0
Family Eschrichtiidae (gray whale):					
Gray whale	Eastern North Pacific	41	0	[1] 181	0
	Western North Pacific†	0	0	0	0
Suborder Odontoceti (toothed whales)					
Family Delphinidae (dolphins):					
Bottlenose dolphin	California, Oregon, Washington, Offshore	3	0	14	0
Killer whale	Alaska Resident	34	0	202	0
	Eastern North Pacific Offshore	89	0	412	0
	Northern Resident	0	0	0	0
	West Coast Transient	154	0	831	0
	Southern Resident †	48	0	228	0
Northern right whale dolphin	California, Oregon, Washington	13,759	1	[1] 66,456	7
Pacific white-sided dolphin	North Pacific	101	0	603	0
	California, Oregon, Washington	15,681	1	[1] 76,978	[1] 7
Risso's dolphin	California, Oregon, Washington	4,069	0	[1] 19,636	0
Short-beaked common dolphin	California, Oregon, Washington	984	0	3,442	0
Short-finned pilot whale	California, Oregon, Washington	31	0	126	0
Striped dolphin	California, Oregon, Washington	344	0	1,294	0
Family Kogiidae (Kogia spp.):					
Kogia whales	California, Oregon, Washington	[2] 500	[2] 2	[1 2] 2,375	9
Family Phocoenidae (porpoises):					
Dall's porpoise	Alaska	638	0	3,711	0
	California, Oregon, Washington	20,398	90	[1] 98,241	[1] 456
Harbor porpoise	Southeast Alaska	130	0	794	0
	Northern Oregon/Washington Coast	52,113	103	[1] 264,999	[1] 359
	Northern California/Southern Oregon	2,018	86	[1] 11,525	[1] 261
	Washington Inland Waters	17,228	137	115,770	930
Family Physeteridae (sperm whale):					
Sperm whale *	California, Oregon, Washington	327	0	1,443	0
Family Ziphiidae (beaked whales):					
Baird's beaked whale	California, Oregon, Washington	420	0	1,738	0
Cuvier's beaked whale	California, Oregon, Washington	1,077	0	4,979	0
Mesoplodon spp	California, Oregon, Washington	470	0	2,172	0
Suborder Pinnipedia					
Family Otariidae (sea lions and fur seals):					
California sea lion	U.S. Stock	20,474	1	[1] 93,901	[1] 4
Steller sea lion	Eastern U.S.	2,130	0	[1] 10,744	0
Guadalupe fur seal *	Mexico	887	0	4,022	0
Northern fur seal	Eastern Pacific	9,458	0	45,813	0
	California	189	0	920	0
Family Phocidae (true seals):					
Harbor seal	Southeast Alaska—Clarence Strait	2,352	0	13,384	0
	Oregon/Washington Coastal	1,180	2	[1] 6,182	[1] 6
	Washington Northern Inland Waters	578	0	3,227	0
	Hood Canal	58,784	0	396,883	0
	Southern Puget Sound	5,748	3	39,511	[1] 21
Northern elephant seal	California	2,935	3	[1] 14,110	[1] 17

* ESA-listed species (all stocks) within the NWTT Study Area. † Only designated populations are ESA-listed.
[1] The take estimate for these species decreased since the proposed rule, as the Navy has adjusted their planned activity by reducing the number of times Mine Countermeasure and Neutralization testing could occur over the seven-year period of the rule.
[2] For *Kogia* Spp., the proposed rule indicated 501 annual takes by Level B harassment, 1 annual take by Level A harassment, and 2,376 takes by Level B harassment over the seven-year period of the rule. These updated take estimates reflect clarifications due to rounding errors in the proposed rule.

Estimated Take From Vessel Strikes by Serious Injury or Mortality

Vessel strikes from commercial, recreational, and military vessels are known to affect large whales and have resulted in serious injury and occasional fatalities to cetaceans (Berman-Kowalewski *et al.,* 2010; Calambokidis, 2012; Douglas *et al.,* 2008; Laggner 2009; Lammers *et al.,* 2003). Records of collisions date back to the early 17th century, and the worldwide number of collisions appears to have increased steadily during recent decades (Laist *et al.,* 2001; Ritter 2012).

Numerous studies of interactions between surface vessels and marine

mammals have demonstrated that free-ranging marine mammals often, but not always (*e.g.,* McKenna *et al.,* 2015), engage in avoidance behavior when surface vessels move toward them. It is not clear whether these responses are caused by the physical presence of a surface vessel, the underwater noise generated by the vessel, or an interaction between the two (Amaral and Carlson, 2005; Au and Green, 2000; Bain *et al.,* 2006; Bauer 1986; Bejder *et al.,* 1999; Bejder and Lusseau, 2008; Bejder *et al.,* 2009; Bryant *et al.,* 1984; Corkeron, 1995; Erbe, 2002; Félix, 2001; Goodwin and Cotton, 2004; Greig *et al.,* 2020; Guilpin *et al.,* 2020; Keen *et al.,* 2019; Lemon *et al.,* 2006; Lusseau, 2003; Lusseau, 2006; Magalhaes *et al.,* 2002; Nowacek *et al.,* 2001; Redfern *et al.,* 2020; Richter *et al.,* 2003; Scheidat *et al.,* 2004; Simmonds, 2005; Szesciorka *et al.,* 2019; Watkins, 1986; Williams *et al.,* 2002; Wursig *et al.,* 1998). Several authors suggest that the noise generated during motion is probably an important factor (Blane and Jaakson, 1994; Evans *et al.,* 1992; Evans *et al.,* 1994). Water disturbance may also be a factor. These studies suggest that the behavioral responses of marine mammals to surface vessels are similar to their behavioral responses to predators. Avoidance behavior is expected to be even stronger in the subset of instances during which the Navy is conducting training or testing activities using active sonar or explosives.

The marine mammals most vulnerable to vessel strikes are those that spend extended periods of time at the surface in order to restore oxygen levels within their tissues after deep dives (*e.g.,* sperm whales). In addition, some baleen whales seem generally unresponsive to vessel sound, making them more susceptible to vessel collisions (Nowacek *et al.,* 2004). These species are primarily large, slow moving whales.

Some researchers have suggested the relative risk of a vessel strike can be assessed as a function of animal density and the magnitude of vessel traffic (*e.g.,* Fonnesbeck *et al.,* 2008; Vanderlaan *et al.,* 2008). Differences among vessel types also influence the probability of a vessel strike. The ability of any ship to detect a marine mammal and avoid a collision depends on a variety of factors, including environmental conditions, ship design, size, speed, and ability and number of personnel observing, as well as the behavior of the animal. Vessel speed, size, and mass are all important factors in determining if injury or death of a marine mammal is likely due to a vessel strike. For large vessels, speed and angle of approach can influence the severity of a strike. For example, Vanderlaan and Taggart (2007) found that between vessel speeds of 8.6 and 15 knots, the probability that a vessel strike is lethal increases from 0.21 to 0.79. Large whales also do not have to be at the water's surface to be struck. Silber *et al.* (2010) found when a whale is below the surface (about one to two times the vessel draft), under certain circumstances (vessel speed and location of the whale relative to the ship's centerline), there is likely to be a pronounced propeller suction effect. This suction effect may draw the whale into the hull of the ship, increasing the probability of propeller strikes.

There are some key differences between the operation of military and non-military vessels, which make the likelihood of a military vessel striking a whale lower than some other vessels (*e.g.,* commercial merchant vessels). Key differences include:

- Many military ships have their bridges positioned closer to the bow, offering better visibility ahead of the ship (compared to a commercial merchant vessel);
- There are often aircraft associated with the training or testing activity (which can serve as Lookouts), which can more readily detect cetaceans in the vicinity of a vessel or ahead of a vessel's present course before crew on the vessel would be able to detect them;
- Military ships are generally more maneuverable than commercial merchant vessels, and if cetaceans are spotted in the path of the ship, could be capable of changing course more quickly;
- The crew size on military vessels is generally larger than merchant ships, allowing for stationing more trained Lookouts on the bridge. At all times when Navy vessels are underway, trained Lookouts and bridge navigation teams are used to detect objects on the surface of the water ahead of the ship, including cetaceans. Additional personnel, beyond those already stationed on the bridge and on navigation teams, are positioned as Lookouts during some training events; and
- When submerged, submarines are generally slow moving (to avoid detection) and therefore marine mammals at depth with a submarine are likely able to avoid collision with the submarine. When a submarine is transiting on the surface, there are Lookouts serving the same function as they do on surface ships.

Vessel strike to marine mammals is not associated with any specific training or testing activity but is rather an extremely limited and sporadic, but possible, accidental result of Navy vessel movement within the NWTT Study Area or while in transit.

Data from the ports of Vancouver, British Columbia; Seattle, Washington; and Tacoma, Washington indicate there were more than 7,000 commercial vessel transits in 2017 associated with visits to just those ports (The Northwest Seaport Alliance, 2018; Vancouver Fraser Port Authority). This number of vessel transits does not account for other vessel traffic in the Strait of Juan de Fuca or Puget Sound including commercial ferries, tourist vessels, or recreational vessels. Additional commercial traffic in the NWTT Study Area also includes vessels transiting offshore along the Pacific coast, bypassing ports in Canada and Washington; traffic associated with ports to the south along the coast of Washington and in Oregon; and vessel traffic in Southeast Alaska (Nuka Research & Planning Group, 2012). Navy vessel traffic accounts for only a small portion of vessel activities in the NWTT Study Area. The Navy has, in total, the following homeported operational vessels: 2 aircraft carriers, 6 destroyers, 14 submarines, and 22 smaller security vessels with a combined annual total of 241 Navy vessel transits (see Appendix A (Navy Activities Descriptions) of the 2020 FSEIS/OEIS for descriptions of the number of vessels used during the various types of Navy's planned activities). Activities involving military vessel movement would be widely dispersed throughout the NWTT Study Area.

Navy vessel strike records have been kept since 1995, and since 1995 there have been two recorded strikes of whales by Navy vessels (or vessels being operated on behalf of the Navy) in the NWTT Study Area. Neither strike was associated with training or testing activities. The first strike occurred in 2012 by a Navy destroyer off the southern coast of Oregon while in transit to San Diego. The whale was suspected to be a minke whale due to the appearance and size (25 ft, dark with white belly), however the Navy could not rule out the possibility that it was a juvenile fin whale. The whale was observed swimming after the strike and no blood or injury was sighted. The second strike occurred in 2016 by a U.S. Coast Guard cutter operating on behalf of the Navy as part of a Maritime Security Operation escort vessel in the Strait of Juan de Fuca. The whale was positively identified as a humpback whale. It was observed for 10 minutes post-collision and appeared normal at the surface. There was no blood

observed in the water and the whale subsequently swam away.

In order to account for the potential risk from vessel movement within the NWTT Study Area within the seven-year period in particular, the Navy requested incidental takes based on probabilities derived from a Poisson distribution using ship strike data between 2009–2018 in the NWTT Study Area (the time period from when current mitigation measures to reduce the likelihood of vessel strikes were instituted until the Navy conducted the analysis for the Navy's application), as well as historical at-sea days in the NWTT Study Area from 2009–2018 and estimated potential at-sea days for the period from 2020 to 2027 covered by the requested regulations. This distribution predicted the probabilities of a specific number of strikes (n=0, 1, 2, *etc.*) over the period from 2020 to 2027. The analysis for the period of 2020 to 2027 is described in detail in Chapter 6.6 (Vessel Strike Analysis) of the Navy's rulemaking/LOA application.

For the same reasons listed above, describing why a Navy vessel strike is comparatively unlikely, it is highly unlikely that a Navy vessel would strike a whale, dolphin, porpoise, or pinniped without detecting it and, accordingly, NMFS is confident that the Navy's reported strikes are accurate and appropriate for use in the analysis. Specifically, Navy ships have multiple Lookouts, including on the forward part of the ship that can visually detect a hit animal, in the unlikely event ship personnel do not feel the strike. Unlike the situation for non-Navy ships engaged in commercial activities, NMFS and the Navy have no evidence that the Navy has struck a whale and not detected it. Navy's strict internal procedures and mitigation requirements include reporting of any vessel strikes of marine mammals, and the Navy's discipline, extensive training (not only for detecting marine mammals, but for detecting and reporting any potential navigational obstruction), and strict chain of command give NMFS a high level of confidence that all strikes actually get reported.

The Navy used those two whale strikes in their calculations to determine the number of strikes likely to result from their activities and evaluated data beginning in 2009. The Navy's Marine Species Awareness Training was first used in 2006 and was fully integrated across the Navy in 2009, which is why the Navy uses 2009 as the date to begin the analysis. The adoption of additional mitigation measures to address ship strike also began in 2009, and will remain in place along with additional mitigation measures during the seven years of this rule. The probability analysis concluded that there was a 26 percent chance that zero whales would be struck by Navy vessels over the seven-year period, and a 35, 24, 11, and 4 percent chance that one, two, three, or four whales, respectively, would be struck over the seven-year period (with a 74 percent chance total that at least one whale would be struck over the seven-year period). Therefore, the Navy estimates, and NMFS agrees, that there is some probability (an 11 percent chance) that the Navy could strike, and take by serious injury or mortality, up to three large whales incidental to training and testing activities within the NWTT Study Area over the course of the seven years.

Small whales, delphinids, porpoises, and pinnipeds are not expected to be struck by Navy vessels. In addition to the reasons listed above that make it unlikely that the Navy will hit a large whale (more maneuverable ships, larger crews, *etc.*), the following are the additional reasons that vessel strike of dolphins, small whales, porpoises, and pinnipeds is considered very unlikely. Dating back more than 20 years and for as long as it has kept records, the Navy has no records of individuals of these groups (including Southern Resident killer whales) being struck by a vessel as a result of Navy activities and, further, their smaller size and maneuverability make a strike unlikely. Also, NMFS has never received any reports from other authorized activities indicating that these species have been struck by vessels. Worldwide ship strike records show little evidence of strikes of these groups from the shipping sector and larger vessels, and the majority of the Navy's activities involving faster-moving vessels (that could be considered more likely to hit a marine mammal) are located in offshore areas where smaller delphinid, porpoise, and pinniped densities are lower. Since 2005, though, three vessel strikes of Southern Resident killer whales have been recorded: one collision with a commercial whale watch vessel in 2005 (the whale recovered), one collision with a tug boat in 2006 (the whale was killed), and one animal found dead in 2016 with evidence of blunt force trauma consistent with a vessel strike. However, given the information above regarding the overall low likelihood of vessel strikes of small whales, delphinids, porpoises, and pinnipeds by Navy vessels, as well as the enhanced mitigation for, and high visibility of, Southern Resident killer whales, Southern Resident killer whales are not expected to be struck by Navy vessels. Based on this information and the Navy's assessment, NMFS concludes that there is the potential for incidental take by vessel strike of large whales only (*i.e.,* no dolphins, small whales, porpoises, or pinnipeds) over the course of the seven-year regulations from training and testing activities.

Taking into account the available information regarding how many of any given stock could be struck and therefore should be authorized for take, NMFS considered three factors in addition to those considered in the Navy's request: (1)The relative likelihood of hitting one stock versus another based on available strike data from all vessel types as denoted in the SARs, (2) whether the Navy has ever definitively struck an individual from a particular species or stock in the NWTT Study Area, and if so, how many times, and (3) whether there are records that an individual from a particular species or stock has been struck by any vessel in the NWTT Study Area, and if so, how many times (based on ship strike records provided by the NMFS West Coast Region in February 2020). To address number (1) above, NMFS compiled information from NMFS' SARs on detected annual rates of large whale serious injury or mortality (M/SI) from vessel collisions (Table 34). The annual rates of large whale serious injury or mortality from vessel collisions from the SARs help inform the relative susceptibility of large whale species to vessel strike in NWTT Study Area as recorded systematically over the last five years (the period used for the SARs). However, we note that the SARs present strike data from the stock's entire range, which is much larger than the NWTT Study Area, and available ship strike records show that the majority of strikes that occur off the U.S. West Coast occur in southern California. We summed the annual rates of serious injury or mortality from vessel collisions as reported in the SARs, then divided each species' annual rate by this sum to get the proportion of strikes for each species/stock. To inform the likelihood of striking a particular species of large whale, we multiplied the proportion of striking each species by the probability of striking at least one whale (*i.e.,* 74 percent, as described by the Navy's probability analysis above). We note that these probabilities vary from year to year as the average annual mortality for a given five-year window in the SAR changes; however, over the years and through changing SARs, stocks tend to consistently maintain a relatively higher or relatively lower

likelihood of being struck (and we include the annual averages from 2017 SARs in Table 34 to illustrate).

The probabilities calculated as described above are then considered in combination with the information indicating the species that the Navy has definitively hit in the NWTT Study Area since 1995 (since they started tracking consistently) and the species that are known to have been struck by any vessel (through regional stranding data) in the NWTT Study Area. We also note that Rockwood *et al.* (2017) modeled the likely vessel strike of blue whales, fin whales, and humpback whales on the U.S. West Coast (discussed in more detail in the *Serious Injury or Mortality* subsection of the Analysis and Negligible Impact Determination section), and those numbers help inform the relative likelihood that the Navy will hit those stocks.

For each indicated stock, Table 34 includes the percent likelihood of hitting an individual whale once based on SAR data, total strikes from Navy vessels (from 1995), total strikes from any vessel (from 2000 from regional stranding data), and modeled vessel strikes from Rockwood *et al.* (2017). The last column indicates the annual serious injury or mortality authorized.

TABLE 34—SUMMARY OF FACTORS CONSIDERED IN DETERMINING THE NUMBER OF INDIVIDUALS IN EACH STOCK POTENTIALLY STRUCK BY A VESSEL

ESA status	Species	Stock	Annual rate of M/SI from vessel collision (observed from 2017 SARs)	Annual rate of M/SI from vessel collision (observed from 2019 SARs)	Percent likelihood of hitting individual from species/ stock once (from 2019 SARs data)	Total known strikes in OR, WA, northern CA (from 2000 to present) [1]	Total known navy strikes in NWTT study area	Rockwood *et al.* (2017) modeled vessel strikes [5]	MMPA authorized takes (from the 3 total)	Annual authorized take
Listed	Blue whale	Eastern North Pacific	0	0.4	3.7			18	0	0
	Fin whale	Northeast Pacific	0.2	0.4	3.7	[2] 10			2	0.29
		CA/OR/WA	1.8	1.6	14.8	[2] 10		43	2	0.29
	Sei whale	Eastern North Pacific	0	0.2	1.85				0	0
	Humpback whale	CA/OR/WA (Mexico and Central America DPS).	1.1	2.1	19.425	[3] 4	[4] 1	22	2	0.29
	Sperm whale	CA/OR/WA	0.2	0	0	3			1	0.14
Not Listed	Minke whale	Alaska	0	0	0				0	0
		CA/OR/WA	0	0	0	1	1		1	0.14
	Gray whale	Eastern North Pacific	2	0.8	7.4	9			1	0.14
	Humpback whale	Central North Pacific (Hawaii DPS)	2.6	2.5	23.125	[3] 4	[4] 1		2	0.29

Note: A "-" indicates that the field does not apply.

[1] Only one ship strike was reported in California in the NWTT Study Area (which is limited to Humboldt and Del Norte Counties). This strike occurred in 2004 in Humboldt County and was not identified to species.

[2] A total of 10 fin whale strikes are reported in the regional stranding database, however no information on stock is provided. As these two stocks of fin whales are known to overlap spatially and temporally in the NWTT Study Area, the 10 reported strikes could come from either stock or a combination of both stocks.

[3] A total of 4 humpback whales strikes are reported in the regional stranding database, however no information on stock is provided. As these two stocks of humpback whales are known to overlap spatially and temporally in the NWTT Study Area, the 4 reported strikes could come from either stock or a combination of both stocks.

[4] One humpback whale was reported as struck by a U.S. Coast Guard cutter operating on behalf of the Navy, however it was not possible for the Navy to determine which stock this whale came from. As these two stocks of humpback whales are known to overlap spatially and temporally in the NWTT Study Area, this whale could have come from either stock.

[5] Rockwood *et al.* modeled likely annual vessel strikes off the U.S. West Coast for these three species only.

Accordingly, stocks that have no record of having been struck by any vessel are considered unlikely to be struck by the Navy in the seven-year period of the rule. Stocks that have never been struck by the Navy, have rarely been struck by other vessels, and have a low likelihood of being struck based on the SAR calculation and a low relative abundance (Eastern North Pacific stock of blue whales, Eastern North Pacific stock of sei whales, and Alaska stock of minke whales) are also considered unlikely to be struck by the Navy during the seven-year rule. This rules out all but seven stocks.

The two stocks of humpback whales (California/Oregon/Washington (CA/OR/WA) and Central North Pacific) and two stocks of fin whales (CA/OR/WA and Northeast Pacific) are known to overlap spatially and temporally in the NWTT Study Area, and it is not possible to distinguish the difference between individuals of these stocks based on visual sightings in the field. The Navy has previously struck a humpback whale in the NWTT Study Area, and it is the second most common species struck by any vessel in the Study Area based on stranding data. Based on the SAR data, the two stocks of humpback whales also have the highest likelihood of being struck. Though the Navy has not definitively struck a fin whale in the NWTT Study Area (noting that the Navy could not rule out that the minke whale strike could have been a juvenile fin whale), fin whales are the most common species struck by any vessel in the Study Area based on stranding data. Based on the SAR data, the CA/OR/WA stock has the third highest likelihood of being struck. Based on all of these factors, it is considered reasonable that humpback whales (from either the CA/OR/WA or Central North Pacific stocks) could be struck twice and fin whales (from either the CA/OR/WA or Northeast Pacific stocks) could be struck twice during the seven-year rule.

Based on the SAR data, the CA/OR/WA stock of sperm whales and CA/OR/WA stock of minke whales have a very low likelihood of being struck. However, 3 sperm whales have been struck by non-Navy vessels in the NWTT Study Area (in 2002, 2007, and 2012) and the Navy has previously struck a minke whale in the NWTT Study Area. Therefore, we consider it reasonable that an individual from each of these stocks could be struck by the Navy once during the seven-year rule. Finally, based on stranding data, gray whales are the second most commonly struck whale in the NWTT Study Area and the SAR data indicates that on average, 0.8 whales from this stock are struck throughout the stock's range each year. Based on these data, we consider it reasonable that an individual from the Eastern North Pacific stock of gray whales could be struck by the Navy once during the seven-year rule.

In conclusion, although it is generally unlikely that any whales will be struck in a year, based on the information and analysis above, NMFS anticipates that no more than three whales have the potential to be taken by serious injury or mortality over the seven-year period of the rule. Of those three whales over the seven years, no more than two may come from any of the following species/stocks: Fin whale (which may come from either the Northeast Pacific or CA/OR/WA stock) and humpback whale (which may come from either the Central North Pacific or CA/OR/WA stock). Additionally, of those three whales over the seven years no more than one may come from any of the

following species/stocks: Sperm whale (CA/OR/WA stock), minke whale (CA/OR/WA stock), and gray whale (Eastern North Pacific stock). Accordingly, NMFS has evaluated under the negligible impact standard the mortality or serious injury (M/SI) of 0.14 or 0.29 whales annually from each of these stocks (*i.e.,* 1 or 2 takes, respectively, divided by seven years to get the annual number), along with the expected incidental takes by harassment. We do not anticipate, nor have we authorized, ship strike takes to blue whales (Eastern North Pacific stock), minke whales (Alaska stock), or sei whales (Eastern North Pacific stock).

Mitigation Measures

Under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable adverse impact on the 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 subsistence uses (''least practicable adverse impact''). NMFS does not have a regulatory definition for least practicable adverse impact. The 2004 NDAA amended the MMPA as it relates to military readiness activities and the incidental take authorization process such that a determination of ''least practicable adverse impact'' on the species or stock shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

In *Conservation Council for Hawaii* v. *National Marine Fisheries Service,* 97 F. Supp. 3d 1210, 1229 (D. Haw. 2015), the Court stated that NMFS ''appear[s] to think [it] satisf[ies] the statutory 'least practicable adverse impact' requirement with a 'negligible impact' finding.'' Expressing similar concerns in a challenge to a U.S. Navy Surveillance Towed Array Sensor System Low Frequency Active Sonar (SURTASS LFA) incidental take rule (77 FR 50290), the Ninth Circuit Court of Appeals in *Natural Resources Defense Council (NRDC)* v. *Pritzker,* 828 F.3d 1125, 1134 (9th Cir. 2016), stated, ''[c]ompliance with the 'negligible impact' requirement does not mean there [is] compliance with the 'least practicable adverse impact' standard.'' As the Ninth Circuit noted in its opinion, however, the Court was interpreting the statute without the benefit of NMFS' formal interpretation. We state here explicitly that NMFS is in full agreement that the ''negligible impact'' and ''least practicable adverse impact'' requirements are distinct, even though both statutory standards refer to species and stocks. With that in mind, we provide further explanation of our interpretation of least practicable adverse impact, and explain what distinguishes it from the negligible impact standard. This discussion is consistent with previous rules we have issued, such as the Navy's Hawaii-Southern California Training and Testing (HSTT) rule (85 FR 41780; July 10, 2020), Atlantic Fleet Training and Testing (AFTT) rule (84 FR 70712; December 23, 2019), and Mariana Islands Training and Testing (MITT) rule (85 FR 46302; July 31, 2020).

Before NMFS can issue incidental take regulations under section 101(a)(5)(A) of the MMPA, it must make a finding that the total taking will have a ''negligible impact'' on the affected ''species or stocks'' of marine mammals. NMFS' and U.S. Fish and Wildlife Service's implementing regulations for section 101(a)(5) both define ''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 and 50 CFR 18.27(c)). Recruitment (*i.e.,* reproduction) and survival rates are used to determine population growth rates [4] and, therefore are considered in evaluating population level impacts.

As stated in the preamble to the proposed rule for the MMPA incidental take implementing regulations, not every population-level impact violates the negligible impact requirement. The negligible impact standard does not require a finding that the anticipated take will have ''no effect'' on population numbers or growth rates: The statutory standard does not require that the same recovery rate be maintained, rather that no significant effect on annual rates of recruitment or survival occurs. The key factor is the significance of the level of impact on rates of recruitment or survival. (54 FR 40338, 40341–42; September 29, 1989).

While some level of impact on population numbers or growth rates of a species or stock may occur and still satisfy the negligible impact requirement—even without consideration of mitigation—the least practicable adverse impact provision separately requires NMFS to prescribe means of effecting the least practicable adverse impact on the species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, 50 CFR 216.102(b), which are typically identified as mitigation measures.[5]

The negligible impact and least practicable adverse impact standards in the MMPA both call for evaluation at the level of the ''species or stock.'' The MMPA does not define the term ''species.'' However, Merriam-Webster Dictionary defines ''species'' to include ''related organisms or *populations* potentially capable of interbreeding.'' See *www.merriam-webster.com/dictionary/species* (emphasis added). Section 3(11) of the MMPA defines ''stock'' as a group of marine mammals of the same species or smaller taxa in a common spatial arrangement that interbreed when mature. The definition of ''population'' is a group of interbreeding organisms that represents the level of organization at which speciation begins. *www.merriam-webster.com/dictionary/population.* The definition of ''population'' is strikingly similar to the MMPA's definition of ''stock,'' with both involving groups of individuals that belong to the same species and located in a manner that allows for interbreeding. In fact under MMPA section 3(11), the term ''stock'' in the MMPA is interchangeable with the statutory term ''population stock.'' Both the negligible impact standard and the least practicable adverse impact standard call for evaluation at the level of the species or stock, and the terms ''species'' and ''stock'' both relate to populations; therefore, it is appropriate to view both the negligible impact standard and the least practicable adverse impact standard as having a population-level focus.

This interpretation is consistent with Congress' statutory findings for enacting the MMPA, nearly all of which are most applicable at the species or stock (*i.e.,* population) level. *See* MMPA section 2 (finding that it is species and population stocks that are or may be in danger of extinction or depletion; that it is species and population stocks that should not diminish beyond being significant functioning elements of their ecosystems; and that it is species and population stocks that should not be permitted to diminish below their optimum sustainable population level). Annual rates of recruitment (*i.e.,* reproduction) and survival are the key biological metrics used in the evaluation of population-level impacts, and

[4] A growth rate can be positive, negative, or flat.

[5] Separately, NMFS also must prescribe means of effecting the least practicable adverse impact on the availability of the species or stocks for subsistence uses, when applicable. See the Subsistence Harvest of Marine Mammals section for separate discussion of the effects of the specified activities on Alaska Native subsistence use.

accordingly these same metrics are also used in the evaluation of population level impacts for the least practicable adverse impact standard.

Recognizing this common focus of the least practicable adverse impact and negligible impact provisions on the ''species or stock'' does not mean we conflate the two standards; despite some common statutory language, we recognize the two provisions are different and have different functions. First, a negligible impact finding is required before NMFS can issue an incidental take authorization. Although it is acceptable to use the mitigation measures to reach a negligible impact finding (*see* 50 CFR 216.104(c)), no amount of mitigation can enable NMFS to issue an incidental take authorization for an activity that still would not meet the negligible impact standard. Moreover, even where NMFS can reach a negligible impact finding—which we emphasize does allow for the possibility of some ''negligible'' population-level impact—the agency must still prescribe measures that will effect the least practicable amount of adverse impact upon the affected species or stocks.

Section 101(a)(5)(A)(i)(II) requires NMFS to issue, in conjunction with its authorization, binding—and enforceable—restrictions (in the form of regulations) setting forth how the activity must be conducted, thus ensuring the activity has the ''least practicable adverse impact'' on the affected species or stocks. In situations where mitigation is specifically needed to reach a negligible impact determination, section 101(a)(5)(A)(i)(II) also provides a mechanism for ensuring compliance with the ''negligible impact'' requirement. Finally, the least practicable adverse impact standard also requires consideration of measures for marine mammal habitat, with particular attention to rookeries, mating grounds, and other areas of similar significance, and for subsistence impacts, whereas the negligible impact standard is concerned solely with conclusions about the impact of an activity on annual rates of recruitment and survival.[6] In *NRDC* v. *Pritzker,* the Court stated, ''[t]he statute is properly read to mean that even if population levels are not threatened *significantly,* still the agency must adopt mitigation measures aimed at protecting *marine mammals* to the greatest extent practicable in light of military readiness needs.'' *Pritzker* at 1134 (emphases added). This statement is consistent with our understanding stated above that even when the effects of an action satisfy the negligible impact standard (*i.e.,* in the Court's words, ''population levels are not threatened significantly''), still the agency must prescribe mitigation under the least practicable adverse impact standard. However, as the statute indicates, the focus of both standards is ultimately the impact on the affected ''species or stock,'' and not solely focused on or directed at the impact on individual marine mammals.

We have carefully reviewed and considered the Ninth Circuit's opinion in *NRDC* v. *Pritzker* in its entirety. While the Court's reference to ''marine mammals'' rather than ''marine mammal species or stocks'' in the italicized language above might be construed as holding that the least practicable adverse impact standard applies at the individual ''marine mammal'' level, *i.e.,* that NMFS must require mitigation to minimize impacts to each individual marine mammal unless impracticable, we believe such an interpretation reflects an incomplete appreciation of the Court's holding. In our view, the opinion as a whole turned on the Court's determination that NMFS had not given separate and independent meaning to the least practicable adverse impact standard apart from the negligible impact standard, and further, that the Court's use of the term ''marine mammals'' was not addressing the question of whether the standard applies to individual animals as opposed to the species or stock as a whole. We recognize that while consideration of mitigation can play a role in a negligible impact determination, consideration of mitigation measures extends beyond that analysis. In evaluating what mitigation measures are appropriate, NMFS considers the potential impacts of the specified activities, the availability of measures to minimize those potential impacts, and the practicability of implementing those measures, as we describe below.

Implementation of Least Practicable Adverse Impact Standard

Given the *NRDC* v. *Pritzker* decision, we discuss here how we determine whether a measure or set of measures meets the ''least practicable adverse impact'' standard. Our separate analysis of whether the take anticipated to result from Navy's activities meets the ''negligible impact'' standard appears in the Analysis and Negligible Impact Determination section below.

Our evaluation of potential mitigation measures includes consideration of two primary factors:

(1) The manner in which, and the degree to which, implementation of the potential measure(s) is expected to reduce adverse impacts to marine mammal species or stocks, their habitat, and their availability for subsistence uses (where relevant[7]). This analysis considers such things as the nature of the potential adverse impact (such as likelihood, scope, and range), the likelihood that the measure will be effective if implemented, and the likelihood of successful implementation; and

(2) The practicability of the measures for applicant implementation. Practicability of implementation may consider such things as cost, impact on the specified activities, and, in the case of a military readiness activity, specifically considers personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity (when evaluating measures to reduce adverse impact on the species or stocks).

Evaluation of Measures for Least Practicable Adverse Impact on Species or Stocks

While the language of the least practicable adverse impact standard calls for minimizing impacts to affected species or stocks, we recognize that the reduction of impacts to those species or stocks accrues through the application of mitigation measures that limit impacts to individual animals. Accordingly, NMFS' analysis focuses on measures that are designed to avoid or minimize impacts on individual marine mammals that are likely to increase the probability or severity of population-level effects.

While direct evidence of impacts to species or stocks from a specified activity is rarely available, and additional study is still needed to understand how specific disturbance events affect the fitness of individuals of certain species, there have been improvements in understanding the process by which disturbance effects are translated to the population. With recent scientific advancements (both marine mammal energetic research and the development of energetic frameworks), the relative likelihood or degree of impacts on species or stocks may often be inferred given a detailed understanding of the activity, the

[6] Outside of the military readiness context, mitigation may also be appropriate to ensure compliance with the ''small numbers'' language in MMPA sections 101(a)(5)(A) and (D).

[7] For more information on measures to effect the least practicable adverse impact on the availability of species or stocks for subsistence uses, see the Subsistence Harvest of Marine Mammals section below.

environment, and the affected species or stocks—and the best available science has been used here. This same information is used in the development of mitigation measures and helps us understand how mitigation measures contribute to lessening effects (or the risk thereof) to species or stocks. We also acknowledge that there is always the potential that new information, or a new recommendation could become available in the future and necessitate reevaluation of mitigation measures (which may be addressed through adaptive management) to see if further reductions of population impacts are possible and practicable.

In the evaluation of specific measures, the details of the specified activity will necessarily inform each of the two primary factors discussed above (expected reduction of impacts and practicability), and are carefully considered to determine the types of mitigation that are appropriate under the least practicable adverse impact standard. Analysis of how a potential mitigation measure may reduce adverse impacts on a marine mammal stock or species, consideration of personnel safety, practicality of implementation, and consideration of the impact on effectiveness of military readiness activities are not issues that can be meaningfully evaluated through a yes/no lens. The manner in which, and the degree to which, implementation of a measure is expected to reduce impacts, as well as its practicability in terms of these considerations, can vary widely. For example, a time/area restriction could be of very high value for decreasing population-level impacts (*e.g.,* avoiding disturbance of feeding females in an area of established biological importance) or it could be of lower value (*e.g.,* decreased disturbance in an area of high productivity but of less biological importance). Regarding practicability, a measure might involve restrictions in an area or time that impede the Navy's ability to certify a strike group (higher impact on mission effectiveness and national security), or it could mean delaying a small in-port training event by 30 minutes to avoid exposure of a marine mammal to injurious levels of sound (lower impact). A responsible evaluation of ''least practicable adverse impact'' will consider the factors along these realistic scales. Accordingly, the greater the likelihood that a measure will contribute to reducing the probability or severity of adverse impacts to the species or stock or its habitat, the greater the weight that measure is given when considered in combination with practicability to determine the appropriateness of the mitigation measure, and vice versa. We discuss consideration of these factors in greater detail below.

1. *Reduction of adverse impacts to marine mammal species or stocks and their habitat.* The emphasis given to a measure's ability to reduce the impacts on a species or stock considers the degree, likelihood, and context of the anticipated reduction of impacts to individuals (and how many individuals) as well as the status of the species or stock.

The ultimate impact on any individual from a disturbance event (which informs the likelihood of adverse species- or stock-level effects) is dependent on the circumstances and associated contextual factors, such as duration of exposure to stressors. Though any proposed mitigation needs to be evaluated in the context of the specific activity and the species or stocks affected, measures with the following types of effects have greater value in reducing the likelihood or severity of adverse species- or stock-level impacts: Avoiding or minimizing injury or mortality; limiting interruption of known feeding, breeding, mother/young, or resting behaviors; minimizing the abandonment of important habitat (temporally and spatially); minimizing the number of individuals subjected to these types of disruptions; and limiting degradation of habitat. Mitigating these types of effects is intended to reduce the likelihood that the activity will result in energetic or other types of impacts that are more likely to result in reduced reproductive success or survivorship. It is also important to consider the degree of impacts that are expected in the absence of mitigation in order to assess the added value of any potential measures. Finally, because the least practicable adverse impact standard gives NMFS discretion to weigh a variety of factors when determining appropriate mitigation measures and because the focus of the standard is on reducing impacts at the species or stock level, the least practicable adverse impact standard does not compel mitigation for every kind of take, or every individual taken, if that mitigation is unlikely to meaningfully contribute to the reduction of adverse impacts on the species or stock and its habitat, even when practicable for implementation by the applicant.

The status of the species or stock is also relevant in evaluating the appropriateness of potential mitigation measures in the context of least practicable adverse impact. The following are examples of factors that may (either alone, or in combination) result in greater emphasis on the importance of a mitigation measure in reducing impacts on a species or stock: The stock is known to be decreasing or status is unknown, but believed to be declining; the known annual mortality (from any source) is approaching or exceeding the potential biological removal (PBR) level (as defined in MMPA section 3(20)); the affected species or stock is a small, resident population; or the stock is involved in a UME or has other known vulnerabilities, such as recovering from an oil spill.

Habitat mitigation, particularly as it relates to rookeries, mating grounds, and areas of similar significance, is also relevant to achieving the standard and can include measures such as reducing impacts of the activity on known prey utilized in the activity area or reducing impacts on physical habitat. As with species- or stock-related mitigation, the emphasis given to a measure's ability to reduce impacts on a species or stock's habitat considers the degree, likelihood, and context of the anticipated reduction of impacts to habitat. Because habitat value is informed by marine mammal presence and use, in some cases there may be overlap in measures for the species or stock and for use of habitat.

We consider available information indicating the likelihood of any measure to accomplish its objective. If evidence shows that a measure has not typically been effective or successful, then either that measure should be modified or the potential value of the measure to reduce effects should be lowered.

2. *Practicability.* Factors considered may include cost, impact on activities, and, in the case of a military readiness activity, will include personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity (see MMPA section 101(a)(5)(A)(ii)).

Assessment of Mitigation Measures for NWTT Study Area

Section 216.104(a)(11) of NMFS' implementing regulations requires an applicant for incidental take authorization to include in its request, among other things, ''the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, their habitat, and [where applicable] on their availability for subsistence uses, paying particular attention to rookeries, mating grounds, and areas of similar significance.'' Thus NMFS' analysis of

the sufficiency and appropriateness of an applicant's measures under the least practicable adverse impact standard will always begin with evaluation of the mitigation measures presented in the application.

NMFS has fully reviewed the specified activities together with the mitigation measures included in the Navy's rulemaking/LOA application and the 2020 NWTT FSEIS/OEIS to determine if the mitigation measures would result in the least practicable adverse impact on marine mammals and their habitat. NMFS worked with the Navy in the development of the Navy's initially proposed measures, which are informed by years of implementation and monitoring. A complete discussion of the Navy's evaluation process used to develop, assess, and select mitigation measures, which was informed by input from NMFS, can be found in Section 5 (*Mitigation*) and Appendix K (*Geographic Mitigation Assessment*) of the 2020 NWTT FSEIS/OEIS. The process described in Chapter 5 (*Mitigation*) and Appendix K (*Geographic Mitigation Assessment*) of the 2020 NWTT FSEIS/OEIS robustly supported NMFS' independent evaluation of whether the mitigation measures meet the least practicable adverse impact standard.

As a general matter, where an applicant proposes measures that are likely to reduce impacts to marine mammals, the fact that they are included in the application indicates that the measures are practicable, and it is not necessary for NMFS to conduct a detailed analysis of the measures the applicant proposed (rather, they are simply included). However, it is still necessary for NMFS to consider whether there are additional practicable measures that would meaningfully reduce the probability or severity of impacts that could affect reproductive success or survivorship.

Since publication of the proposed rule, and in consideration of public comments received, additional mitigation requirements have been added that will further reduce the likelihood and/or severity of adverse impacts on marine mammal species and their habitat and are practicable for implementation. Below we describe the added measures that the Navy will implement and explain the manner in which they are expected to reduce the likelihood or severity of adverse impacts on marine mammals and their habitats.

1. The Navy will only conduct explosive Mine Countermeasure and Neutralization testing in daylight hours and in Beaufort Sea state number 3 conditions or less. This will assist Navy Lookouts in effectively sighting potential marine mammals, including Southern Resident killer whales, in the procedural mitigation zones.

2. The Navy will implement a new mitigation area, the Juan de Fuca Eddy Marine Species Mitigation Area, in which the Navy will not conduct explosive Mine Countermeasure and Neutralization Testing activities and will limit surface ship hull-mounted MF1 mid-frequency active sonar, eliminating impacts to marine mammals in this area from Mine Countermeasure and Neutralization activities, and minimizing impacts to marine mammals from MF1 sonar in this area. Specifically, the Navy will conduct no more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in this new Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined.

3. The Navy will issue seasonal awareness notification messages within 50 nmi from shore to alert Navy ships and aircraft operating within the Marine Species Coastal Mitigation Area to the possible presence of increased concentrations of Southern Resident killer whales from December 1 to June 30, humpback whales from May 1 through December 31, and gray whales from May 1 to November 30. To assist in avoiding interactions with whales, the Navy will instruct vessels to remain vigilant to the presence of Southern Resident killer whales, humpback whales, and gray whales that may be vulnerable to vessel strikes or potential impacts from training and testing activities. Platforms will use the information from the awareness notification messages to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation.

4. The Navy will implement seasonal restrictions and distance-from-shore requirements for certain explosive bins, as described in detail in the *Mitigation Areas* section of this final rule. Additionally, the Navy will implement new annual and seven-year explosive ordnance limitations specific to explosive mine countermeasure and neutralization testing. These restrictions and limitations will further reduce impacts to marine mammals from explosives in nearshore and offshore habitats, including important feeding and migration areas for Southern Resident killer whales and humpback whales.

5. As noted above in #2, the Navy will conduct no more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the new Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined. The annual restriction for testing previously only applied to the Olympic Coast National Marine Sanctuary Mitigation Area. This final rule also removes an exception that excluded the Quinault Range Site from the annual sonar restrictions that was included in the proposed rule. Now, the annual restrictions will apply throughout the entire Olympic Coastal National Marine Sanctuary Mitigation Area, including within the portion of the mitigation area that overlaps the Quinault Range Site. This reduction in activities is in areas that are important for Southern Resident killer whale and humpback whale feeding and migration.

6. The Navy will conduct a maximum of one Unmanned Underwater Vehicle Training event within 12 nmi from shore at the Quinault Range Site, and will cancel or move Unmanned Underwater Vehicle Training events within 12 nmi from shore at the Quinault Range Site if Southern Resident killer whales are detected at the planned training location during the event planning process, or immediately prior to the event, as applicable. This measure is expected to help avoid any potential impacts on Southern Resident killer whales during Unmanned Underwater Vehicle Training events.

7. NMFS has included several new measures in the Puget Sound and Strait of Juan de Fuca Mitigation Area that the Navy had been voluntarily implementing previously during Phase II activities, but are now required mitigation measures. Specifically, the Navy will not use low-, mid-, or high-frequency active sonar during training or testing unless a required element (*i.e.,* a criterion necessary for the success of the event) necessitates the activity be conducted in NWTT Inland Waters during (1) Unmanned Underwater Vehicle Training, (2) Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises, (3) activities conducted by Naval Sea Systems Command at designated locations, or (4) pierside sonar maintenance or testing at designated locations. Additionally, the Navy will use the lowest active sonar source levels practical to successfully accomplish

each event, and will not use explosives during testing. The Navy will not use explosives during training except at the Hood Canal Explosive Ordnance Disposal (EOD) Range and Crescent Harbor EOD Range during explosive mine neutralization activities involving the use of Navy divers. Additionally, Navy event planners are required to coordinate with Navy biologists during the event planning process prior to these events. The Navy will not conduct non-explosive live fire events (except firing blank weapons), including gunnery exercises, missile exercises, torpedo exercises, bombing exercises, and Kinetic Energy Weapon Testing.

8. In addition to the previous voluntary measures that the Navy will now implement as mitigation measures, the Navy will also implement several new mitigation measures within the Puget Sound and Strait of Juan de Fuca Mitigation Area. Within the Puget Sound and Strait of Juan de Fuca Mitigation Area, the Navy will conduct a maximum of one Unmanned Underwater Vehicle Training activity annually at the Navy 3 Operating Area, Navy 7 Operating Area, and Manchester Fuel Depot (*i.e.,* a maximum of one event at each location). Additionally, Navy event planners are required to coordinate with Navy biologists during the event planning process prior to conducting Unmanned Underwater Vehicle Training at the Navy 3 Operating Area, Manchester Fuel Depot, Crescent Harbor Explosive Ordnance Disposal Range, and Navy 7 Operating Area, and to cancel or move events to another training location if the presence of Southern Resident killer whales is reported through available monitoring networks. Additionally, the Navy will issue annual seasonal awareness notification messages to alert Navy ships and aircraft operating within the Puget Sound and Strait of Juan de Fuca Mitigation Area to the possible presence of concentrations of Southern Resident killer whales and gray whales. These messages are expected to help further avoid potential impacts from training and testing activities on Southern Resident killer whales and gray whales, and will coincide with the seasons in which Southern Resident killer whales and gray whales are most likely to be observed in the mitigation area (July 1 to November 30 for Southern Resident killer whales, and March 1 to May 31 for gray whales).

As described in the *Mitigation Areas* section of this final rule, the Puget Sound and Strait of Juan de Fuca Mitigation Area encompasses the full extent of NWTT Inland Waters, and includes feeding and potential migration habitat for gray whales and critical habitat for Southern Resident killer whales and one of their primary sources of prey, Puget Sound Chinook salmon. New mitigation in the Puget Sound and Strait of Juan de Fuca Mitigation Area is designed to help avoid any potential impacts from training and testing on Southern Resident killer whales in NWTT Inland Waters. As stated in the *Mitigation Areas* section of this final rule, with implementation of these new mitigation measures, we do not anticipate any take of Southern Resident killer whales in NWTT Inland Waters due to NWTT training and testing activities. Additionally, we expect that the new mitigation in this mitigation area will help reduce potential impacts on gray whales from testing and training activities.

In addition, the Navy has agreed to procedural mitigation measures that will reduce the probability and/or severity of impacts expected to result from acute exposure to acoustic sources and explosives, such as hearing impairment, more severe behavioral disturbance, as well as the probability of vessel strike. Specifically, the Navy will use a combination of delayed starts, powerdowns, and shutdowns to avoid or minimize mortality or serious injury, minimize the likelihood or severity of PTS or other injury, and reduce instances of TTS or more severe behavioral disturbance caused by acoustic sources or explosives. The Navy will also implement multiple time/area restrictions that will reduce take of marine mammals (as well as impacts on marine mammal habitat) in areas where or at times when they are known to engage in important behaviors, such as feeding, where the disruption of those behaviors would have a higher probability of resulting in impacts on reproduction or survival of individuals that could lead to population-level impacts.

The Navy assessed the practicability of these measures in the context of personnel safety, practicality of implementation, and their impacts on the Navy's ability to meet their Title 10 requirements and found that the measures are supportable. NMFS has independently evaluated the measures the Navy proposed in the manner described earlier in this section (*i.e.,* in consideration of their ability to reduce adverse impacts on marine mammal species and their habitat and their practicability for implementation). We have determined that the measures will significantly and adequately reduce impacts on the affected marine mammal species and stocks and their habitat and, further, be practicable for Navy implementation. Therefore, the mitigation measures assure that the Navy's activities will have the least practicable adverse impact on the species or stocks and their habitat.

Measures Evaluated but not Included

The Navy also evaluated numerous measures in the 2020 NWTT FSEIS/OEIS that were not included in the Navy's rulemaking/LOA application, and NMFS independently reviewed and concurs with the Navy's analysis that their inclusion was not appropriate under the least practicable adverse impact standard based on our assessment. The Navy considered these additional potential mitigation measures in two groups. First, Section 5 (*Mitigation)* of the 2020 NWTT FSEIS/OEIS, in the *Measures Considered but Eliminated* section, includes an analysis of an array of different types of mitigation that have been recommended over the years by non-governmental organizations or the public, through scoping or public comment on environmental compliance documents. Appendix K (*Geographic Mitigation Assessment*) of the 2020 NWTT FSEIS/OEIS includes an in-depth analysis of time/area restrictions that have been recommended over time. As described in Chapter 5 (*Mitigation*) of the 2020 NWTT FSEIS/OEIS, commenters sometimes recommend that the Navy reduce its overall amount of training, reduce explosive use, modify its sound sources, completely replace live training and testing with computer simulation, or include time of day restrictions. Many of these mitigation measures could potentially reduce the number of marine mammals taken, via direct reduction of the activities or amount of sound energy put in the water. However, as described in Section 5 (*Mitigation*) of the 2020 NWTT FSEIS/OEIS, the Navy needs to train and test in the conditions in which it fights—and these types of modifications fundamentally change the activity in a manner that will not support the purpose and need for the training and testing (*i.e.,* are entirely impracticable) and therefore are not considered further. NMFS finds the Navy's explanation for why adoption of these recommendations would unacceptably undermine the purpose of the testing and training persuasive. After independent review, NMFS finds Navy's judgment on the impacts of potential mitigation measures to personnel safety, practicality of implementation, and the effectiveness of training and testing within the NWTT Study Area persuasive, and for these

reasons, NMFS finds that these measures do not meet the least practicable adverse impact standard because they are not practicable.

Second, in Chapter 5 (*Mitigation*) of the 2020 NWTT FSEIS/OEIS, the Navy evaluated additional potential procedural mitigation measures, including increased mitigation zones, ramp-up measures, additional passive acoustic and visual monitoring, and decreased vessel speeds. Some of these measures have the potential to incrementally reduce take to some degree in certain circumstances, though the degree to which this would occur is typically low or uncertain. However, as described in the Navy's analysis, the measures would have significant direct negative effects on mission effectiveness and are considered impracticable (see Section 5 *Mitigation* of 2020 NWTT FSEIS/OEIS). NMFS independently reviewed the Navy's evaluation and concurs with this assessment, which supports NMFS' findings that the impracticability of this additional mitigation would greatly outweigh any potential minor reduction in marine mammal impacts that might result; therefore, these additional mitigation measures are not warranted.

Last, Appendix K (*Geographic Mitigation Assessment*) of the 2020 NWTT FSEIS/OEIS describes a comprehensive method for analyzing potential geographic mitigation that includes consideration of both a biological assessment of how the potential time/area limitation would benefit the species and its habitat (*e.g.,* is a key area of biological importance or would result in avoidance or reduction of impacts) in the context of the stressors of concern in the specific area and an operational assessment of the practicability of implementation (including an assessment of the specific importance of that area for training, considering proximity to training ranges and emergency landing fields and other issues). For most of the areas that were considered in the 2020 NWTT FSEIS/OEIS but not included in this rule, the Navy found that the mitigation was not warranted because the anticipated reduction of adverse impacts on marine mammal species and their habitat was not sufficient to offset the impracticability of implementation. In some cases potential benefits to marine mammals were non-existent, while in others the consequences on mission effectiveness were too great.

NMFS has reviewed the Navy's analysis in Section 5 *Mitigation* and Appendix K *Geographic Mitigation Assessment* of the 2020 NWTT FSEIS/OEIS, which considers the same factors that NMFS considers to satisfy the least practicable adverse impact standard, and concurs with the analysis and conclusions. Therefore, NMFS is not including any of the measures that the Navy ruled out in the 2020 NWTT FSEIS/OEIS.

Below, we describe additional measures that were considered but eliminated during the development of the final rule: (1) A full restriction on Mine Countermeasure and Neutralization testing in water depths less than 650 ft. and (2) A full restriction on Undersea Warfare Testing within 20 nmi from shore in the Marine Species Coastal Mitigation Area (except within the portion of the mitigation area that overlaps the Quinault Range Site).

Regarding the consideration of a full restriction on Mine Countermeasure and Neutralization testing in water depths less than 650 ft, water depths drop rapidly from 650 ft to 1,000 ft in the NWTT Offshore Area, and the Navy plans to conduct this activity in areas where water depths are less than 1,000 ft. Limiting the available testing area to areas deeper than 650 ft would allow the Navy a span of only one to two nmi in some cases to conduct the activity. Given the limited available area beyond 650 ft, and given that the typical testing depth of Mine Countermeasure and Neutralization testing is 300 ft, limiting testing to water depths greater than 650 ft would not be practical to implement with respect to allowing the Navy to meet mission requirements. In consideration of the reductions in potential impacts provided by the restrictions on Mine Countermeasure and Neutralization testing in the geographic mitigation areas, the required procedural mitigation restricting Mine Countermeasure and Neutralization testing to daylight hours only and in a Beaufort sea state of 3 or less, and combined with the impracticability for the Navy, NMFS found that this measure was not warranted.

Regarding the consideration of a full restriction on Undersea Warfare Testing within 20 nmi from shore in the Marine Species Coastal Mitigation Area (except within the portion of the mitigation area that overlaps with the Quinault Range Site), this final rule instead includes a cap of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined. NMFS concurred with the Navy's analysis that it would be impracticable to fully restrict Undersea Warfare testing in this area, and this limitation is expected to minimize impacts from sonar in the three areas combined.

The following sections describe the mitigation measures that will be implemented in association with the training and testing activities analyzed in this document. These are the mitigation measures that NMFS has determined will ensure the least practicable adverse impact on all affected species and their habitat, including the specific considerations for military readiness activities. The mitigation measures are organized into two categories: procedural mitigation and mitigation areas.

Procedural Mitigation

Procedural mitigation is mitigation that the Navy will implement whenever and wherever an applicable training or testing activity takes place within the NWTT Study Area. Procedural mitigation is customized for each applicable activity category or stressor. Procedural mitigation generally involves: (1) The use of one or more trained Lookouts to diligently observe for specific biological resources (including marine mammals) within a mitigation zone, (2) requirements for Lookouts to immediately communicate sightings of these specific biological resources to the appropriate watch station for information dissemination, and (3) requirements for the watch station to implement mitigation (*e.g.,* halt an activity) until certain recommencement conditions have been met. The first procedural mitigation (Table 35) is designed to aid Lookouts and other applicable Navy personnel in their observation, environmental compliance, and reporting responsibilities. The remainder of the procedural mitigation measures (Tables 36 through 49) are organized by stressor type and activity category and include acoustic stressors (*i.e.,* active sonar, weapons firing noise), explosive stressors (*i.e.,* sonobuoys, torpedoes, medium-caliber and large-caliber projectiles, missiles, bombs, mine counter-measure and neutralization activities, mine neutralization involving Navy divers), and physical disturbance and strike stressors (*i.e.,* vessel movement, towed in-water devices, small-, medium-, and large-caliber non-explosive practice munitions, non-explosive missiles, non-explosive bombs and mine shapes).

TABLE 35—PROCEDURAL MITIGATION FOR ENVIRONMENTAL AWARENESS AND EDUCATION

Procedural Mitigation Description
Stressor or Activity: • All training and testing activities, as applicable. *Mitigation Requirements:* • Appropriate Navy personnel (including civilian personnel) involved in mitigation and training or testing activity reporting under the specified activities will complete one or more modules of the U.S. Navy Afloat Environmental Compliance Training Series, as identified in their career path training plan. Modules include: —Introduction to the U.S. Navy Afloat Environmental Compliance Training Series. The introductory module provides information on environmental laws (*e.g.,* Endangered Species Act, Marine Mammal Protection Act) and the corresponding responsibilities that are relevant to Navy training and testing activities. The material explains why environmental compliance is important in supporting the Navy's commitment to environmental stewardship. —Marine Species Awareness Training. All bridge watch personnel, Commanding Officers, Executive Officers, maritime patrol aircraft aircrews, anti-submarine warfare and mine warfare rotary-wing aircrews, Lookouts, and equivalent civilian personnel must successfully complete the Marine Species Awareness Training prior to standing watch or serving as a Lookout. The Marine Species Awareness Training provides information on sighting cues, visual observation tools and techniques, and sighting notification procedures. Navy biologists developed Marine Species Awareness Training to improve the effectiveness of visual observations for biological resources, focusing on marine mammals and sea turtles, and including floating vegetation, jellyfish aggregations, and flocks of seabirds. —U.S. Navy Protective Measures Assessment Protocol. This module provides the necessary instruction for accessing mitigation requirements during the event planning phase using the Protective Measures Assessment Protocol software tool. —U.S. Navy Sonar Positional Reporting System and Marine Mammal Incident Reporting. This module provides instruction on the procedures and activity reporting requirements for the Sonar Positional Reporting System and marine mammal incident reporting.

TABLE 36—PROCEDURAL MITIGATION FOR ACTIVE SONAR

Procedural Mitigation Description
Stressor or Activity: • Low-frequency active sonar, mid-frequency active sonar, high-frequency active sonar —For vessel-based active sonar activities, mitigation applies only to sources that are positively controlled and deployed from manned surface vessels (*e.g.,* sonar sources towed from manned surface platforms). —For aircraft-based active sonar activities, mitigation applies only to sources that are positively controlled and deployed from manned aircraft that do not operate at high altitudes (*e.g.,* rotary-wing aircraft). Mitigation does not apply to active sonar sources deployed from unmanned aircraft or aircraft operating at high altitudes (*e.g.,* maritime patrol aircraft). *Number of Lookouts and Observation Platform:* • Hull-mounted sources: —1 Lookout: Platforms with space or manning restrictions while underway (at the forward part of a small boat or ship) and platforms using active sonar while moored or at anchor (including pierside). —2 Lookouts: Platforms without space or manning restrictions while underway (at the forward part of the ship). Sources that are not hull-mounted: —1 Lookout on the ship or aircraft conducting the activity. *Mitigation Requirements:* • Mitigation zones: —1,000 yd power down, 500 yd power down, and 200 yd or 100 yd shut down for low-frequency active sonar at 200 decibels (dB) and hull-mounted mid-frequency active sonar (see *During the activity* below). —200 yd or 100 yd shut down for low-frequency active sonar <200 dB, mid-frequency active sonar sources that are not hull-mounted, and high-frequency active sonar (see *During the activity* below). • Prior to the initial start of the activity (*e.g.,* when maneuvering on station): —Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear. —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of active sonar transmission. • During the activity: —Low-frequency active sonar at 200 decibels (dB) and hull-mounted mid-frequency active sonar: (1) Navy personnel must observe the mitigation zone for marine mammals; Navy personnel will power down active sonar transmission by 6 dB if a marine mammal is observed within 1,000 yd of the sonar source; Navy personnel will power down an additional 4 dB (10 dB total) if a marine mammal is observed within 500 yd of the sonar source; Navy personnel must cease transmission if cetaceans are observed within 200 yd of the sonar source in any location in the Study Area; (2) Navy personnel must cease transmission if pinnipeds in the NWTT Offshore Area or Western Behm Canal are observed within 200 yd of the sonar source and cease transmission if pinnipeds in NWTT Inland Waters are observed within 100 yd of the sonar source (except if hauled out on, or in the water near, man-made structures and vessels). —Low-frequency active sonar <200 dB, mid-frequency active sonar sources that are not hull-mounted, and high-frequency active sonar: Navy personnel must observe the mitigation zone for marine mammals; Navy personnel will cease transmission if cetaceans are observed within 200 yd of the sonar source in any location in the Study Area. Navy personnel will cease transmission if pinnipeds in the NWTT Offshore Area or Western Behm Canal are observed within 200 yd of the sonar source; Navy personnel will cease transmission if pinnipeds in NWTT Inland Waters is observed within 100 yd of the sonar source (except if hauled out on, or in the water near, man-made structures and vessels). • Commencement/recommencement conditions after a marine mammal sighting before or during the activity:

TABLE 36—PROCEDURAL MITIGATION FOR ACTIVE SONAR—Continued

Procedural Mitigation Description
—Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing or powering up active sonar transmission) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonar source; (3) the mitigation zone has been clear from any additional sightings for 10 minutes for aircraft-deployed sonar sources or 30 minutes for vessel-deployed sonar sources; (4) for mobile activities, the active sonar source has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting; or (5) for activities using hull-mounted sonar, the Lookout concludes that dolphins are deliberately closing in on the ship to ride the ship's bow wave, and are therefore out of the main transmission axis of the sonar (and there are no other marine mammal sightings within the mitigation zone).

TABLE 37—PROCEDURAL MITIGATION FOR WEAPONS FIRING NOISE

Procedural Mitigation Description
Stressor or Activity: • Weapons firing noise associated with large-caliber gunnery activities. *Number of Lookouts and Observation Platform:* • 1 Lookout positioned on the ship conducting the firing. —Depending on the activity, the Lookout could be the same one described for Procedural Mitigation for Explosive Medium-Caliber and Large-Caliber Projectiles (Table 40) or Procedural Mitigation for Small-, Medium-, and Large-Caliber Non-Explosive Practice Munitions (Table 47). *Mitigation Requirements:* • Mitigation zone: —30° on either side of the firing line out to 70 yd from the muzzle of the weapon being fired. • Prior to the initial start of the activity: —Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear. —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of weapons firing. • During the activity: —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will cease weapons firing. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing weapons firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the firing ship; (3) the mitigation zone has been clear from any additional sightings for 30 minutes; or (4) for mobile activities, the firing ship has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

TABLE 38—PROCEDURAL MITIGATION FOR EXPLOSIVE SONOBUOYS

Procedural Mitigation Description
Stressor or Activity: • Explosive sonobuoys. *Number of Lookouts and Observation Platform:* • 1 Lookout positioned in an aircraft or on a small boat. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) will support observing the mitigation zone for marine mammals while performing their regular duties. *Mitigation Requirements:* • Mitigation zone: —600 yd. around an explosive sonobuoy. • Prior to the initial start of the activity (*e.g.,* during deployment of a sonobuoy field, which typically lasts 20–30 minutes): —Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear. —Navy personnel will conduct passive acoustic monitoring for marine mammals; personnel will use information from detections to assist visual observations. —Navy personnel will visually observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of sonobuoy or source/receiver pair detonations. • During the activity: —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will cease sonobuoy or source/receiver pair detonations. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonobuoy; or (3) the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

TABLE 38—PROCEDURAL MITIGATION FOR EXPLOSIVE SONOBUOYS—Continued

Procedural Mitigation Description
• After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel will observe the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel will follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel positioned on these assets will assist in the visual observation of the area where detonations occurred.

TABLE 39—PROCEDURAL MITIGATION FOR EXPLOSIVE TORPEDOES

Procedural Mitigation Description
Stressor or Activity: • Explosive torpedoes. *Number of Lookouts and Observation Platform:* • 1 Lookout positioned in an aircraft. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) will support observing the mitigation zone for marine mammals while performing their regular duties. *Mitigation Requirements:* • Mitigation zone: —2,100 yd around the intended impact location. • Prior to the initial start of the activity (*e.g.,* during deployment of the target): —Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear. —Navy personnel will conduct passive acoustic monitoring for marine mammals; personnel will use information from detections to assist visual observations. —Navy personnel will visually observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of firing. • During the activity: —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will cease firing. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or (3) the mitigation zone has been clear from any additional sightings for 10 minutes when the activity involves aircraft that have fuel constraints, or 30 minutes when the activity involves aircraft that are not typically fuel constrained. • After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel will observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel will follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel positioned on these assets will assist in the visual observation of the area where detonations occurred.

TABLE 40—PROCEDURAL MITIGATION FOR EXPLOSIVE MEDIUM-CALIBER AND LARGE-CALIBER PROJECTILES

Procedural Mitigation Description
Stressor or Activity: • Gunnery activities using explosive medium-caliber and large-caliber projectiles —Mitigation applies to activities using a surface target. *Number of Lookouts and Observation Platform:* • 1 Lookout on the vessel conducting the activity. —For activities using explosive large-caliber projectiles, depending on the activity, the Lookout could be the same as the one described for Procedural Mitigation for Weapons Firing Noise (Table 37). • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) will support observing the mitigation zone for marine mammals while performing their regular duties. *Mitigation Requirements:* • Mitigation zones: —600 yd around the intended impact location for explosive medium-caliber projectiles. —1,000 yd around the intended impact location for explosive large-caliber projectiles. • Prior to the initial start of the activity (*e.g.,* when maneuvering on station): —Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear. —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of firing. • During the activity: —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will cease firing.

TABLE 40—PROCEDURAL MITIGATION FOR EXPLOSIVE MEDIUM-CALIBER AND LARGE-CALIBER PROJECTILES—Continued

Procedural Mitigation Description
• Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; (3) the mitigation zone has been clear from any additional sightings for 30 minutes for vessel-based firing; or (4) for activities using mobile targets, the intended impact location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting. • After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel will observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel will follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel positioned on these assets will assist in the visual observation of the area where detonations occurred.

TABLE 41—PROCEDURAL MITIGATION FOR EXPLOSIVE MISSILES

Procedural Mitigation Description
Stressor or Activity: • Aircraft-deployed explosive missiles. —Mitigation applies to activities using a surface target. *Number of Lookouts and Observation Platform* • 1 Lookout positioned in an aircraft • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) will support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties. *Mitigation Requirements:* • Mitigation zone: —2,000 yd around the intended impact location. • Prior to the initial start of the activity (*e.g.,* during a fly-over of the mitigation zone): —Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear. —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of firing. • During the activity: —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will cease firing. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or (3) the mitigation zone has been clear from any additional sightings for 10 minutes when the activity involves aircraft that have fuel constraints, or 30 minutes when the activity involves aircraft that are not typically fuel constrained. • After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel will observe the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel will follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel positioned on these assets will assist in the visual observation of the area where detonations occurred.

TABLE 42—PROCEDURAL MITIGATION FOR EXPLOSIVE BOMBS

Procedural Mitigation Description
Stressor or Activity: • Explosive bombs. *Number of Lookouts and Observation Platform:* • 1 Lookout positioned in the aircraft conducting the activity. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) will support observing the mitigation zone for marine mammals while performing their regular duties. *Mitigation Requirements:* • Mitigation zone: —2,500 yd around the intended target. • Prior to the initial start of the activity (*e.g.,* when arriving on station): —Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear. —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of bomb deployment. • During the activity (*e.g.,* during target approach):

TABLE 42—PROCEDURAL MITIGATION FOR EXPLOSIVE BOMBS—Continued

Procedural Mitigation Description
—Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will cease bomb deployment. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment) until one of the following conditions has been met: (1) the animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target; (3) the mitigation zone has been clear from any additional sightings for 10 min; or (4) for activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting. • After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel will observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel will follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel positioned on these assets will assist in the visual observation of the area where detonations occurred.

TABLE 43—PROCEDURAL MITIGATION FOR EXPLOSIVE MINE COUNTERMEASURE AND NEUTRALIZATION ACTIVITIES

Procedural Mitigation Description
Stressor or Activity: • Explosive Mine Countermeasure and Neutralization activities. *Number of Lookouts and Observation Platform:* • 1 Lookout positioned on a vessel or in an aircraft when implementing the smaller mitigation zone. • 2 Lookouts (one positioned in an aircraft and one on a small boat) when implementing the larger mitigation zone. • If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) will support observing the mitigation zone for marine mammals while performing their regular duties. *Mitigation Requirements:* • Mitigation zones: —600 yd around the detonation site for activities using ≤5 lb net explosive weight. —2,100 yd around the detonation site for activities using >5–60 lb net explosive weight. • Prior to the initial start of the activity (*e.g.,* when maneuvering on station; typically, 10 minutes when the activity involves aircraft that have fuel constraints, or 30 minutes when the activity involves aircraft that are not typically fuel constrained): —Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear. —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of detonations. • During the activity: —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will cease detonations. —Navy personnel will use the smallest practicable charge size for each activity. —Navy personnel will conduct activities in daylight hours and only in Beaufort Sea state number 3 conditions or less. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: (1) the animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to detonation site; or (3) the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained. • After completion of the activity (typically 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained): —Navy personnel will observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel will follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel positioned on these assets will assist in the visual observation of the area where detonations occurred.

TABLE 44—PROCEDURAL MITIGATION FOR EXPLOSIVE MINE NEUTRALIZATION ACTIVITIES LNVOLVING NAVY DIVERS

Procedural Mitigation Description
Stressor or Activity: • Explosive mine neutralization activities involving Navy divers. *Number of Lookouts and Observation Platform:* • 2 Lookouts on two small boats with one Lookout each, one of which will be a Navy biologist. • All divers placing the charges on mines will support the Lookouts while performing their regular duties and will report applicable sightings to the lead Lookout, the supporting small boat, or the Range Safety Officer. • If additional platforms are participating in the activity, personnel positioned on those assets (*e.g.,* safety observers, evaluators) will support observing the mitigation zone for marine mammals while performing their regular duties. *Mitigation Requirements:* • Mitigation zone:

TABLE 44—PROCEDURAL MITIGATION FOR EXPLOSIVE MINE NEUTRALIZATION ACTIVITIES LNVOLVING NAVY DIVERS—Continued

Procedural Mitigation Description
—500 yd around the detonation site during activities using >0.5–2.5 lb net explosive weight.
• Prior to the initial start of the activity (starting 30 minutes before the first planned detonation):
—Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear.
—Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of detonations.
—Navy personnel will ensure the mitigation zone is clear of marine mammals for 30 minutes prior to commencing a detonation.
—A Navy biologist will serve as the lead Lookout and will make the final determination that the mitigation zone is clear of any biological resource sightings, including marine mammals, prior to the commencement of a detonation. The Navy biologist will maintain radio communication with the unit conducting the event and the other Lookout.
• During the activity:
—Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will cease detonations.
—To the maximum extent practical depending on mission requirements, safety, and environmental conditions, boats will position themselves near the midpoint of the mitigation zone radius (but outside of the detonation plume and human safety zone), will position themselves on opposite sides of the detonation location (when two boats are used), and will travel in a circular pattern around the detonation location with one Lookout observing inward toward the detonation site and the other observing outward toward the perimeter of the mitigation zone.
—Navy personnel will use only positively controlled charges (*i.e.,* no time-delay fuses).
—Navy personnel will use the smallest practicable charge size for each activity.
—Activities will be conducted in Beaufort sea state number 2 conditions or better and will not be conducted in low visibility conditions.
• Commencement/recommencement conditions after a marine mammal sighting before or during the activity:
—Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonation) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the detonation site; or (3) the mitigation zone has been clear from any additional sightings for 30 minutes.
• After each detonation and the completion of an activity (for 30 minutes):
—Navy personnel will observe for marine mammals in the vicinity of where detonations occurred and immediately downstream of the detonation location; if any injured or dead marine mammals are observed, Navy personnel will follow established incident reporting procedures.
—If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel positioned on these assets will assist in the visual observation of the area where detonations occurred.

TABLE 45—PROCEDURAL MITIGATION FOR VESSEL MOVEMENT

Procedural Mitigation Description
Stressor or Activity:
• Vessel movement:
—The mitigation will not be applied if: (1) The vessel's safety is threatened, (2) the vessel is restricted in its ability to maneuver (*e.g.,* during launching and recovery of aircraft or landing craft, during towing activities, when mooring, and during Transit Protection Program exercises or other events involving escort vessels), (3) the vessel is submerged [1] or operated autonomously, or (4) when impractical based on mission requirements (*e.g.,* during test body retrieval by range craft).
Number of Lookouts and Observation Platform:
• 1 Lookout on the vessel that is underway.
Mitigation Requirements:
• Mitigation zones:
—500 yd around whales.
—200 yd (for surface ships, which do not include small boats) around marine mammals other than whales (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels).
—100 yd (for small boats, such as range craft) around marine mammals other than whales (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels).
• During the activity:
—When underway, Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will maneuver to maintain distance.
• Additional requirement:
—If a marine mammal vessel strike occurs, Navy personnel will follow the established incident reporting procedures.

[1] NMFS has clarified in this final rule that this measure does not apply to submerged vessels. This does not change the scope of the mitigation measure, however, as the description of mitigation zones in the proposed rule as well as this rule explain that these zones apply to surface vessels and small boats, neither of which include submerged vessels.

TABLE 46—PROCEDURAL MITIGATION FOR TOWED IN-WATER DEVICES

Procedural Mitigation Description
Stressor or Activity:
• Towed in-water devices:

TABLE 46—PROCEDURAL MITIGATION FOR TOWED IN-WATER DEVICES—Continued

Procedural Mitigation Description
—Mitigation applies to devices that are towed from a manned surface platform or manned aircraft, or when a manned support craft is already participating in an activity involving in-water devices being towed by unmanned platforms. —The mitigation will not be applied if the safety of the towing platform or in-water device is threatened. *Number of Lookouts and Observation Platform:* • 1 Lookout positioned on the towing platform or support craft. *Mitigation Requirements:* • Mitigation zones: —250 yd (for in-water devices towed by aircraft or surface ships) around marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels). —100 yd (for in-water devices towed by small boats, such as range craft) around marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels). • During the activity (*i.e.,* when towing an in-water device): —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will maneuver to maintain distance.

TABLE 47—PROCEDURAL MITIGATION FOR SMALL-, MEDIUM-, AND LARGE-CALIBER NON-EXPLOSIVE PRACTICE MUNITIONS

Procedural Mitigation Description
Stressor or Activity: • Gunnery activities using small-, medium-, and large-caliber non-explosive practice munitions. —Mitigation applies to activities using a surface target. *Number of Lookouts and Observation Platform:* • 1 Lookout positioned on the platform conducting the activity. • Depending on the activity, the Lookout could be the same as the one described for Procedural Mitigation for Weapons Firing Noise (Table 37). *Mitigation Requirements:* • Mitigation zone: —200 yd around the intended impact location. • Prior to the initial start of the activity (*e.g.,* when maneuvering on station): —Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear. —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of firing. • During the activity: —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will cease firing. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; (3) the mitigation zone has been clear from any additional sightings for 10 minutes for aircraft-based firing or 30 minutes for vessel-based firing; or (4) for activities using a mobile target, the intended impact location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

TABLE 48—PROCEDURAL MITIGATION FOR NON-EXPLOSIVE MISSILES

Procedural Mitigation Description
Stressor or Activity: • Aircraft-deployed non-explosive missiles. • Mitigation applies to activities using a surface target. *Number of Lookouts and Observation Platform:* • 1 Lookout positioned in an aircraft. *Mitigation Requirements:* • Mitigation zone: —900 yd around the intended impact location. • Prior to the initial start of the activity (*e.g.,* during a fly-over of the mitigation zone): —Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear. —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of firing. • During the activity: —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will cease firing. • Commencement/recommencement conditions after a marine mammal sighting prior to or during the activity:

TABLE 48—PROCEDURAL MITIGATION FOR NON-EXPLOSIVE MISSILES—Continued

Procedural Mitigation Description
—Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or (3) the mitigation zone has been clear from any additional sightings for 10 minutes when the activity involves aircraft that have fuel constraints, or 30 minutes when the activity involves aircraft that are not typically fuel constrained.

TABLE 49—PROCEDURAL MITIGATION FOR NON-EXPLOSIVE BOMBS AND MINE SHAPES

Procedural Mitigation Description
Stressor or Activity: • Non-explosive bombs. • Non-explosive mine shapes during mine laying activities. *Number of Lookouts and Observation Platform:* • 1 Lookout positioned in an aircraft. *Mitigation Requirements:* • Mitigation zone: —1,000 yd around the intended target. • Prior to the initial start of the activity (*e.g.,* when arriving on station): —Navy personnel will observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel will relocate or delay the start until the mitigation zone is clear. —Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will relocate or delay the start of bomb deployment or mine laying. • During the activity (*e.g.,* during approach of the target or intended minefield location): – Navy personnel will observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel will cease bomb deployment or mine laying. • Commencement/recommencement conditions after a marine mammal sighting prior to or during the activity: —Navy personnel will allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment or mine laying) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target or minefield location; (3) the mitigation zone has been clear from any additional sightings for 10 minutes; or (4) for activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

Mitigation Areas

In addition to procedural mitigation, the Navy will implement mitigation measures within mitigation areas to avoid or minimize potential impacts on marine mammals. A full technical analysis (for which the methods were discussed above) of the mitigation areas that the Navy considered for marine mammals is provided in Appendix K (*Geographic Mitigation Assessment*) of the 2020 NWTT FSEIS/OEIS. NMFS and the Navy took into account public comments received on the 2019 NWTT DSEIS/OEIS and the 2020 NWTT proposed rule, best available science, and the practicability of implementing additional mitigation measures and has enhanced the mitigation areas and mitigation measures, beyond the 2015–2020 regulations, to further reduce impacts to marine mammals. Of note specifically, the 2015–2020 regulations included area-specific mitigation in Puget Sound and coastal areas. Mitigation in Puget Sound included required approval from the Navy's U.S. Pacific Fleet's designated authority or System Command designated authority prior to MFAS training or pierside maintenance/testing of sonar systems, and required pierside maintenance and testing to be conducted in accordance with the Navy's Protective Measures Assessment Protocol (PMAP). Additionally, prior to Maritime Homeland Defense/Security Mine Countermeasure Integrated Exercises, the Navy was required to conduct pre-event planning and training to ensure environmental awareness of all exercise participants, and Navy event planners were required to consult with Navy biologists who contacted NMFS (Protected Resources Division, West Coast Marine Species Branch Chief) during the planning process in order to determine likelihood of gray whale or southern resident killer whale presence in the proposed exercise area as planners considered specifics of the event. Additionally, prior to Small Boat Attack training in Puget Sound, the Navy was also required to conduct pre-event planning and training to ensure environmental awareness of all exercise participants. When this event was proposed to be conducted in and around Naval Station Everett, Naval Base Kitsap Bangor, or Naval Base Kitsap Bremerton in Puget Sound, Navy event planners consulted with Navy biologists who contacted NMFS early in the planning process in order to determine the extent that marine mammals may have been present in the immediate vicinity of the proposed exercise area as planners considered the specifics of the event. Finally, the Navy continued an existing permission and approval process through the U.S. Third Fleet for in-water explosives training conducted at Hood Canal or Crescent Harbor. In coastal areas, the Navy conducted Missile Exercises using high explosives at least 50 nmi from shore in the NWTRC Offshore Area, conducted BOMBEX (high explosive munitions) events at least 50 nmi from shore, and conducted BOMBEX (non-explosive practice munitions) events at least 20 nmi from shore. Functionally, the protections provided by these mitigation area requirements from the previous rule have been carried forward into this rule (though they may be worded slightly differently) and, further, significant additional geographic mitigation has been added.

Descriptions of the mitigation measures that the Navy will implement

within mitigation areas is provided in Table 50 (see below). The mitigation applies year-round unless specified otherwise in the table. The Changes from the Proposed Rule to the Final Rule section summarizes the mitigation area changes that have occurred since the proposed rule and the changes are further detailed in the descriptions of each mitigation area.

NMFS conducted an independent analysis of the mitigation areas that the Navy will implement and that are included in this rule. NMFS' analysis indicates that the measures in these mitigation areas will reduce the likelihood or severity of adverse impacts to marine mammal species or their habitat in the manner described in this rule and are practicable for the Navy.

Specifically, below we describe how certain activities are limited in feeding areas, migratory corridors, or other important habitat. To avoid repetition in those sections, we describe here how these measures reduce the likelihood or severity of effects on marine mammals and their habitat. As described previously, exposure to active sonar and explosive detonations has the potential to both disrupt behavioral patterns and reduce hearing sensitivity (temporarily or permanently, depending on the intensity and duration of the exposure). Disruption of feeding behaviors can have negative energetic consequences as a result of either obtaining less food in a given time or expending more energy (in the effort to avoid the stressor) to find the necessary food elsewhere, and extensive disruptions of this sort (especially over multiple sequential days) could accumulate in a manner that could negatively impact reproductive success or survival. By limiting impacts in known feeding areas, the overall severity of any take in those areas is reduced and the likelihood of impacts on reproduction or survival is further lessened. Similarly, reducing impacts on prey species, either by avoiding causing mortality or changing their expected distribution, can also lessen these sorts of detrimental energetic consequences. In migratory corridors, training and testing activities can result in additional energetic expenditures to avoid the loud sources—lessening training and testing in these areas also reduces the likelihood of detrimental energetic effects. In all of the mitigation areas, inasmuch as the density of certain species may be higher at certain times, a selective reduction of training and testing activities in those higher-density areas and times is expected to lessen the magnitude of take overall, as well as the specific likelihood of hearing impairment or vessel strike.

Regarding operational practicability, NMFS is heavily reliant on the Navy's description and conclusions, since the Navy is best equipped to describe the degree to which a given mitigation measure affects personnel safety or mission effectiveness, and is practical to implement. The Navy considers the measures in this rule to be practicable, and NMFS concurs.

TABLE 50—GEOGRAPHIC MITIGATION AREAS FOR MARINE MAMMALS IN THE NWTT STUDY AREA

Mitigation Area Description
Stressor or Activity:
• Sonar (mitigation does not apply to active sonar sources used for safety of navigation).
• Explosives.
• Physical disturbance and strikes.
Resource Protection Focus:
• Marine mammals (humpback whale, gray whale, Southern Resident killer whale, harbor porpoise).
• Fish (including Chinook salmon).
Mitigation Requirements: [1]
• *Marine Species Coastal Mitigation Area (year-round or seasonal if specified):*
—Within 50 nmi from shore in the Marine Species Coastal Mitigation Area:
▪ The Navy will not conduct explosive training activities.
▪ The Navy will not conduct explosive testing activities (except explosive Mine Countermeasure and Neutralization Testing).
▪ The Navy will not conduct non-explosive missile training activities.
▪ The Navy will issue annual seasonal awareness notification messages to alert Navy ships and aircraft to the possible presence of increased concentrations of Southern Resident killer whales from December 1 to June 30, humpback whales from May 1 through December 31, and gray whales from May 1 to November 30. For safe navigation and to avoid interactions with large whales, the Navy will instruct vessels to remain vigilant to the presence of Southern Resident killer whales, humpback whales, and gray whales that may be vulnerable to vessel strikes or potential impacts from training and testing activities. Platforms will use the information from the awareness notification messages to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation.[2]
—Within 20 nmi from shore in the Marine Species Coastal Mitigation Area:
▪ The Navy will conduct no more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined.
▪ To the maximum extent practical, the Navy will conduct explosive Mine Countermeasure and Neutralization Testing from July 1 through September 30 when operating within 20 nmi from shore.
▪ From October 1 through June 30, the Navy will conduct a maximum of one explosive Mine Countermeasure and Neutralization Testing event, not to exceed the use of 20 explosives from bin E4 and 3 explosives from bin E7 annually, and not to exceed the use of 60 explosives from bin E4 and 9 explosives from bin E7 over the seven-year period of the rule.
▪ The Navy will not conduct non-explosive large-caliber gunnery training activities.
▪ The Navy will not conduct non-explosive bombing training activities.
—Within 12 nmi from shore in the Marine Species Coastal Mitigation Area:
▪ The Navy will not conduct Anti-Submarine Warfare Tracking Exercise—Helicopter,—Maritime Patrol Aircraft,—Ship, or—Submarine training activities (which involve the use of mid-frequency or high-frequency active sonar).
▪ The Navy will not conduct non-explosive Anti-Submarine Warfare Torpedo Exercise—Submarine training activities (which involve the use of mid-frequency or high-frequency active sonar).
▪ The Navy will conduct a maximum of one Unmanned Underwater Vehicle Training event per year within 12 nmi from shore at the Quinault Range Site. In addition, Unmanned Underwater Vehicle Training events within 12 nmi from shore at the Quinault Range Site will be cancelled or moved to another training location if Southern Resident killer whales are detected at the planned training location during the event planning process, or immediately prior to the event, as applicable.

TABLE 50—GEOGRAPHIC MITIGATION AREAS FOR MARINE MAMMALS IN THE NWTT STUDY AREA—Continued

Mitigation Area Description
▪ During explosive Mine Countermeasure and Neutralization Testing, the Navy will not use explosives in bin E7 closer than 6 nmi from shore in the Quinault Range Site.
▪ The Navy will not conduct non-explosive small- and medium-caliber gunnery training activities.
• *Olympic Coast National Marine Sanctuary Mitigation Area (year-round):*
—Within the Olympic Coast National Marine Sanctuary Mitigation Area:
▪ The Navy will conduct a maximum of 32 hours of surface ship hull-mounted MF1 mid-frequency active sonar during training annually.
▪ The Navy will conduct no more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined.
▪ The Navy will not conduct explosive Mine Countermeasure and Neutralization Testing activities.
▪ The Navy will not conduct non-explosive bombing training activities.
• *Juan de Fuca Eddy Marine Species Mitigation Area (year-round):*
—Within the Juan de Fuca Eddy Marine Species Mitigation Area:
▪ The Navy will conduct no more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined.
▪ The Navy will not conduct explosive Mine Countermeasure and Neutralization Testing activities.
• *Stonewall and Heceta Bank Humpback Whale Mitigation Area (May 1–November 30):*
—Within the Stonewall and Heceta Bank Humpback Whale Mitigation Area from May 1 to November 30:
▪ The Navy will not use surface ship hull-mounted MF1 mid-frequency active sonar during training or testing.
▪ The Navy will not conduct explosive Mine Countermeasure and Neutralization Testing.
• *Point St. George Humpback Whale Mitigation Area (July 1–November 30):*
—Within the Point St. George Humpback Whale Mitigation Area from July 1 to November 30:
▪ The Navy will not use surface ship hull-mounted MF1 mid-frequency active sonar during training or testing.
▪ The Navy will not conduct explosive Mine Countermeasure and Neutralization Testing.
• *Northern Puget Sound Gray Whale Mitigation Area (March 1–May 31):*
—Within the Northern Puget Sound Gray Whale Mitigation Area from March 1 to May 31:
▪ The Navy will not conduct Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises.
• *Puget Sound and Strait of Juan de Fuca Mitigation Area (year-round or seasonal if specified):*
—Within the Puget Sound and Strait of Juan de Fuca Mitigation Area:
▪ The Navy will not use low-frequency, mid-frequency, or high-frequency active sonar during training or testing within the Puget Sound and Strait of Juan de Fuca Mitigation Area, unless a required element (*i.e.,* a criterion necessary for the success of the event) necessitates that the activity be conducted in NWTT Inland Waters during (1) Unmanned Underwater Vehicle Training, (2) Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises, (3) activities conducted by Naval Sea Systems Command at designated locations, or (4) pierside sonar maintenance or testing at designated locations.
▪ The Navy will use the lowest active sonar source levels practical to successfully accomplish each event.
▪ Naval units will obtain permission from the appropriate designated Command authority prior to commencing pierside maintenance or testing with hull-mounted mid-frequency active sonar.
▪ The Navy will conduct a maximum of one Unmanned Underwater Vehicle Training activity annually at the Navy 3 OPAREA, Navy 7 OPAREA, and Manchester Fuel Depot (*i.e.,* a maximum of one event at each location).
▪ The Navy will not use explosives during testing.
▪ The Navy will not use explosives during training except at the Hood Canal EOD Range and Crescent Harbor EOD Range during explosive mine neutralization activities involving the use of Navy divers.
▪ The Navy will not use explosives in bin E4 (>2.5–5 lb. net explosive weight) or above, and will instead use explosives in bin E0 (<0.1 lb. net explosive weight) or bin E3 (>0.5–2.5 lb. net explosive weight).
▪ During February, March, and April at the Hood Canal EOD Range, the Navy will not use explosives in bin E3 (>0.5–2.5 lb. net explosive weight), and will instead use explosives in bin E0 (<0.1 lb. net explosive weight).
▪ During August, September, and October at the Hood Canal EOD Range, the Navy will avoid using explosives in bin E3 (>0.5–2.5 lb. net explosive weight) and will instead use explosives in bin E0 (<0.1 lb. net explosive weight) to the maximum extent practical unless necessitated by mission requirements.
▪ At the Crescent Harbor EOD Range, the Navy will conduct explosive activities at least 1,000 m from the closest point of land.
▪ The Navy will not conduct non-explosive live fire events in the mitigation area (except firing blank weapons), including gunnery exercises, missile exercises, torpedo exercises, bombing exercises, and Kinetic Energy Weapon Testing.
▪ Navy event planners will coordinate with Navy biologists during the event planning process prior to conducting (1) Unmanned Underwater Vehicle Training at the NAVY 3 OPAREA, Manchester Fuel Depot, Crescent Harbor Explosive Ordnance Disposal Range, and NAVY 7 OPAREA (for Southern Resident killer whales), (2) Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises (for Southern Resident killer whales and gray whales), (3) explosive mine neutralization activities involving the use of Navy divers (for Southern Resident killer whales), and (4) Small Boat Attack Exercises, which involve firing blank small-caliber weapons (for Southern Resident killer whales and gray whales). Navy biologists will work with NMFS and will initiate communication with the appropriate marine mammal detection networks to determine the likelihood of applicable marine mammal species presence in the planned training location. Navy biologists will notify event planners of the likelihood of species presence. To the maximum extent practical, Navy planners will use this information when planning specific details of the event (*e.g.,* timing, location, duration) to avoid planning activities in locations or seasons where species presence is expected. The Navy will ensure environmental awareness of event participants. Environmental awareness will help alert participating crews to the possible presence of applicable species in the training location. Lookouts will use the information to assist visual observation of applicable mitigation zones and to aid in the implementation of procedural mitigation. In addition, Unmanned Underwater Vehicle Training events at the NAVY 3 OPAREA, Manchester Fuel Depot, Crescent Harbor Explosive Ordnance Disposal Range, and NAVY 7 OPAREA will be cancelled or moved to another training location if the presence of Southern Resident killer whales is reported through available monitoring networks during the event planning process, or immediately prior to the event, as applicable.

TABLE 50—GEOGRAPHIC MITIGATION AREAS FOR MARINE MAMMALS IN THE NWTT STUDY AREA—Continued

Mitigation Area Description
▪ The Navy will issue annual seasonal awareness notification messages to alert Navy ships and aircraft operating within the Puget Sound and Strait of Juan de Fuca Mitigation Area to the possible presence of concentrations of Southern Resident killer whales from July 1 to November 30 in the Puget Sound and Strait of Juan de Fuca, and concentrations of gray whales from March 1 to May 31 in the Strait of Juan de Fuca and northern Puget Sound. For safe navigation and to avoid interactions with large whales, the Navy will instruct vessels to remain vigilant to the presence of Southern Resident killer whales and gray whales that may be vulnerable to vessel strikes or potential impacts from training and testing activities. Platforms will use the information from the awareness notification messages to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation.

[1] Should national security present a requirement to conduct training or testing prohibited by the mitigation requirements specified in this table, naval units must obtain permission from the appropriate designated Command authority prior to commencement of the activity. The Navy will provide NMFS with advance notification and include relevant information about the event (*e.g.,* sonar hours, explosives use, non-explosive practice munitions use) in its annual activity reports to NMFS.

[2] The Navy will send these notification messages to all units operating throughout the NWTT Study Area.

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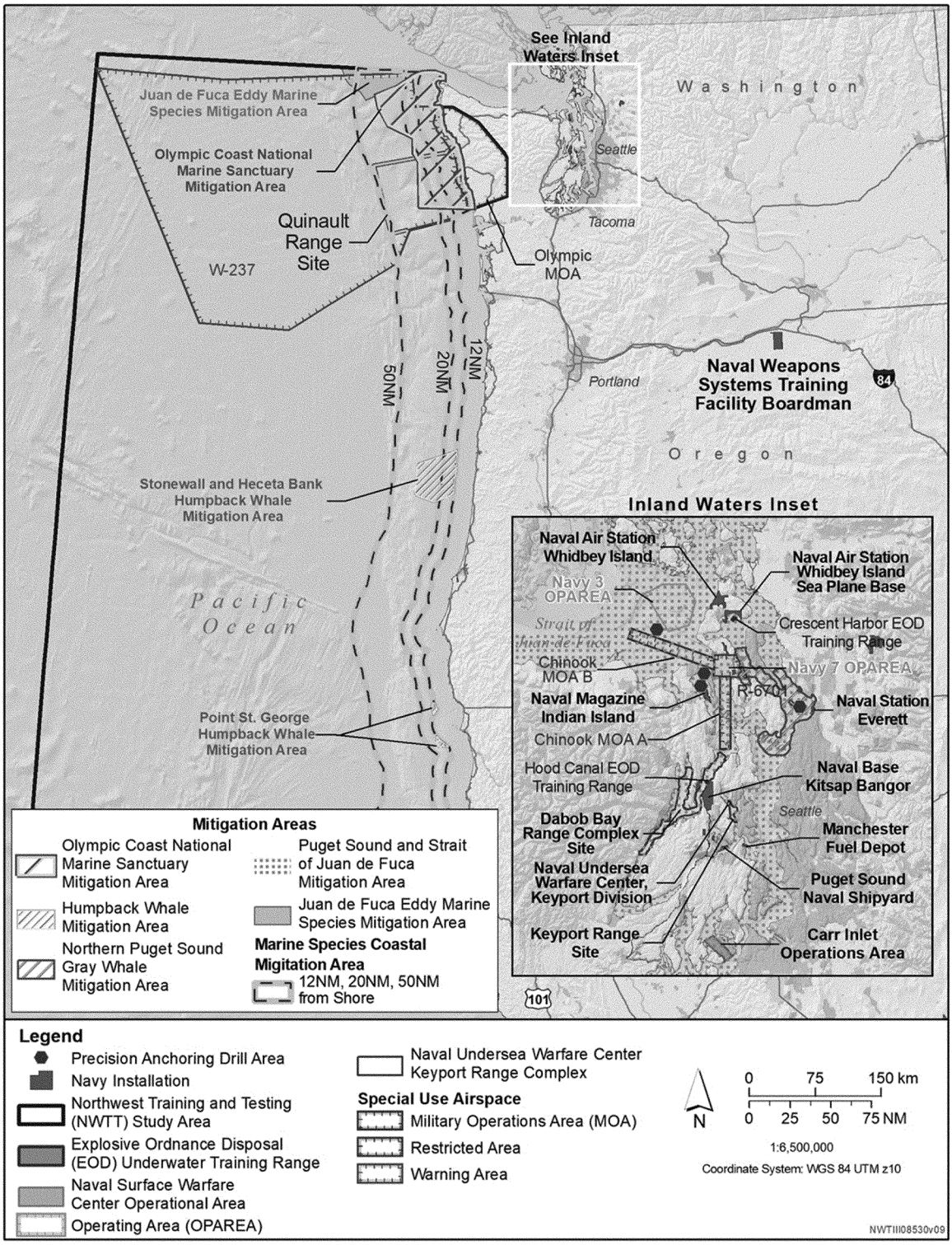

Figure 1 -- Geographic Mitigation Areas for Marine Mammals in the NWTT Study Area

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Marine Species Coastal Mitigation Area

Within 50 nmi from shore—The 50 nmi from shore portion of the Marine Species Coastal Mitigation Area overlaps important feeding, migration, and/or proposed ESA critical habitat for humpback whale, gray whale, Southern Resident killer whale, and harbor porpoise. The Olympic Coast National Marine Sanctuary and Quinault, Grays, Guide, Willapa, Astoria, and Eel canyons are also located within 50 nmi from shore in the Marine Species Coastal Mitigation Area.

See Table 50 for the specific mitigation measures. Mitigation within 50 nmi from shore will result in an

avoidance of potential impacts on marine mammals within their important habitat areas from all explosive training activities, all explosive testing activities except explosive Mine Countermeasure and Neutralization Testing activities, and non-explosive missile training exercises. Additionally, this mitigation will eliminate impacts from active sonar used in conjunction with these prohibited activities, such as mid-frequency and high-frequency active sonar used during explosive torpedo events (*e.g.,* MF1 and MF4 sonar during Torpedo [Explosive] Testing).

Since publication of the proposed rule, an additional measure has been added in this mitigation area that requires the Navy to issue annual seasonal awareness notification messages to further help avoid potential impacts from vessel strikes and training and testing activities on humpback whales, gray whales, and Southern Resident killer whales in the Marine Species Coastal Mitigation Area. The awareness notification messages will coincide with the seasons in which humpback whales, gray whales, and Southern Resident killer whales are most likely to be observed in concentrations in the mitigation area. Southern Resident killer whales are most likely to be observed in the NWTT Offshore Area in winter and spring (December 1 to June 30), due to prey availability. Gray whales and humpback whales are most likely to be observed in the NWTT Offshore Area from late spring through fall (May 1 to November 30 and May 1 through December 31, respectively), which correlates to feeding or migration seasons.

Within 20 nmi from shore—The 20 nmi from shore portion of the Marine Species Coastal Mitigation Area overlaps important feeding, migration, or ESA-designated critical habitat, as described in Section K.3.2.1 of the 2020 FSEIS/OEIS (Resource Description), for gray whales, humpback whales, and Southern Resident killer whales. The mitigation area also overlaps a significant portion of the Olympic Coast National Marine Sanctuary, and Astoria and Eel canyons.

See Table 50 for the specific mitigation measures. As included in the proposed rule, mitigation requirements within 20 nmi from shore will (in addition to the avoided impacts described above for within 50 nmi) avoid or reduce potential impacts on marine mammals within these habitats from non-explosive large-caliber gunnery training and non-explosive bombing training. Additionally, since publication of the proposed rule, a measure has been added limiting the Navy from conducting more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined.

Mitigation has also been added to limit explosive Mine Countermeasure and Neutralization Testing events in this area during certain times of year and limit the number of explosives in each event. This mitigation is designed primarily to avoid or reduce potential impacts on ESA-listed fish species based on their typical occurrence seasonally and at certain water depths (see the 2020 NWTT FSEIS/OEIS for depth considerations). The mitigation may also benefit feeding or migrating humpback whales, migrating gray whales, and feeding or transiting Southern Resident killer whales. One of these new mitigation measures requires the Navy to conduct explosive Mine Countermeasure and Neutralization Testing from July 1 through September 30 to the maximum extent practical when operating within 20 nmi from shore. An additional new measure requires that the Navy can only conduct a maximum of one explosive Mine Countermeasure and Neutralization Testing event annually from October 1 through June 30, not to exceed the use of 20 explosives from bin E4 and 3 explosives from bin E7 annually, and not to exceed the use of 60 explosives from bin E4 and 9 explosives from bin E7 over the seven-year period of the rule. The new limit on the number of explosives used annually and over the seven-year period is designed primarily to reduce potential impacts on ESA-listed fish, including Chinook salmon, the preferred prey source of Southern Resident Killer Whales. This mitigation will reduce the maximum potential exposure to explosives in bin E4 and bin E7 by approximately 40 percent in the months and locations where ESA-listed fish species (some of which are prey species for killer whales), including Chinook salmon Upper Columbia River Spring-Run Evolutionarily Significant Unit, and Chinook salmon Central Valley Spring-Run Evolutionarily Significant Unit, are expected to be present in the NWTT Offshore Area.

Within 12 nmi from shore—The 12 nmi from shore portion of the Marine Species Coastal Mitigation Area overlaps important feeding, migration, and ESA-designated critical habitat for gray whales, humpback whales, and Southern Resident killer whales, as described in Section K.3.2.1 (Resource Description) of the 2020 FSEIS/OEIS. Additionally, part of the Marine Species Coastal Mitigation Area within 12 nmi from shore overlaps a portion of the Olympic Coast National Marine Sanctuary.

See Table 50 for the specific mitigation measures. As described in the proposed rule, mitigation requirements within 12 nmi from shore (which apply in addition to the measures described above for within 50 nmi and within 20 nmi from shore) prohibit non-explosive small- and medium-caliber gunnery training activities and Anti-Submarine Warfare Tracking Exercise—Helicopter, Maritime Patrol Aircraft, Ship, or Submarine training activities (which involve mid-frequency active sonar [including surface ship hull-mounted MF1 mid-frequency active sonar and MF4 dipping sonar] and high-frequency active sonar). Additionally, new mitigation since publication of the proposed rule prohibits non-explosive Anti-Submarine Warfare Torpedo Exercise—Submarine training activities (which involves mid-frequency and high-frequency active sonar) within this area. We expect these measures to result in an avoidance of potential impacts to marine mammals from these activities.

Since publication of the proposed rule, another additional measure has been added, limiting the Navy to conducting a maximum of one Unmanned Underwater Vehicle Training event per year within 12 nmi from shore at the Quinault Range Site, and requiring the Navy to cancel or move Unmanned Underwater Vehicle Training events if Southern Resident killer whales are detected within 12 nmi from shore at the Quinault Range Site. This measure is expected to help avoid any potential impacts on Southern Resident killer whales during Unmanned Underwater Vehicle Training events.

Within 6 nmi from shore—Finally, in addition to the mitigation measures described above, new mitigation during explosive Mine Countermeasure and Neutralization Testing prohibits the use of explosives in bin E7 closer than 6 nmi from shore in the Quinault Range Site. This measure is primarily designed to avoid overlap of the larger of the explosive bins used in this activity with ESA-listed fish species, including Chinook salmon, which are an important prey species for killer whales.

Olympic Coast National Marine Sanctuary Mitigation Area

Mitigation within the Olympic Coast National Marine Sanctuary Mitigation

Area is designed to avoid or reduce potential impacts from surface ship hull-mounted MF1 mid-frequency active sonar, explosives during Mine Countermeasure and Neutralization Testing activities, and non-explosive practice munitions during non-explosive bombing training in important feeding or migration habitat for gray whales, humpback whales, Southern Resident killer whales, and other sanctuary resources, including Chinook salmon, which serve as an important prey species for killer whales. Mitigation within the Olympic Coast National Marine Sanctuary Mitigation Area may avoid or reduce impacts to other marine mammal species that inhabit, forage in, and migrate through the sanctuary. As detailed in Section 6.1.2.1 (Olympic Coast National Marine Sanctuary) of the 2015 NWTT Final EIS/OEIS, the Olympic Coast National Marine Sanctuary consists of an area of 2,408 square nmi of marine waters and the submerged lands off the Olympic Peninsula Coastline of Washington. The sanctuary extends approximately 38 nmi seaward, covering much of the continental shelf and the Quinault Canyon. Due to the Juan de Fuca Eddy ecosystem created from localized currents at the entrance to the Strait of Juan de Fuca and the diversity of bottom habitats, the Olympic Coast National Marine Sanctuary supports a variety of marine life. The diversity of habitats, and the nutrient-rich upwelling zone (which exhibits the greatest volume of upwelling in North America) that drives high primary productivity in this area, contribute to the high species diversity in the Olympic Coast National Marine Sanctuary. According to the Office of National Marine Sanctuaries (2008), the Sanctuary provides important foraging and migration habitat for 29 species of marine mammals.

As included in the proposed rule, the Navy will conduct a maximum of 32 hours annually of surface ship hull-mounted MF1 mid-frequency active sonar during training in the Olympic Coast National Marine Sanctuary Mitigation Area. Additionally, since publication of the proposed rule, and as discussed in the *Marine Species Coastal Mitigation Area* section above, an additional measure has been added limiting the Navy from conducting more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined.

As included in the proposed rule, the Navy will not conduct explosive Mine Countermeasure and Neutralization Testing activities or non-explosive bombing training activities in the Olympic Coast National Marine Sanctuary Mitigation Area. Because this mitigation area is located entirely within 50 nmi from shore in the Marine Species Coastal Mitigation Area, the combined mitigation will ensure that marine mammals and their habitat are not exposed to explosives in the Sanctuary from any training or testing activities. Furthermore, additive mitigation within 20 nmi and 12 nmi from shore in the Marine Species Coastal Mitigation Area will help further avoid or reduce potential impacts from active sonar and non-explosive practice munitions on Sanctuary resources.

Juan de Fuca Eddy Marine Species Mitigation Area

The Juan de Fuca Eddy system is located off Cape Flattery and contains elevated macronutrient levels from spring to fall, derived primarily from upwelling of nutrient-rich deep waters from the California Undercurrent combined with lesser contributions from the Strait of Juan de Fuca outflow (MacFadyen *et al.,* 2008). Mitigation within the Juan de Fuca Eddy Marine Species Mitigation Area is designed to avoid or reduce potential impacts from surface ship hull-mounted MF1 mid-frequency active sonar and explosives during Mine Countermeasure and Neutralization Testing activities on Southern Resident killer whales and humpback whales within important migration and feeding habitats. The Navy will not conduct explosive Mine Countermeasure and Neutralization Testing activities in this mitigation area, and will conduct no more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined.

Additional measures were considered in this area, however, NMFS determined that additional measures were not warranted, given that the Navy does not generally schedule other training and testing activities in this portion of the Study Area due to the high volume of commercial vessel traffic. Therefore the potential for impacts to marine mammals is low. As described in Section K.3.2.2.2 (Operational Assessment) of the 2020 NWTT FSEIS/OEIS, when scheduling activities, the Navy considers the need to minimize sea space and airspace conflicts between its own activities and other users with consideration for public safety.

Waters within the Juan de Fuca Eddy Marine Species Mitigation Area (including areas off Cape Flattery) are important foraging habitat for aggregations of humpback whales and migration habitat for Southern Resident killer whales as they transit between Inland Waters and the Offshore Area (see Section K.3.2.1.1 (Humpback Whale) and Section K.3.2.1.3 (Southern Resident Killer Whale) of the 2020 FSEIS/OEIS). The full extent of the Juan de Fuca Eddy is not incorporated into the Northern Washington humpback whale biologically important feeding area because the development of biologically important areas was restricted to U.S. waters only. Therefore, the Northern Washington biologically important humpback whale feeding area extends northward to the boundary of the U.S. Exclusive Economic Zone (Calambokidis *et al.,* 2015; Ferguson et al., 2015a; Ferguson *et al.,* 2015b). However, humpback whale aggregations feed across this political boundary in the nutrient rich waters throughout the Juan de Fuca Eddy. Therefore, waters within the Juan de Fuca Eddy between the Northern Washington humpback whale biologically important area and the northern boundary of the NWTT Offshore Area are included in the Juan de Fuca Eddy Marine Species Mitigation Area.

Migrating gray whales may also use this area, as well as other species of marine mammals, including sperm whales. Sperm whale concentrations typically correlate with areas of high productivity near drop-offs and areas with strong currents and steep topography (Gannier and Praca, 2007; Jefferson *et al.,* 2015), such as the conditions present seasonally in the Juan de Fuca Eddy (MacFadyen *et al.,* 2008). The mitigation area's nutrient-rich waters and seasonal upwelling provide an abundance of marine mammal prey species and favorable foraging conditions for concentrations of marine mammals. The mitigation will also help avoid or reduce potential impacts on other species, including Southern Resident killer whale preferred prey, Chinook salmon.

Stonewall and Heceta Bank Humpback Whale Mitigation Area

Mitigation in the Stonewall and Heceta Bank Humpback Whale Mitigation Area, which is required from

May 1 to November 30, is primarily designed to avoid or reduce potential impacts from surface ship hull-mounted MF1 mid-frequency active sonar and explosive Mine Countermeasure and Neutralization Testing activities to humpback whales in an important seasonal feeding area. See Table 50 for the specific mitigation measures.

The Stonewall and Heceta Bank Humpback Whale Mitigation Area is within 50 nmi from shore in the Marine Species Coastal Mitigation Area. Therefore, given the combined mitigation in these two areas, no explosive training or testing will occur in this mitigation area from May 1 to November 30. Additionally, a portion of the Stonewall and Heceta Bank Humpback Whale Mitigation Area is within 20 nmi from shore in the Marine Species Coastal Mitigation Area. Mitigation measures between these two areas will help further reduce potential impacts from additional sources of active sonar, as well as non-explosive practice munitions, year round, given that the Marine Species Coastal Mitigation Area is effective year round.

From May to November, humpback whales aggregate to feed on krill and small fish in this area. Enhanced vertical and horizontal mixing associated with Heceta Bank results in higher prey densities, which improves foraging conditions for humpback whales and harbor porpoise (Tynan *et al.,* 2005). Humpback whales and harbor porpoise aggregate in this area in the summer when prey concentrations are thought to be highest.

In addition to containing humpback whale and harbor porpoise feeding habitat, the Stonewall and Heceta Bank Humpback Whale Mitigation Area overlaps important habitats for several other species, including potential gray whale migration habitat; Southern Resident killer whale feeding, migration and proposed ESA critical habitat; and Chinook salmon migration habitat. Other marine mammal species have also been observed in the vicinity of Heceta Bank. The enhanced vertical and horizontal mixing associated with Heceta Bank that results in higher prey densities and improved foraging conditions for humpback whales and harbor porpoise may also serve to influence the presence of other marine mammal species in this area (Tynan *et al.,* 2005). For example, sperm whales, Baird's beaked whales, Cuvier's beaked whales, Pacific white-sided dolphins, northern right whale dolphins, Risso's dolphins, and Dall's porpoise have been observed at Heceta Bank in spring or summer during past surveys (Tynan *et al.,* 2005). Sperm whales have been observed at Heceta Bank during spring and summer, possibly indicating a correlation between the abundance of prey species, such as large cephalopods (*e.g.,* squid) and fish (Tynan *et al.,* 2005). Therefore, in addition to benefits to humpback whales and harbor porpoise in important foraging habitat, mitigation within the Stonewall and Heceta Bank Humpback Whale Mitigation Area will likely help avoid or reduce potential impacts to additional marine mammal species that may feed in or migrate through this area.

Point St. George Humpback Whale Mitigation Area

The Point St. George Humpback Whale Mitigation area contains important humpback whale feeding habitat. From July to November, humpback whales feed in an area off of Oregon and California at Point St. George, an area that has similar productive upwelling conditions as Heceta Bank. Additionally, the area overlaps important habitats for several other species, including potential gray whale migration habitat and Southern Resident killer whale feeding and migration habitat. Migrating Chinook salmon may occur in this area as well.

Mitigation in the Point St. George Humpback Whale Mitigation Area, effective from July 1 to November 30, was initially designed to avoid or reduce potential impacts from mid-frequency active sonar on humpback whales, as this is an important seasonal feeding area. Since the proposed rule, an additional measure has been added that prohibits the Navy from conducting explosive Mine Countermeasure and Neutralization Testing activities in this mitigation area.

The Point St. George Humpback Whale Mitigation Area is located entirely within 20 nmi from shore in the Marine Species Coastal Mitigation Area. Therefore, given the combined mitigation in these two areas, no explosive training or testing will occur in the Point St. George Humpback Whale Mitigation Area from July 1 to November 30. Additionally, potential impacts to marine mammals from surface ship hull-mounted MF1 mid-frequency active sonar as well as non-explosive practice munitions will be avoided or reduced year round.

Northern Puget Sound Gray Whale Mitigation Area

The Northern Puget Sound Gray Whale Mitigation Area fully overlaps the biologically important gray whale feeding habitat identified by Calambokidis *et al.* (2015) and a portion of the gray whale migration biologically important area. Gray whales feed in this area from March 1 to May 31. The Navy will not conduct Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises during this same time period (March 1 to May 31) in this mitigation area. Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises are multi-day events that involve aircraft, surface vessels, and unmanned underwater vehicles using high-frequency active sonar and other systems to train to detect non-explosive underwater mine shapes. Therefore, with the Navy restricted from conducting this activity in the Northern Puget Sound Gray Whale Mitigation Area during the specified time period, potential impacts from vessel movements, towed in-water devices, and active sonar on gray whales will be avoided during important times in this feeding area.

The Northern Puget Sound Gray Whale Mitigation Area is located entirely within the Puget Sound and Strait of Juan de Fuca Mitigation Area. Therefore, mitigation in the Puget Sound and Strait of Juan de Fuca Mitigation Area, described below, will further reduce potential impacts on gray whale feeding in this location.

Puget Sound and Strait of Juan de Fuca Mitigation Area

The Puget Sound and Strait of Juan de Fuca Mitigation Area encompasses the full extent of NWTT Inland Waters and, therefore, the mitigation area fully overlaps each known important marine mammal feeding and migration habitat area in NWTT inland waters. (See Section K.3.3.1 (*Resource Description*) of the 2020 FSEIS/OEIS for a full description of these areas.) This includes feeding and potential migration habitat for gray whales and ESA-designated critical habitat for Southern Resident killer whales, as well as for one of the Southern Resident killer whales' primary sources of prey, Puget Sound Chinook salmon. Mitigation in the Puget Sound and Strait of Juan de Fuca Mitigation Area is designed to minimize potential impacts on these species and their habitat in NWTT Inland Waters. See Table 50 for the specific mitigation measures.

As included in the proposed rule, naval units are required to obtain approval from the appropriate designated Command authority prior to commencing pierside maintenance or testing with hull-mounted mid-frequency active sonar. This measure will elevate the situational and environmental awareness of respective Command authorities during the event

planning process. Requiring designated Command authority approval provides an increased level of assurance that mid-frequency active sonar is a required element (*i.e.,* a criterion necessary for the success of the event) for each event. Such authorizations are typically based on the unique characteristics of the area from a military readiness perspective, taking into account the importance of the area for marine species and the need to mitigate potential impacts on Southern Resident killer whales (and other marine mammals, such as gray whales) to the maximum extent practical.

Also included in the proposed rule, year-round mitigation at the Crescent Harbor Explosive Ordnance Disposal (EOD) Range prohibits explosive activities within 1,000 m of the closest point of land. This measure is primarily intended to avoid or reduce potential impacts on bull trout, however, it may also benefit other species, such as Southern Resident killer whales (although they have not been observed regularly at the Crescent Harbor EOD Range), gray whales, and Puget Sound Chinook salmon. Finally, as also included in the proposed rule, for Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises, Navy event planners will coordinate with Navy biologists during the event planning process. Navy biologists will work with NMFS to determine the likelihood of gray whale and Southern Resident killer whale presence in the planned training location. Navy biologists will notify event planners of the likelihood of killer whale and gray whale presence as they plan specific details of the event (*e.g.,* timing, location, duration), with the goal of minimizing impacts to killer whales and gray whales through the adjustment of event details, where practical. The Navy will also ensure environmental awareness of event participants. Environmental awareness will help alert participating ship and aircraft crews to the possible presence of marine mammals in the training location, such as gray whales and Southern Resident killer whales.

As described previously, this final rule includes many new mitigation measures in the Puget Sound and Strait of Juan de Fuca Mitigation Area to further protect marine mammals, particularly Southern Resident killer whales. The *Assessment of Mitigation Measures for NWTT Study Area* section describes mitigation that is new to this final rule, and distinguishes between new mitigation that is a continuation of the Navy's voluntary Phase II mitigation, and new measures that were not implemented by the Navy in NWTT Phase II. See that section and Table 50 for all other mitigation measures.

New mitigation in the Puget Sound and Strait of Juan de Fuca Mitigation Area is designed to help avoid any potential impacts from training and testing on Southern Resident killer whales in NWTT Inland Waters. With implementation of these new mitigation measures, we do not anticipate any take of Southern Resident killer whales in NWTT Inland Waters due to NWTT training and testing activities. Based on seasonal density data, Southern Resident killer whale occurrence is either not anticipated or is expected to be infrequent at Naval Sea Systems Command testing sites and in the locations where pierside maintenance and testing are designated to occur. Additionally, given the sheltered, calm waters, there is an increased likelihood that any Southern Resident killer whales or gray whales in these areas would be observed by Navy Lookouts, as described in Section 5.3.2.1 (Active Sonar) of the 2020 NWTT FSEIS/OEIS.

New mitigation in this mitigation area will reduce the types of active sonar activities and the active sonar source levels when practical, and therefore the overall amount of active sonar (*i.e.,* number of hours) conducted in the mitigation area, and the overall potential for marine mammal exposure, while allowing the Navy to successfully accomplish events that require the use of active sonar in designated locations. Additionally, new mitigation will effectively reduce the locations, charge sizes, and overall annual number of explosive detonations in the mitigation area, which will avoid or reduce potential overlap of explosive activities within Southern Resident killer whale and gray whale habitat to the maximum extent practical. New mitigation will also help avoid any impacts from explosives and non-explosive practice munitions on marine mammals throughout NWTT Inland Waters.

Availability for Subsistence Uses

The nature of subsistence activities by Alaskan Natives in the NWTT Study Area are discussed in detail below, in the Subsistence Harvest of Marine Mammals section of this final rule. As noted in that section, testing activities in the Western Behm Canal are the only activities within the NWTT Study Area that have the potential to affect subsistence uses of marine mammals. The Navy will notify the following Alaskan Native communities of the issuance of Notices to Mariners of Navy operations that involve restricting access in the Western Behm Canal at least 72 hours in advance: Central Council of the Tlingit and Haida Indian Tribes, Ketchikan Indian Corporation, Organized Village of Saxman, and Metlakatla Indian Community, Annette Island Reserve. These notifications will minimize potential impacts on subsistence hunters.

Mitigation Conclusions

NMFS has carefully evaluated the mitigation measures—many of which were developed with NMFS' input during the previous phases of Navy training and testing authorizations but several of which are new since implementation of the 2015 to 2020 regulations or new since publication of the proposed rule (and addressing some of the information or recommendations received during the public comment period). NMFS has also considered a broad range of other measures (*e.g.,* the measures considered but eliminated in the 2020 NWTT FSEIS/OEIS, which reflect other comments that have arisen via NMFS or public input in past years) in the context of ensuring that NMFS prescribes the means of effecting the least practicable adverse impact on the affected marine mammal species or stocks and their habitat and on the availability of the species or stocks for subsistence uses. Our evaluation of potential measures included consideration of the following factors in relation to one another: The manner in which, and the degree to which, the successful implementation of the mitigation measures is expected to reduce the likelihood and/or magnitude of adverse impacts to marine mammal species or stocks and their habitat; the manner in which, and the degree to which, the successful implementation of the mitigation measures is expected to reduce the likelihood and/or magnitude of adverse impacts on subsistence uses; the proven or likely efficacy of the measures; and the practicability of the measures for applicant implementation, including (for measures to address adverse impacts to marine mammal species or stocks and their habitat) consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Based on our evaluation of the Navy's proposed measures, as well as other measures considered by the Navy and NMFS, NMFS has determined that the mitigation measures included in this final rule are the appropriate means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar

significance, and considering specifically personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity, and on the availability of the species and stocks for subsistence uses. Additionally, an adaptive management provision ensures that mitigation is regularly assessed and provides a mechanism to improve the mitigation, based on the factors above, through modification as appropriate. Thus, NMFS concludes that the mitigation measures outlined in this final rule satisfy the statutory standard and that any adverse impacts that remain cannot be practicably further mitigated.

Monitoring

Section 101(a)(5)(A) of the MMPA states that in order to authorize incidental take for an activity, 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 incidental take 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.

Although the Navy has been conducting research and monitoring in the NWTT Study Area for over 20 years, it developed a formal marine species monitoring program in support of the MMPA and ESA authorizations in 2009. This robust program has resulted in hundreds of technical reports and publications on marine mammals that have informed Navy and NMFS analyses in environmental planning documents, MMPA rules, and ESA Biological Opinions. The reports are made available to the public on the Navy's marine species monitoring website (*www.navymarinespeciesmonitoring.us*) and the data on the Ocean Biogeographic Information System Spatial Ecological Analysis of Megavertebrate Populations (OBIS–SEAMAP) site (*http://seamap.env.duke.edu/*) and the Animal Telemetry Network (*https://atn.ioos.us/*).

The Navy will continue collecting monitoring data to inform our understanding of the occurrence of marine mammals in the NWTT Study Area; the likely exposure of marine mammals to stressors of concern in the NWTT Study Area; the response of marine mammals to exposures to stressors; the consequences of a particular marine mammal response to their individual fitness and, ultimately, populations; and the effectiveness of implemented mitigation measures. Taken together, mitigation and monitoring comprise the Navy's integrated approach for reducing environmental impacts from the specified activities. The Navy's overall monitoring approach seeks to leverage and build on existing research efforts whenever possible.

As agreed upon between the Navy and NMFS, the monitoring measures presented here, as well as the mitigation measures described above, focus on the protection and management of potentially affected marine mammals. A well-designed monitoring program can provide important feedback for validating assumptions made in analyses and allow for adaptive management of marine resources.

Integrated Comprehensive Monitoring Program (ICMP)

The Navy's ICMP is intended to coordinate marine species monitoring efforts across all regions and to allocate the most appropriate level and type of effort for each range complex based on a set of standardized objectives, and in acknowledgement of regional expertise and resource availability. The ICMP is designed to be flexible, scalable, and adaptable through the adaptive management and strategic planning processes to periodically assess progress and reevaluate objectives. This process includes conducting an annual adaptive management review meeting, at which the Navy and NMFS jointly consider the prior-year goals, monitoring results, and related scientific advances to determine if monitoring plan modifications are warranted to more effectively address program goals. Although the ICMP does not specify actual monitoring field work or individual projects, it does establish a matrix of goals and objectives that have been developed in coordination with NMFS. As the ICMP is implemented through the Strategic Planning Process (see the section below), detailed and specific studies that support the Navy's and NMFS' top-level monitoring goals will continue to be developed. In essence, the ICMP directs that monitoring activities relating to the effects of Navy training and testing activities on marine species should be designed to contribute towards one or more of the following top-level goals:

- An increase in the understanding of the likely occurrence of marine mammals and/or ESA-listed marine species in the vicinity of the action (*i.e.,* presence, abundance, distribution, and density of species);
- An increase in the understanding of the nature, scope, or context of the likely exposure of marine mammals and/or ESA-listed species to any of the potential stressors associated with the action (*e.g.,* sound, explosive detonation, or military expended materials), through better understanding of one or more of the following: (1) The action and the environment in which it occurs (*e.g.,* sound-source characterization, propagation, and ambient noise levels), (2) the affected species (*e.g.,* life history or dive patterns), (3) the likely co-occurrence of marine mammals and/or ESA-listed marine species with the action (in whole or part), and (4) the likely biological or behavioral context of exposure to the stressor for the marine mammal and/or ESA-listed marine species (*e.g.,* age class of exposed animals or known pupping, calving, or feeding areas);
- An increase in the understanding of how individual marine mammals or ESA-listed marine species respond (behaviorally or physiologically) to the specific stressors associated with the action (in specific contexts, where possible, *e.g.,* at what distance or received level);
- An increase in the understanding of how anticipated individual responses, to individual stressors or anticipated combinations of stressors, may impact either (1) the long-term fitness and survival of an individual; or (2) the population, species, or stock (*e.g.,* through impacts on annual rates of recruitment or survival);
- An increase in the understanding of the effectiveness of mitigation and monitoring measures;
- A better understanding and record of the manner in which the Navy complies with the incidental take regulations and LOAs and the ESA Incidental Take Statement;
- An increase in the probability of detecting marine mammals (through improved technology or methods), both specifically within the mitigation zones (thus allowing for more effective implementation of the mitigation) and in general, to better achieve the above goals; and
- Ensuring that adverse impact of activities remains at the least practicable level.

Strategic Planning Process for Marine Species Monitoring

The Navy also developed the Strategic Planning Process for Marine Species Monitoring, which establishes the guidelines and processes necessary to

develop, evaluate, and fund individual projects based on objective scientific study questions. The process uses an underlying framework designed around intermediate scientific objectives and a conceptual framework incorporating a progression of knowledge spanning occurrence, exposure, response, and consequence. The Strategic Planning Process for Marine Species Monitoring is used to set overarching intermediate scientific objectives; develop individual monitoring project concepts; identify potential species of interest at a regional scale; evaluate, prioritize, and select specific monitoring projects to fund or continue supporting for a given fiscal year; execute and manage selected monitoring projects; and report and evaluate progress and results. This process addresses relative investments to different range complexes based on goals across all range complexes, and monitoring leverages multiple techniques for data acquisition and analysis whenever possible. The Strategic Planning Process for Marine Species Monitoring is also available online (*http://www.navymarinespeciesmonitoring.us/*).

Past and Current Monitoring in the NWTT Study Area

The monitoring program has undergone significant changes since the first rule was issued for the NWTT Study Area in 2010, which highlights the monitoring program's evolution through the process of adaptive management. The monitoring program developed for the first cycle of environmental compliance documents (*e.g.,* U.S. Department of the Navy, 2008a, 2008b) utilized effort-based compliance metrics that were somewhat limiting. Through adaptive management discussions, the Navy designed and conducted monitoring studies according to scientific objectives, thereby eliminating basing requirements upon metrics of level-of-effort. Furthermore, refinements of scientific objectives have continued through the latest authorization cycle.

Progress has also been made on the conceptual framework categories from the Scientific Advisory Group for Navy Marine Species Monitoring (U.S. Department of the Navy, 2011), ranging from occurrence of animals, to their exposure, response, and population consequences. The Navy continues to manage the Atlantic and Pacific program as a whole, with monitoring in each range complex taking a slightly different but complementary approach. The Navy has continued to use the approach of layering multiple simultaneous components in many of the range complexes to leverage an increase in return of the progress toward answering scientific monitoring questions. This includes in the NWTT Study Area, for example, (a) satellite tagging of blue whales, fin whales, humpback whales, and Southern Resident killer whales; (b) analysis of existing passive acoustic monitoring datasets; and (c) line-transect aerial surveys for marine mammals in Puget Sound, Washington.

Numerous publications, dissertations, and conference presentations have resulted from research conducted under the marine species monitoring program (*https://www.navymarinespeciesmonitoring.us/reading-room/publications/*), resulting in a significant contribution to the body of marine mammal science. Publications on occurrence, distribution, and density have fed the modeling input, and publications on exposure and response have informed Navy and NMFS analysis of behavioral response and consideration of mitigation measures.

Furthermore, collaboration between the monitoring program and the Navy's research and development (*e.g.,* the Office of Naval Research) and demonstration-validation (*e.g.,* Living Marine Resources) programs has been strengthened, leading to research tools and products that have already transitioned to the monitoring program. These include Marine Mammal Monitoring on Ranges (M3R), controlled exposure experiment behavioral response studies (CEE BRS), acoustic sea glider surveys, and global positioning system-enabled satellite tags. Recent progress has been made with better integration with monitoring across all Navy at-sea study areas, including study areas in the Pacific and the Atlantic Oceans, and various other testing ranges. Publications from the Living Marine Resources and Office of Naval Research programs have also resulted in significant contributions to information on hearing ranges and acoustic criteria used in effects modeling, exposure, and response, as well as in developing tools to assess biological significance (*e.g.,* population-level consequences).

NMFS and the Navy also consider data collected during procedural mitigations as monitoring. Data are collected by shipboard personnel on hours spent training, hours of observation, hours of sonar, and marine mammals observed within the mitigation zones when mitigations are implemented. These data are provided to NMFS in both classified and unclassified annual exercise reports, which will continue under this rule.

NMFS has received multiple years' worth of annual exercise and monitoring reports addressing active sonar use and explosive detonations within the NWTT Study Area and other Navy range complexes. The data and information contained in these reports have been considered in developing mitigation and monitoring measures for the training and testing activities within the NWTT Study Area. The Navy's annual exercise and monitoring reports may be viewed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities* and *https://www.navymarinespeciesmonitoring.us/reporting/.*

The Navy's marine species monitoring program typically supports several monitoring projects in the NWTT Study Area at any given time. Additional details on the scientific objectives for each project can be found at *https://www.navymarinespeciesmonitoring.us/regions/pacific/current-projects/.* Projects can be either major multi-year efforts, or one to two-year special studies. The emphasis on species-specific monitoring in the Pacific Northwest is directed towards collecting and analyzing tagging data related to the occurrence of blue whales, fin whales, humpback whales, and Southern Resident killer whales. In 2017, researchers deployed 28 tags on blue whales and one tag on a fin whale (Mate *et al.,* 2017, 2018a). Humpback whales have been tagged with satellite tags, and biopsy samples have been collected (Mate *et al.,* 2017, 2018b, 2019, 2020). Location information on Southern Resident killer whales was provided via satellite tag data and acoustic detections (Emmons *et al.,* 2019; Hanson *et al.,* 2018; Riera *et al.,* 2019). Also, distribution of Chinook salmon (a key prey species of Southern Resident killer whales) in coastal waters from Alaska to Northern California was studied (Shelton *et al.,* 2018).

Specific monitoring under the 2015–2020 regulations included the following projects:

- QRS Unmanned Acoustic Glider;
- PAM for Marine Mammals in the NWTRC;
- Modeling the Offshore Distribution of Southern Resident Killer Whales in the Pacific Northwest;
- Marine Mammal Density Surveys in the Pacific Northwest (Inland Puget Sound);
- Blue and Fin Whale Tagging and Genetics; Tagging and Behavioral Monitoring of Sea Lions in the Pacific Northwest in Proximity to Navy Facilities;

• Harbor Seal Density Estimation; Humpback Whale Tagging in Support of Marine Mammal Monitoring Across Multiple Navy Training Areas in the Pacific Ocean;

• Modeling the Offshore Distribution of Chinook Salmon in the Pacific Northwest;

• Characterizing the Distribution of ESA-Listed Salmonids in the Pacific Northwest;

• Guadalupe Fur Seal Satellite Tracking;

Future monitoring efforts in the NWTT Study Area are anticipated to continue along the same objectives: determining the species and populations of marine mammals present and potentially exposed to Navy training and testing activities in the NWTT Study Area, through tagging, passive acoustic monitoring, refined modeling, photo identification, biopsies, and visual monitoring.

Currently planned monitoring projects for the 2020–2027 rule are listed below. Monitoring projects are typically planned one year in advance; therefore, this list does not include all projects that will occur over the entire period of the rule.

• Offshore Distribution of Southern Resident Killer Whales in the Pacific Northwest (ongoing and planned through 2022)—Objectives include: (1) Identify and classify Southern Resident killer whale detections from acoustic recorders and satellite tag tracking; (2) Develop a model to estimate the seasonal and annual occurrence patterns of Southern Resident killer whales relative to offshore Navy training ranges; (3) Characterize occurrence of anthropogenic sounds in potential Southern Resident killer whale habitat; and (4) Develop state space habitat model for Southern Resident killer whale prey, based on fall Chinook salmon tagged and released from California to British Columbia between 1977 and 1990 to estimate seasonal distribution along the West Coast. Methods include: Passive acoustic monitoring, model development, visual survey, satellite tagging, and analysis of archived data.

• Characterizing the Distribution of ESA-Listed Salmonids in the Pacific Northwest (ongoing and planned through 2022)—Objectives include: To use a combination of acoustic and pop-up satellite tagging technology to provide critical information on spatial and temporal distribution of salmonids to inform salmon management, U.S. Navy training activities, and Southern Resident killer whale conservation. The study seeks to (1) determine the occurrence and timing of salmonids within the Navy training ranges; (2) describe the influence of environmental covariates on salmonid occurrence; and (3) describe the occurrence of salmonids in relation to Southern Resident killer whale distribution. Methods include: Acoustic telemetry (pinger tags) and pop-up satellite tagging.

Adaptive Management

The regulations governing the take of marine mammals incidental to Navy training and testing activities in the NWTT Study Area contain an adaptive management component. Our understanding of the effects of Navy training and testing activities (*e.g.,* acoustic and explosive stressors) on marine mammals continues to evolve, which makes the inclusion of an adaptive management component both valuable and necessary within the context of seven-year regulations.

The reporting requirements associated with this rule are designed to provide NMFS with monitoring data from the previous year to allow NMFS to consider whether any changes to existing mitigation and monitoring requirements are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from the Navy regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or deletions). Mitigation measures could be modified if new data suggests that such modifications will have a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring and if the measures are practicable. If the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS will publish a notice of the planned LOAs in the **Federal Register** and solicit public comment.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring and exercise reports, as required by MMPA authorizations; (2) compiled results of Navy funded research and development studies; (3) results from specific stranding investigations; (4) results from general marine mammal and sound research; and (5) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOAs. The results from monitoring reports and other studies may be viewed at *https://www.navymarinespeciesmonitoring.us.*

Reporting

In order to issue incidental take authorization for an activity, section 101(a)(5)(A) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring. Reports from individual monitoring events, results of analyses, publications, and periodic progress reports for specific monitoring projects will be posted to the Navy's Marine Species Monitoring web portal: *http://www.navymarinespeciesmonitoring.us.*

There were several different reporting requirements pursuant to the 2015–2020 regulations. All of these reporting requirements will continue under this rule for the seven-year period.

Notification of Injured, Live Stranded, or Dead Marine Mammals

The Navy will consult the Notification and Reporting Plan, which sets out notification, reporting, and other requirements when injured, live stranded, or dead marine mammals are detected. The Notification and Reporting Plan is available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

Annual NWTT Monitoring Report

The Navy will submit an annual report to NMFS of the NWTT Study Area monitoring, which will be included in a Pacific-wide monitoring report including results specific to the NWTT Study Area, describing the implementation and results from the previous calendar year. Data collection methods will be standardized across Pacific Range Complexes including the MITT, HSTT, NWTT, and Gulf of Alaska (GOA) Study Areas to the best extent practicable, to allow for comparison in different geographic locations. The report must be submitted to the Director, Office of Protected Resources, NMFS, either within three months after the end of the calendar year, or within three months after the conclusion of the monitoring year, to be determined by the Adaptive Management process. NMFS will submit comments or questions on the draft monitoring report, if any, within three months of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or three months after submittal of the draft if NMFS does not provide comments on the draft report. The report will describe progress of

knowledge made with respect to monitoring study questions across multiple Navy ranges associated with the ICMP. Similar study questions will be treated together so that progress on each topic is summarized across multiple Navy ranges. The report need not include analyses and content that does not provide direct assessment of cumulative progress on the monitoring plan study question. This will allow the Navy to provide a cohesive monitoring report covering multiple ranges (as per ICMP goals), rather than entirely separate reports for the MITT, HSTT, NWTT, and GOA Study Areas.

NWTT Annual Training Exercise Report and Annual Testing Activity Report

Each year, the Navy will submit two preliminary reports (Quick Look Reports) to NMFS detailing the status of applicable sound sources within 21 days after the anniversary of the date of issuance of the LOAs. The Navy will also submit detailed reports (NWTT Annual Training Exercise and Annual Testing Activity Reports) to NMFS within three months after the one-year anniversary of the date of issuance of the LOAs. If desired, the Navy may elect to consolidate the NWTT Annual Training Exercise Report and the Annual Testing Activity Report with other exercise and activity reports from other range complexes in the Pacific Ocean for a single Pacific Training Exercise and Testing Activity Report. NMFS will submit comments or questions on the reports, if any, within one month of receipt. The reports will be considered final after the Navy has addressed NMFS' comments, or one month after submittal of the drafts if NMFS does not provide comments on the draft reports. The annual reports will contain a summary of all sound sources used (total hours or quantity of each bin of sonar or other non-impulsive source; total annual number of each type of explosive; and total annual expended/detonated rounds (missiles, bombs, sonobuoys, *etc.*) for each explosive bin).

Both reports will also contain both current year's sonar and explosive use data as well as cumulative sonar and explosive use quantity from previous years' reports. Additionally, if there were any changes to the sound source allowance in the reporting year, or cumulatively, the report will include a discussion of why the change was made and include analysis to support how the change did or did not affect the analysis in the 2020 NWTT FSEIS/OEIS and MMPA final rule. See the regulations below for more detail on the content of the annual report.

Within the annual classified training exercise and testing activity reports, separate from the unclassified reports described above, the Navy will specifically include the following information:

- Total hours of authorized low-frequency, mid-frequency, and high-frequency active sonar (all bins, by bin) used during training and testing annually within the Olympic Coast National Marine Sanctuary; and
- Total hours of surface ship hull-mounted MF1 mid-frequency active sonar used in the following mitigation areas:

1. Testing annually in three combined areas: 20 nmi from shore in the Marine Species Coastal Mitigation Area, the Juan de Fuca Eddy Marine Species Mitigation Area, and the Olympic Coast National Marine Sanctuary Mitigation Area.
2. Training and testing from May 1 to November 30 within the Stonewall and Heceta Bank Humpback Whale Mitigation Area.
3. Training and testing from July 1 to November 30 within the Point St. George Humpback Whale Mitigation Area.

The final annual reports at the conclusion of the authorization period (year seven) will also serve as the comprehensive close-out report and include both the final year annual use compared to annual authorization as well as a cumulative seven-year annual use compared to seven-year authorization. NMFS must submit comments on the draft close-out report, if any, within three months of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or three months after the submittal of the draft if NMFS does not provide comments.

Information included in the annual reports may be used to inform future adaptive management of activities within the NWTT Study Area.

Other Reporting and Coordination

The Navy will continue to report and coordinate with NMFS for the following:

- Annual marine species monitoring technical review meetings (in-person or remote, as circumstances allow and agreed upon by NMFS and the Navy) that also include researchers and the Marine Mammal Commission (currently, every two years a joint Pacific-Atlantic meeting is held); and
- Annual Adaptive Management meetings (in-person or remote, as circumstances allow and agreed upon by NMFS and the Navy) that also include the Marine Mammal Commission (recently modified to occur in conjunction with the annual monitoring technical review meeting).

Analysis and Negligible Impact Determination

General Negligible Impact Analysis

Introduction

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 considering how Level A harassment or Level B harassment (as presented in Tables 32 and 33), factor into the negligible impact analysis, in addition to considering the number of estimated takes, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration) and the context of any responses (*e.g.,* critical reproductive time or location, migration), 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 environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size, and growth rate where known).

In the Estimated Take of Marine Mammals section, we identified the subset of potential effects that are expected to rise to the level of takes both annually and over the seven-year period covered by this rule, and then identified the maximum number of takes we believe could occur (mortality) or are reasonably expected to occur (harassment) based on the methods described. The impact that any given take will have on an individual, and ultimately the species or stock, is dependent on many case-specific factors that need to be considered in the negligible impact analysis (*e.g.,* the context of behavioral exposures such as duration or intensity of a disturbance, the health of impacted animals, the status of a species that incurs fitness-

level impacts to individuals, *etc.*). For this rule we evaluated the likely impacts of the enumerated maximum number of harassment takes that are reasonably expected to occur, and are authorized, in the context of the specific circumstances surrounding these predicted takes. We also specifically assessed serious injury or mortality (hereafter referred to as M/SI) takes that could occur, as well as considering the traits and statuses of the affected species and stocks. Last, we collectively evaluated this information, as well as other more taxa-specific information and mitigation measure effectiveness, in group-specific assessments that support our negligible impact conclusions for each stock or species. Because all of the Navy's specified activities will occur within the ranges of the marine mammal stocks identified in the rule, all negligible impact analyses and determinations are at the stock level (*i.e.,* additional species-level determinations are not needed).

The specified activities reflect representative levels of training and testing activities. The Description of the Specified Activities section describes annual activities. There may be some flexibility in the exact number of hours, items, or detonations that may vary from year to year, but take totals will not exceed the maximum annual totals and seven-year totals indicated in Tables 32 and 33. We base our analysis and negligible impact determination on the maximum number of takes that are reasonably expected to occur and are authorized, although, as stated before, the number of takes are only a part of the analysis, which includes extensive qualitative consideration of other contextual factors that influence the degree of impact of the takes on the affected individuals. To avoid repetition, we provide some general analysis in this *General Negligible Impact Analysis* section that applies to all the species listed in Tables 32 and 33, given that some of the anticipated effects of the Navy's training and testing activities on marine mammals are expected to be relatively similar in nature. Then, in the *Group and Species-Specific Analyses* section, we subdivide into discussions of Mysticetes, Odontocetes, and pinnipeds, as there are broad life history traits that support an overarching discussion of some factors considered within the analysis for those groups (*e.g.,* high-level differences in feeding strategies). Last, we break our analysis into species (and/or stocks), or groups of species (and the associated stocks) where relevant similarities exist, to provide more specific information related to the anticipated effects on individuals of a specific stock or where there is information about the status or structure of any species or stock that would lead to a differing assessment of the effects on the species or stock. Organizing our analysis by grouping species or stocks that share common traits or that will respond similarly to effects of the Navy's activities and then providing species- or stock-specific information allows us to avoid duplication while assuring that we have analyzed the effects of the specified activities on each affected species or stock.

Harassment

The Navy's harassment take request is based on a model that includes a quantitative assessment of procedural mitigation, which NMFS reviewed and concurs appropriately predicts the maximum amount of harassment that is likely to occur. The model calculates sound energy propagation from sonar, other active acoustic sources, and explosives during naval activities; the sound or impulse received by animat dosimeters representing marine mammals distributed in the area around the modeled activity; and whether the sound or impulse energy received by a marine mammal exceeds the thresholds for effects. Assumptions in the Navy model intentionally err on the side of overestimation when there are unknowns. Naval activities are modeled as though they would occur regardless of proximity to marine mammals, meaning that no mitigation is considered (*e.g.,* no power down or shut down) and without any avoidance of the activity by the animal. The final step of the quantitative analysis of acoustic effects, which occurs after the modeling, is to consider the implementation of mitigation and the possibility that marine mammals would avoid continued or repeated sound exposures. NMFS provided input to, independently reviewed, and concurred with the Navy on this process and the Navy's analysis, which is described in detail in Section 6 of the Navy's rulemaking/LOA application, was used to quantify harassment takes for this rule.

Generally speaking, the Navy and NMFS anticipate more severe effects from takes resulting from exposure to higher received levels (though this is in no way a strictly linear relationship for behavioral effects throughout species, individuals, or circumstances) and less severe effects from takes resulting from exposure to lower received levels. However, there is also growing evidence of the importance of distance in predicting marine mammal behavioral response to sound—*i.e.,* sounds of a similar level emanating from a more distant source have been shown to be less likely to evoke a response of equal magnitude (DeRuiter 2012, Falcone *et al.,* 2017). The estimated number of takes by Level A harassment and Level B harassment does not equate to the number of individual animals the Navy expects to harass (which is lower), but rather to the instances of take (*i.e.,* exposures above the Level A harassment and Level B harassment threshold) that are anticipated to occur annually and over the seven-year period. These instances may represent either brief exposures (seconds or minutes) or, in some cases, longer durations of exposure within a day. Some individuals may experience multiple instances of take (*i.e.,* on multiple days) over the course of a year, which means that the number of individuals taken is smaller than the total estimated takes. Generally speaking, the higher the number of takes as compared to the population abundance, the more repeated takes of individuals are likely, and the higher the actual percentage of individuals in the population that are likely taken at least once in a year. We look at this comparative metric to give us a relative sense of where a larger portion of a species or stock is being taken by Navy activities, where there is a higher likelihood that the same individuals are being taken on multiple days, and where that number of days might be higher or more likely sequential. Where the number of instances of take is 100 percent or less of the abundance and there is no information to specifically suggest that a small subset of animals will be repeatedly taken over a high number of sequential days, the overall magnitude is generally considered low, as it could on one extreme mean that every individual taken will be taken on no more than one day annually (a very minimal impact) or, more likely, that some smaller portion of individuals are taken on one day annually, some are taken on a few not likely sequential days annually, and some are not taken at all.

In the ocean, the Navy's use of sonar and other active acoustic sources is often transient and is unlikely to repeatedly expose the same individual animals within a short period, for example within one specific exercise. However, for some individuals of some species or stocks repeated exposures across different activities could occur over the year, especially where events occur in generally the same area with more resident species (*e.g.,* pinnipeds in

inland waters). In short, for some species or stocks we expect that the total anticipated takes represent exposures of a smaller number of individuals of which some will be exposed multiple times, but based on the nature of the Navy activities and the movement patterns of marine mammals, it is unlikely that individuals from most stocks (with the exception of one stock of harbor seals) will be taken over more than a few non-sequential days and, as described elsewhere, the nature of the majority of the exposures is expected to be of a less severe nature.

Physiological Stress Response

Some of the lower level physiological stress responses (*e.g.,* orientation or startle response, change in respiration, change in heart rate) discussed in the proposed rule would likely co-occur with the predicted harassments, although these responses are more difficult to detect and fewer data exist relating these responses to specific received levels of sound. Takes by Level B harassment, then, may have a stress-related physiological component as well; however, we would not expect the Navy's generally short-term, intermittent, and (typically in the case of sonar) transitory activities to create conditions of long-term continuous noise leading to long-term physiological stress responses in marine mammals that could affect reproduction or survival.

Behavioral Response

The estimates calculated using the BRF do not differentiate between the different types of behavioral responses that rise to the level of take by Level B harassment. As described in the Navy's application, the Navy identified (with NMFS' input) the types of behaviors that would be considered a take: Moderate behavioral responses as characterized in Southall *et al.* (2007) (*e.g.,* altered migration paths or dive profiles; interrupted nursing, breeding, or feeding; or avoidance) that also would be expected to continue for the duration of an exposure. The Navy then compiled the available data indicating at what received levels and distances those responses have occurred, and used the indicated literature to build biphasic behavioral response curves and cutoff distances that are used to predict how many instances of Level B harassment by behavioral disturbance occur in a day. Take estimates alone do not provide information regarding the potential fitness or other biological consequences of the reactions on the affected individuals. We therefore consider the available activity-specific, environmental, and species-specific information to determine the likely nature of the modeled behavioral responses and the potential fitness consequences for affected individuals.

Use of sonar and other transducers would typically be transient and temporary. The majority of acoustic effects to individual animals from sonar and other active sound sources during training and testing activities would be primarily from ASW events. Unlike other Navy training and testing Study Areas, no major training exercises (MTEs) are planned in the NWTT Study Area. In the range of potential behavioral effects that might expect to be part of a response that qualifies as an instance of Level B harassment by behavioral disturbance (which by nature of the way it is modeled/counted, occurs within one day), the less severe end might include exposure to comparatively lower levels of a sound, at a detectably greater distance from the animal, for a few or several minutes. A less severe exposure of this nature could result in a behavioral response such as avoiding an area that an animal would otherwise have chosen to move through or feed in for some amount of time or breaking off one or a few feeding bouts. More severe effects could occur if an animal gets close enough to the source to receive a comparatively higher level, is exposed continuously to one source for a longer time, or is exposed intermittently to different sources throughout a day. Such effects might result in an animal having a more severe flight response and leaving a larger area for a day or more or potentially losing feeding opportunities for a day. However, such severe behavioral effects are expected to occur infrequently.

To help assess this, for sonar (LFAS/MFAS/HFAS) used in the NWTT Study Area, the Navy provided information estimating the percentage of animals that may be taken by Level B harassment under each BRF that would occur within 6-dB increments (percentages discussed below in the *Group and Species-Specific Analyses* section). As mentioned above, all else being equal, an animal's exposure to a higher received level is more likely to result in a behavioral response that is more likely to lead to adverse effects, which could more likely accumulate to impacts on reproductive success or survivorship of the animal, but other contextual factors (such as distance) are also important. The majority of takes by Level B harassment are expected to be in the form of milder responses (*i.e.,* lower-level exposures that still rise to the level of take, but would likely be less severe in the range of responses that qualify as take) of a generally shorter duration. We anticipate more severe effects from takes when animals are exposed to higher received levels of sound or at closer proximity to the source. However, depending on the context of an exposure *(e.g.,* depth, distance, if an animal is engaged in important behavior such as feeding), a behavioral response can vary between species and individuals within a species. Specifically, given a range of behavioral responses that may be classified as Level B harassment, to the degree that higher received levels are expected to result in more severe behavioral responses, only a smaller percentage of the anticipated Level B harassment from Navy activities might necessarily be expected to potentially result in more severe responses (see the *Group and Species-Specific Analyses* section below for more detailed information). To fully understand the likely impacts of the predicted/authorized take on an individual (*i.e.,* what is the likelihood or degree of fitness impacts), one must look closely at the available contextual information, such as the duration of likely exposures and the likely severity of the exposures (*e.g.,* whether they will occur for a longer duration over sequential days or the comparative sound level that will be received). Ellison *et al.* (2012) and Moore and Barlow (2013), among others, emphasize the importance of context (*e.g.,* behavioral state of the animals, distance from the sound source.) in evaluating behavioral responses of marine mammals to acoustic sources.

Diel Cycle

Many animals perform vital functions, such as feeding, resting, traveling, and socializing on a diel cycle (24-hour cycle). Behavioral reactions to noise exposure, when taking place in a biologically important context, such as disruption of critical life functions, displacement, or avoidance of important habitat, are more likely to be significant if they last more than one day or recur on subsequent days (Southall *et al.,* 2007) due to diel and lunar patterns in diving and foraging behaviors observed in many cetaceans, including beaked whales (Baird *et al.* 2008, Barlow *et al.* 2020, Henderson *et al.* 2016, Schorr *et al.* 2014). Henderson *et al.* (2016) found that ongoing smaller scale events had little to no impact on foraging dives for Blainville's beaked whale, while multi-day training events may decrease foraging behavior for Blainville's beaked whale (Manzano-Roth *et al.,* 2016). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not

considered severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Note that there is a difference between multiple-day substantive behavioral reactions and multiple-day anthropogenic activities. For example, just because an at-sea exercise lasts for multiple days does not necessarily mean that individual animals are either exposed to those exercises for multiple days or, further, exposed in a manner resulting in a sustained multiple day substantive behavioral response. Large multi-day Navy exercises such as ASW activities, typically include vessels that are continuously moving at speeds typically 10–15 kn, or higher, and likely cover large areas that are relatively far from shore (typically more than 3 nmi from shore) and in waters greater than 600 ft deep. Additionally marine mammals are moving as well, which would make it unlikely that the same animal could remain in the immediate vicinity of the ship for the entire duration of the exercise. Further, the Navy does not necessarily operate active sonar the entire time during an exercise. While it is certainly possible that these sorts of exercises could overlap with individual marine mammals multiple days in a row at levels above those anticipated to result in a take, because of the factors mentioned above, it is considered unlikely for the majority of takes. However, it is also worth noting that the Navy conducts many different types of noise-producing activities over the course of the year and it is likely that some marine mammals will be exposed to more than one and taken on multiple days, even if they are not sequential.

Durations of Navy activities utilizing tactical sonar sources and explosives vary and are fully described in Appendix A (*Navy Activity Descriptions*) of the 2020 NWTT FSEIS/OEIS. Sonar used during ASW would impart the greatest amount of acoustic energy of any category of sonar and other transducers analyzed in the Navy's rulemaking/LOA application and include hull-mounted, towed, line array, sonobuoy, helicopter dipping, and torpedo sonars. Most ASW sonars are MFAS (1–10 kHz); however, some sources may use higher or lower frequencies. ASW training activities using hull mounted sonar planned for the NWTT Study Area generally last for only a few hours (see Table 3). Some ASW training and testing activities range from several hours, to days, to up to 3 weeks for Pierside-Sonar Testing and Submarine Sonar Testing/Maintenance (see Table 4). For these multi-day exercises there will typically be extended intervals of non-activity in between active sonar periods. Because of the need to train in a large variety of situations, the Navy does not typically conduct successive ASW exercises in the same locations. Given the average length of ASW exercises (times of sonar use) and typical vessel speed, combined with the fact that the majority of the cetaceans would not likely remain in proximity to the sound source, it is unlikely that an animal would be exposed to LFAS/MFAS/HFAS at levels or durations likely to result in a substantive response that would then be carried on for more than one day or on successive days.

Most planned explosive events are scheduled to occur over a short duration (1–8 hours); however Mine Countermeasure and Neutralization Testing would last 1–10 days (see Tables 3 and 4). The explosive component of these activities only lasts for minutes. Although explosive exercises may sometimes be conducted in the same general areas repeatedly, because of their short duration and the fact that they are in the open ocean and animals can easily move away, it is similarly unlikely that animals would be exposed for long, continuous amounts of time, or demonstrate sustained behavioral responses. All of these factors make it unlikely that individuals would be exposed to the exercise for extended periods or on consecutive days.

Assessing the Number of Individuals Taken and the Likelihood of Repeated Takes

As described previously, Navy modeling uses the best available science to predict the instances of exposure above certain acoustic thresholds, which are equated, as appropriate, to harassment takes (and, for PTS, further corrected to account for mitigation and avoidance). As further noted, for active acoustics it is more challenging to parse out the number of individuals taken by Level B harassment and the number of times those individuals are taken from this larger number of instances. One method that NMFS uses to help better understand the overall scope of the impacts is to compare these total instances of take against the abundance of that species (or stock if applicable). For example, if there are 100 estimated harassment takes in a population of 100, one can assume either that every individual will be exposed above acoustic thresholds in no more than one day, or that some smaller number will be exposed in one day but a few of those individuals will be exposed multiple days within a year and a few not exposed at all. Where the instances of take exceed 100 percent of the population (*i.e.,* are over 100 percent), multiple takes of some individuals are predicted and expected to occur within a year. Generally speaking, the higher the number of takes as compared to the population abundance, the more multiple takes of individuals are likely, and the higher the actual percentage of individuals in the population that are likely taken at least once in a year. We look at this comparative metric to give us a relative sense of where a larger portion of a species or stock is being taken by Navy activities and where there is a higher likelihood that the same individuals are being taken across multiple days and where that number of days might be higher. It also provides a relative picture of the scale of impacts to each species.

In the ocean, unlike a modeling simulation with static animals, the use of sonar and other active acoustic sources is often transient, and is unlikely to repeatedly expose the same individual animals within a short period, for example within one specific exercise. However, some repeated exposures across different activities could occur over the year with more resident species (*e.g.,* pinnipeds in inland waters). In short, we expect that the total anticipated takes represent exposures of a smaller number of individuals of which some could be exposed multiple times, but based on the nature of the Navy's activities and the movement patterns of marine mammals, it is unlikely that any particular subset would be taken over more than a few non-sequential days (with the exception of three harbor seal stocks discussed in the species-specific analyses).

When comparing the number of takes to the population abundance, which can be helpful in estimating both the proportion of the population affected by takes and the number of days over which some individuals may be taken, it is important to choose an appropriate population estimate against which to make the comparison. The SARs, where available, provide the official population estimate for a given species or stock in U.S. waters in a given year (and are typically based solely on the most recent survey data). When the stock is known to range well outside of U.S. EEZ boundaries, population estimates based on surveys conducted only within the U.S. EEZ are known to be underestimates. The information used to estimate take includes the best available survey abundance data to model density layers. Accordingly, in calculating the percentage of takes

versus abundance for each species or stock in order to assist in understanding both the percentage of the species or stock affected, as well as how many days across a year individuals could be taken, we use the data most appropriate for the situation. For all species and stocks except for a few stocks of harbor seals for which SAR data are unavailable and Navy abundance surveys of the inland areas of the NWTT Study Area are used, the most recent NMFS SARs are used to calculate the proportion of a population affected by takes.

The stock abundance estimates in NMFS' SARs are typically generated from the most recent shipboard and/or aerial surveys conducted. In some cases, NMFS' abundance estimates show substantial year-to-year variability. However, for highly migratory species (*e.g.,* large whales) or those whose geographic distribution extends well beyond the boundaries of the NWTT Study Area (*e.g.,* populations with distribution along the entire eastern Pacific Ocean rather than just the NWTT Study Area), comparisons to the SAR are appropriate. Many of the stocks present in the NWTT Study Area have ranges significantly larger than the NWTT Study Area and that abundance is captured by the SAR. A good descriptive example is migrating large whales, which traverse the NWTT Study Area for several days to weeks on their migrations. Therefore, at any one time there may be a stable number of animals, but over the course of the entire year the entire population may pass through the NWTT Study Area. Therefore, comparing the estimated takes to an abundance, in this case the SAR abundance, which represents the total population, may be more appropriate than modeled abundances for only the NWTT Study Area.

Temporary Threshold Shift

NMFS and the Navy have estimated that multiple species and stocks of marine mammals may sustain some level of TTS from active sonar. As discussed in the proposed rule in the Potential Effects of Specified Activities on Marine Mammals and their Habitat section, in general, TTS can last from a few minutes to days, be of varying degree, and occur across various frequency bandwidths, all of which determine the severity of the impacts on the affected individual, which can range from minor to more severe. Tables 52–57 indicate the number of takes by TTS that may be incurred by different species and stocks from exposure to active sonar and explosives. The TTS sustained by an animal is primarily classified by three characteristics:

1. Frequency—Available data (of mid-frequency hearing specialists exposed to mid- or high-frequency sounds; Southall *et al.,* 2007) suggest that most TTS occurs in the frequency range of the source up to one octave higher than the source (with the maximum TTS at ½ octave above). The Navy's MF sources, which are the highest power and most numerous sources and the ones that cause the most take, utilize the 1–10 kHz frequency band, which suggests that if TTS were to be induced by any of these MF sources it would be in a frequency band somewhere between approximately 2 and 20 kHz, which is in the range of communication calls for many odontocetes, but below the range of the echolocation signals used for foraging. There are fewer hours of HF source use and the sounds would attenuate more quickly, plus they have lower source levels, but if an animal were to incur TTS from these sources, it would cover a higher frequency range (sources are between 10 and 100 kHz, which means that TTS could range up to 200 kHz), which could overlap with the range in which some odontocetes communicate or echolocate. However, HF systems are typically used less frequently and for shorter time periods than surface ship and aircraft MF systems, so TTS from these sources is unlikely. There are fewer LF sources and the majority are used in the more readily mitigated testing environment, and TTS from LF sources would most likely occur below 2 kHz, which is in the range where many mysticetes communicate and also where other non-communication auditory cues are located (waves, snapping shrimp, fish prey). Also of note, the majority of sonar sources from which TTS may be incurred occupy a narrow frequency band, which means that the TTS incurred would also be across a narrower band (*i.e.,* not affecting the majority of an animal's hearing range). This frequency provides information about the cues to which a marine mammal may be temporarily less sensitive, but not the degree or duration of sensitivity loss. TTS from explosives would be broadband.

2. Degree of the shift (*i.e.,* by how many dB the sensitivity of the hearing is reduced)—Generally, both the degree of TTS and the duration of TTS will be greater if the marine mammal is exposed to a higher level of energy (which would occur when the peak dB level is higher or the duration is longer). The threshold for the onset of TTS was discussed previously in this rule. An animal would have to approach closer to the source or remain in the vicinity of the sound source appreciably longer to increase the received SEL, which would be difficult considering the Lookouts and the nominal speed of an active sonar vessel (10–15 kn) and the relative motion between the sonar vessel and the animal. In the TTS studies discussed in the Potential Effects of Specified Activities on Marine Mammals and their Habitat section of the proposed rule, some using exposures of almost an hour in duration or up to 217 SEL, most of the TTS induced was 15 dB or less, though Finneran *et al.* (2007) induced 43 dB of TTS with a 64-second exposure to a 20 kHz source. However, since any hull-mounted sonar, such as the SQS–53, engaged in anti-submarine warfare training would be moving at between 10 and 15 knots and nominally pinging every 50 seconds, the vessel will have traveled a minimum distance of approximately 257 m during the time between those pings, and, therefore, incurring those levels of TTS is highly unlikely. A scenario could occur where an animal does not leave the vicinity of a ship or travels a course parallel to the ship, however, the close distances required make TTS exposure unlikely. For a Navy vessel moving at a nominal 10 knots, it is unlikely a marine mammal could maintain speed parallel to the ship and receive adequate energy over successive pings to suffer TTS.

In short, given the anticipated duration and levels of sound exposure, we would not expect marine mammals to incur more than relatively low levels of TTS (*i.e.,* single digits of sensitivity loss). To add context to this degree of TTS, individual marine mammals may regularly experience variations of 6 dB differences in hearing sensitivity across time (Finneran *et al.,* 2000, 2002; Schlundt *et al.,* 2000).

3. Duration of TTS (recovery time)—In the TTS laboratory studies (as discussed in the Potential Effects of Specified Activities on Marine Mammals and their Habitat section of the proposed rule), some using exposures of almost an hour in duration or up to 217 SEL, almost all individuals recovered within 1 day (or less, often in minutes), although in one study (Finneran *et al.,* 2007), recovery took 4 days.

Based on the range of degree and duration of TTS reportedly induced by exposures to non-pulse sounds of energy higher than that to which free-swimming marine mammals in the field are likely to be exposed during LFAS/MFAS/HFAS training and testing exercises in the NWTT Study Area, it is unlikely that marine mammals would ever sustain a TTS from MFAS that

alters their sensitivity by more than 20 dB for more than a few hours—and any incident of TTS would likely be far less severe due to the short duration of the majority of the events and the speed of a typical vessel, especially given the fact that the higher power sources resulting in TTS are predominantly intermittent, which have been shown to result in shorter durations of TTS. Also, for the same reasons discussed in the Analysis and Negligible Impact Determination—*Diel Cycle* section, and because of the short distance within which animals would need to approach the sound source, it is unlikely that animals would be exposed to the levels necessary to induce TTS in subsequent time periods such that their recovery is impeded. Additionally, though the frequency range of TTS that marine mammals might sustain would overlap with some of the frequency ranges of their vocalization types, the frequency range of TTS from MFAS would not usually span the entire frequency range of one vocalization type, much less span all types of vocalizations or other critical auditory cues for any given species.

Tables 52–57 indicate the maximum number of incidental takes by TTS for each species or stock that are likely to result from the Navy's activities. As a general point, the majority of these TTS takes are the result of exposure to hull-mounted MFAS (MF narrower band sources), with fewer from explosives (broad-band lower frequency sources), and even fewer from LFAS or HFAS sources (narrower band). As described above, we expect the majority of these takes to be in the form of mild (single-digit), short-term (minutes to hours), narrower band (only affecting a portion of the animal's hearing range) TTS. This means that for one to several times per year, for several minutes to maybe a few hours (high end) each, a taken individual will have slightly diminished hearing sensitivity (slightly more than natural variation, but nowhere near total deafness). More often than not, such an exposure would occur within a narrower mid- to higher frequency band that may overlap part (but not all) of a communication, echolocation, or predator range, but sometimes across a lower or broader bandwidth. The significance of TTS is also related to the auditory cues that are germane within the time period that the animal incurs the TTS. For example, if an odontocete has TTS at echolocation frequencies, but incurs it at night when it is resting and not feeding, it is not impactful. In short, the expected results of any one of these small number of mild TTS occurrences could be that (1) it does not overlap signals that are pertinent to that animal in the given time period, (2) it overlaps parts of signals that are important to the animal, but not in a manner that impairs interpretation, or (3) it reduces detectability of an important signal to a small degree for a short amount of time—in which case the animal may be aware and be able to compensate (but there may be slight energetic cost), or the animal may have some reduced opportunities (*e.g.,* to detect prey) or reduced capabilities to react with maximum effectiveness (*e.g.,* to detect a predator or navigate optimally). However, given the small number of times that any individual might incur TTS, the low degree of TTS and the short anticipated duration, and the low likelihood that one of these instances would occur in a time period in which the specific TTS overlapped the entirety of a critical signal, it is unlikely that TTS of the nature expected to result from the Navy activities would result in behavioral changes or other impacts that would impact any individual's (of any hearing sensitivity) reproduction or survival.

Auditory Masking or Communication Impairment

The ultimate potential impacts of masking on an individual (if it were to occur) are similar to those discussed for TTS, but an important difference is that masking only occurs during the time of the signal, versus TTS, which continues beyond the duration of the signal. Fundamentally, masking is referred to as a chronic effect because one of the key potential harmful components of masking is its duration—the fact that an animal would have reduced ability to hear or interpret critical cues becomes much more likely to cause a problem the longer it is occurring. Also inherent in the concept of masking is the fact that the potential for the effect is only present during the times that the animal and the source are in close enough proximity for the effect to occur (and further, this time period would need to coincide with a time that the animal was utilizing sounds at the masked frequency). As our analysis has indicated, because of the relative movement of vessels and the sound sources primarily involved in this rule, we do not expect the exposures with the potential for masking to be of a long duration. Masking is fundamentally more of a concern at lower frequencies, because low frequency signals propagate significantly further than higher frequencies and because they are more likely to overlap both the narrower LF calls of mysticetes, as well as many non-communication cues such as fish and invertebrate prey, and geologic sounds that inform navigation. Masking is also more of a concern from continuous sources (versus intermittent sonar signals) where there is no quiet time between pulses within which auditory signals can be detected and interpreted. For these reasons, dense aggregations of, and long exposure to, continuous LF activity are much more of a concern for masking, whereas comparatively short-term exposure to the predominantly intermittent pulses of often narrow frequency range MFAS or HFAS, or explosions are not expected to result in a meaningful amount of masking. While the Navy occasionally uses LF and more continuous sources, it is not in the contemporaneous aggregate amounts that would accrue to a masking concern. Specifically, the nature of the activities and sound sources used by the Navy do not support the likelihood of a level of masking accruing that would have the potential to affect reproductive success or survival. Additional detail is provided below.

Standard hull-mounted MFAS typically pings every 50 seconds. Some hull-mounted anti-submarine sonars can also be used in an object detection mode known as ''Kingfisher'' mode (*e.g.,* used on vessels when transiting to and from port) where pulse length is shorter but pings are much closer together in both time and space since the vessel goes slower when operating in this mode. Kingfisher mode is typically operated for relatively shorter durations. For the majority of other sources, the pulse length is significantly shorter than hull-mounted active sonar, on the order of several microseconds to tens of milliseconds. Some of the vocalizations that many marine mammals make are less than one second long, so, for example with hull-mounted sonar, there would be a 1 in 50 chance (and only if the source was in close enough proximity for the sound to exceed the signal that is being detected) that a single vocalization might be masked by a ping. However, when vocalizations (or series of vocalizations) are longer than the one-second pulse of hull-mounted sonar, or when the pulses are only several microseconds long, the majority of most animals' vocalizations would not be masked.

Most ASW sonars and countermeasures use MF frequencies and a few use LF and HF frequencies. Most of these sonar signals are limited in the temporal, frequency, and spatial domains. The duration of most individual sounds is short, lasting up to a few seconds each. A few systems operate with higher duty cycles or nearly continuously, but they typically

use lower power, which means that an animal would have to be closer, or in the vicinity for a longer time, to be masked to the same degree as by a higher level source. Nevertheless, masking could occasionally occur at closer ranges to these high-duty cycle and continuous active sonar systems, but as described previously, it would be expected to be of a short duration when the source and animal are in close proximity. While data are limited on behavioral responses of marine mammals to continuously active sonars, mysticete species are known to be able to habituate to novel and continuous sounds (Nowacek *et al.,* 2004), suggesting that they are likely to have similar responses to high-duty cycle sonars. Furthermore, most of these systems are hull-mounted on surface ships and ships are moving at least 10 kn, and it is unlikely that the ship and the marine mammal would continue to move in the same direction with the marine mammal subjected to the same exposure due to that movement. Most ASW activities are geographically dispersed and last for only a few hours, often with intermittent sonar use even within this period. Most ASW sonars also have a narrow frequency band (typically less than one-third octave). These factors reduce the likelihood of sources causing significant masking. HF signals (above 10 kHz) attenuate more rapidly in the water due to absorption than do lower frequency signals, thus producing only a very small zone of potential masking. If masking or communication impairment were to occur briefly, it would more likely be in the frequency range of MFAS (the more powerful source), which overlaps with some odontocete vocalizations (but few mysticete vocalizations); however, it would likely not mask the entirety of any particular vocalization, communication series, or other critical auditory cue, because the signal length, frequency, and duty cycle of the MFAS/HFAS signal does not perfectly resemble the characteristics of any single marine mammal species' vocalizations.

Other sources used in Navy training and testing that are not explicitly addressed above, many of either higher frequencies (meaning that the sounds generated attenuate even closer to the source) or lower amounts of operation, are similarly not expected to result in masking. For the reasons described here, any limited masking that could potentially occur would be minor and short-term.

In conclusion, masking is more likely to occur in the presence of broadband, relatively continuous noise sources such as from vessels, however, the duration of temporal and spatial overlap with any individual animal and the spatially separated sources that the Navy uses are not expected to result in more than short-term, low impact masking that will not affect reproduction or survival.

PTS From Sonar Acoustic Sources and Explosives and Tissue Damage From Explosives

Tables 52 through 57 indicate the number of individuals of each species or stock for which Level A harassment in the form of PTS resulting from exposure to active sonar and/or explosives is estimated to occur. The number of individuals to potentially incur PTS annually (from sonar and explosives) for each species/stock ranges from 0 to 180 (the 180 is for the Inland Washington stock of harbor porpoise), but is more typically 0 or 1. As described previously, no species/stocks have the potential to incur tissue damage from sonar or explosives.

Data suggest that many marine mammals would deliberately avoid exposing themselves to the received levels of active sonar necessary to induce injury by moving away from or at least modifying their path to avoid a close approach. Additionally, in the unlikely event that an animal approaches the sonar-emitting vessel at a close distance, NMFS has determined that the mitigation measures (*i.e.,* shutdown/powerdown zones for active sonar) would typically ensure that animals would not be exposed to injurious levels of sound. As discussed previously, the Navy utilizes both aerial (when available) and passive acoustic monitoring (during ASW exercises, passive acoustic detections are used as a cue for Lookouts' visual observations when passive acoustic assets are already participating in an activity) in addition to Lookouts on vessels to detect marine mammals for mitigation implementation. As discussed previously, these Level A harassment take numbers represent the maximum number of instances in which marine mammals would be reasonably expected to incur PTS, and we have analyzed them accordingly.

If a marine mammal is able to approach a surface vessel within the distance necessary to incur PTS in spite of the mitigation measures, the likely speed of the vessel (nominally 10–15 kn) and relative motion of the vessel would make it very difficult for the animal to remain in range long enough to accumulate enough energy to result in more than a mild case of PTS. As discussed previously in relation to TTS, the likely consequences to the health of an individual that incurs PTS can range from mild to more serious dependent upon the degree of PTS and the frequency band it is in. The majority of any PTS incurred as a result of exposure to Navy sources would be expected to be in the 2–20 kHz range (resulting from the most powerful hull-mounted sonar) and could overlap a small portion of the communication frequency range of many odontocetes, whereas other marine mammal groups have communication calls at lower frequencies. Because of the broadband nature of explosives, PTS incurred from exposure to explosives would occur over a lower, but wider, frequency range. For all but harbor porpoises, annual PTS take resulting from exposure to explosives is 1–5 per species or stock. For harbor porpoises, a fair portion of the takes by PTS result from explosive exposure. However, harbor porpoises are high frequency specialists and minor hearing loss at lower frequencies is expected to be less impactful than at higher frequencies because it is less likely to overlap or interfere with the sounds produced by harbor porpoises for communication or echolocation. Regardless of the frequency band, the more important point in this case is that any PTS accrued as a result of exposure to Navy activities would be expected to be of a small amount (single digits). Permanent loss of some degree of hearing is a normal occurrence for older animals, and many animals are able to compensate for the shift, both in old age or at younger ages as the result of stressor exposure. While a small loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale it would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival.

The Navy implements mitigation measures (described in the Mitigation Measures section) during explosive activities, including delaying detonations when a marine mammal is observed in the mitigation zone. Nearly all explosive events will occur during daylight hours to improve the sightability of marine mammals and thereby improve mitigation effectiveness. Observing for marine mammals during the explosive activities will include visual and passive acoustic detection methods (when they are available and part of the activity) before the activity begins, in order to cover the mitigation zones that can range from 500 yd (457 m) to 2,500 yd (2,286 m)

depending on the source (*e.g.,* explosive sonobuoy, explosive torpedo, explosive bombs; see Tables 38–44). For all of these reasons, the mitigation measures associated with explosives are expected to be effective in preventing tissue damage to any potentially affected species or stocks, and no species or stocks are anticipated to incur tissue damage during the period of the rule.

Serious Injury and Mortality

NMFS is authorizing a very small number of serious injuries or mortalities that could occur in the event of a ship strike. We note here that the takes from potential ship strikes enumerated below could result in non-serious injury, but their worst potential outcome (mortality) is analyzed for the purposes of the negligible impact determination.

In addition, we discuss here the connection, and differences, between the legal mechanisms for authorizing incidental take under section 101(a)(5) for activities such as the Navy's testing and training in the NWTT Study Area, and for authorizing incidental take from commercial fisheries. In 1988, Congress amended the MMPA's provisions for addressing incidental take of marine mammals in commercial fishing operations. Congress directed NMFS to develop and recommend a new long-term regime to govern such incidental taking (see MMC, 1994). The need to develop a system suited to the unique circumstances of commercial fishing operations led NMFS to suggest a new conceptual means and associated regulatory framework. That concept, PBR, and a system for developing plans containing regulatory and voluntary measures to reduce incidental take for fisheries that exceed PBR were incorporated as sections 117 and 118 in the 1994 amendments to the MMPA. In *Conservation Council for Hawaii* v. *National Marine Fisheries Service,* 97 F. Supp. 3d 1210 (D. Haw. 2015), which concerned a challenge to NMFS' regulations and LOAs to the Navy for activities assessed in the 2013–2018 HSTT MMPA rulemaking, the Court ruled that NMFS' failure to consider PBR when evaluating lethal takes in the negligible impact analysis under section 101(a)(5)(A) violated the requirement to use the best available science.

PBR is defined in section 3 of 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'' (OSP) and, although not controlling, can be one measure considered among other factors when evaluating the effects of M/SI on a marine mammal species or stock during the section 101(a)(5)(A) process. OSP is defined in section 3 of the MMPA as ''the number of animals which will result in the maximum productivity of the population or the species, keeping in mind the carrying capacity of the habitat and the health of the ecosystem of which they form a constituent element.'' Through section 2, an overarching goal of the statute is to ensure that each species or stock of marine mammal is maintained at or returned to its OSP.

PBR values are calculated by NMFS as the level of annual removal from a stock that will allow that stock to equilibrate within OSP at least 95 percent of the time, and is the product of factors relating to the minimum population estimate of the stock (N_{min}), the productivity rate of the stock at a small population size, and a recovery factor. Determination of appropriate values for these three elements incorporates significant precaution, such that application of the parameter to the management of marine mammal stocks may be reasonably certain to achieve the goals of the MMPA. For example, calculation of the minimum population estimate (N_{min}) incorporates the level of precision and degree of variability associated with abundance information, while also providing reasonable assurance that the stock size is equal to or greater than the estimate (Barlow *et al.,* 1995), typically by using the 20th percentile of a log-normal distribution of the population estimate. In general, the three factors are developed on a stock-specific basis in consideration of one another in order to produce conservative PBR values that appropriately account for both imprecision that may be estimated, as well as potential bias stemming from lack of knowledge (Wade, 1998).

Congress called for PBR to be applied within the management framework for commercial fishing incidental take under section 118 of the MMPA. As a result, PBR cannot be applied appropriately outside of the section 118 regulatory framework without consideration of how it applies within the section 118 framework, as well as how the other statutory management frameworks in the MMPA differ from the framework in section 118. PBR was not designed and is not used as an absolute threshold limiting commercial fisheries. Rather, it serves as a means to evaluate the relative impacts of those activities on marine mammal stocks. Even where commercial fishing is causing M/SI at levels that exceed PBR, the fishery is not suspended. When M/SI exceeds PBR in the commercial fishing context under section 118, NMFS may develop a take reduction plan, usually with the assistance of a take reduction team. The take reduction plan will include measures to reduce and/or minimize the taking of marine mammals by commercial fisheries to a level below the stock's PBR. That is, where the total annual human-caused M/SI exceeds PBR, NMFS is not required to halt fishing activities contributing to total M/SI but rather utilizes the take reduction process to further mitigate the effects of fishery activities via additional bycatch reduction measures. In other words, under section 118 of the MMPA, PBR does not serve as a strict cap on the operation of commercial fisheries that may incidentally take marine mammals.

Similarly, to the extent PBR may be relevant when considering the impacts of incidental take from activities other than commercial fisheries, using it as the sole reason to deny (or issue) incidental take authorization for those activities would be inconsistent with Congress's intent under section 101(a)(5), NMFS' long-standing regulatory definition of ''negligible impact,'' and the use of PBR under section 118. The standard for authorizing incidental take for activities other than commercial fisheries under section 101(a)(5) continues to be, among other things that are not related to PBR, whether the total taking will have a negligible impact on the species or stock. Nowhere does section 101(a)(5)(A) reference use of PBR to make the negligible impact finding or to authorize incidental take through multi-year regulations, nor does its companion provision at section 101(a)(5)(D) for authorizing non-lethal incidental take under the same negligible-impact standard. NMFS' MMPA implementing regulations state that take has a negligible impact when it does not ''adversely affect the species or stock through effects on annual rates of recruitment or survival''—likewise without reference to PBR. When Congress amended the MMPA in 1994 to add section 118 for commercial fishing, it did not alter the standards for authorizing non-commercial fishing incidental take under section 101(a)(5), implicitly acknowledging that the negligible impact standard under section 101(a)(5) is separate from the PBR metric under section 118. In fact, in 1994 Congress also amended section 101(a)(5)(E) (a separate provision governing commercial fishing incidental take for species listed under the ESA) to add compliance with the new section 118 but retained the standard of the

negligible impact finding under section 101(a)(5)(A) (and section 101(a)(5)(D)), showing that Congress understood that the determination of negligible impact and the application of PBR may share certain features but are, in fact, different.

Since the introduction of PBR in 1994, NMFS had used the concept almost entirely within the context of implementing sections 117 and 118 and other commercial fisheries management-related provisions of the MMPA. Prior to the Court's ruling in *Conservation Council for Hawaii* v. *National Marine Fisheries Service* and consideration of PBR in a series of section 101(a)(5) rulemakings, there were a few examples where PBR had informed agency deliberations under other MMPA sections and programs, such as playing a role in the issuance of a few scientific research permits and subsistence takings. But as the Court found when reviewing examples of past PBR consideration in *Georgia Aquarium* v. *Pritzker,* 135 F. Supp. 3d 1280 (N.D. Ga. 2015), where NMFS had considered PBR outside the commercial fisheries context, ''it has treated PBR as only one 'quantitative tool' and [has not used it] as the sole basis for its impact analyses.'' Further, the agency's thoughts regarding the appropriate role of PBR in relation to MMPA programs outside the commercial fishing context have evolved since the agency's early application of PBR to section 101(a)(5) decisions. Specifically, NMFS' denial of a request for incidental take authorization for the U.S. Coast Guard in 1996 seemingly was based on the potential for lethal take in relation to PBR and did not appear to consider other factors that might also have informed the potential for ship strike in relation to negligible impact (61 FR 54157; October 17, 1996).

The MMPA requires that PBR be estimated in SARs and that it be used in applications related to the management of take incidental to commercial fisheries (*i.e.,* the take reduction planning process described in section 118 of the MMPA and the determination of whether a stock is ''strategic'' as defined in section 3), but nothing in the statute requires the application of PBR outside the management of commercial fisheries interactions with marine mammals. Nonetheless, NMFS recognizes that as a quantitative metric, PBR may be useful as a consideration when evaluating the impacts of other human-caused activities on marine mammal stocks. Outside the commercial fishing context, and in consideration of all known human-caused mortality, PBR can help inform the potential effects of M/SI requested to be authorized under section 101(a)(5)(A). As noted by NMFS and the U.S. Fish and Wildlife Service in our implementing regulations for the 1986 amendments to the MMPA (54 FR 40341, September 29, 1989), the Services consider many factors, when available, in making a negligible impact determination, including, but not limited to, the status of the species or stock relative to OSP (if known); whether the recruitment rate for the species or stock is increasing, decreasing, stable, or unknown; the size and distribution of the population; and existing impacts and environmental conditions. In this multi-factor analysis, PBR can be a useful indicator for when, and to what extent, the agency should take an especially close look at the circumstances associated with the potential mortality, along with any other factors that could influence annual rates of recruitment or survival.

When considering PBR during evaluation of effects of M/SI under section 101(a)(5)(A), we first calculate a metric for each species or stock that incorporates information regarding ongoing anthropogenic M/SI from all sources into the PBR value (*i.e.,* PBR minus the total annual anthropogenic mortality/serious injury estimate in the SAR), which is called ''residual PBR'' (Wood *et al.,* 2012). We first focus our analysis on residual PBR because it incorporates anthropogenic mortality occurring from other sources. If the ongoing human-caused mortality from other sources does not exceed PBR, then residual PBR is a positive number, and we consider how the anticipated or potential incidental M/SI from the activities being evaluated compares to residual PBR using the framework in the following paragraph. If the ongoing anthropogenic mortality from other sources already exceeds PBR, then residual PBR is a negative number and we consider the M/SI from the activities being evaluated as described further below.

When ongoing total anthropogenic mortality from the applicant's specified activities does not exceed PBR and residual PBR is a positive number, as a simplifying analytical tool we first consider whether the specified activities could cause incidental M/SI that is less than 10 percent of residual PBR (the ''insignificance threshold,'' see below). If so, we consider M/SI from the specified activities to represent an insignificant incremental increase in ongoing anthropogenic M/SI for the marine mammal stock in question that alone (*i.e.,* in the absence of any other take) will not adversely affect annual rates of recruitment and survival. As such, this amount of M/SI would not be expected to affect rates of recruitment or survival in a manner resulting in more than a negligible impact on the affected stock unless there are other factors that could affect reproduction or survival, such as Level A and/or Level B harassment, or other considerations such as information that illustrates uncertainty involved in the calculation of PBR for some stocks. In a few prior incidental take rulemakings, this threshold was identified as the ''significance threshold,'' but it is more accurately labeled an insignificance threshold, and so we use that terminology here, as we did in the AFTT final rule (83 FR 57076; November 14, 2018), and two-year rule extension (84 FR 70712; December 23, 2019), as well as the HSTT final rule (83 FR 66846; December 27, 2018) and two-year rule extension (85 FR 41780; July 10, 2020). Assuming that any additional incidental take by Level A or Level B harassment from the activities in question would not combine with the effects of the authorized M/SI to exceed the negligible impact level, the anticipated M/SI caused by the activities being evaluated would have a negligible impact on the species or stock. However, M/SI above the 10 percent insignificance threshold does not indicate that the M/SI associated with the specified activities is approaching a level that would necessarily exceed negligible impact. Rather, the 10 percent insignificance threshold is meant only to identify instances where additional analysis of the anticipated M/SI is not required because the negligible impact standard clearly will not be exceeded on that basis alone.

Where the anticipated M/SI is near, at, or above residual PBR, consideration of other factors (positive or negative), including those outlined above, as well as mitigation is especially important to assessing whether the M/SI will have a negligible impact on the species or stock. PBR is a conservative metric and not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based. For example, in some cases stock abundance (which is one of three key inputs into the PBR calculation) is underestimated because marine mammal survey data within the U.S. EEZ are used to calculate the abundance even when the stock range extends well beyond the U.S. EEZ. An underestimate of abundance could result in an underestimate of PBR. Alternatively, we sometimes may not

have complete M/SI data beyond the U.S. EEZ to compare to PBR, which could result in an overestimate of residual PBR. The accuracy and certainty around the data that feed any PBR calculation, such as the abundance estimates, must be carefully considered to evaluate whether the calculated PBR accurately reflects the circumstances of the particular stock. M/SI that exceeds residual PBR or PBR may still potentially be found to be negligible in light of other factors that offset concern, especially when robust mitigation and adaptive management provisions are included.

In *Conservation Council for Hawaii* v. *National Marine Fisheries Service,* which involved the challenge to NMFS' issuance of LOAs to the Navy in 2013 for activities in the HSTT Study Area, the Court reached a different conclusion, stating, ''Because any mortality level that exceeds PBR will not allow the stock to reach or maintain its OSP, such a mortality level could not be said to have only a 'negligible impact' on the stock.'' As described above, the Court's statement fundamentally misunderstands the two terms and incorrectly indicates that these concepts (PBR and ''negligible impact'') are directly connected, when in fact nowhere in the MMPA is it indicated that these two terms are equivalent.

Specifically, PBR was designed as a tool for evaluating mortality and is defined as the number of animals that can be removed while ''allowing that stock to reach or maintain its [OSP].'' OSP is defined as a population that falls within a range from the population level that is the largest supportable within the ecosystem to the population level that results in maximum net productivity, and thus is an aspirational management goal of the overall statute with no specific timeframe by which it should be met. PBR is designed to ensure minimal deviation from this overarching goal, with the formula for PBR typically ensuring that growth towards OSP is not reduced by more than 10 percent (or equilibrates to OSP 95 percent of the time). Given that, as applied by NMFS, PBR certainly allows a stock to ''reach or maintain its [OSP]'' in a conservative and precautionary manner—and we can therefore clearly conclude that if PBR were not exceeded, there would not be adverse effects on the affected species or stocks. Nonetheless, it is equally clear that in some cases the time to reach this aspirational OSP level could be slowed by more than 10 percent (*i.e.,* total human-caused mortality in excess of PBR could be allowed) without adversely affecting a species or stock through effects on its rates of recruitment or survival. Thus even in situations where the inputs to calculate PBR are thought to accurately represent factors such as the species' or stock's abundance or productivity rate, it is still possible for incidental take to have a negligible impact on the species or stock even where M/SI exceeds residual PBR or PBR.

As noted above, in some cases the ongoing human-caused mortality from activities other than those being evaluated already exceeds PBR and, therefore, residual PBR is negative. In these cases (such as is specifically discussed for the CA/OR/WA stock of humpback whales below), any additional mortality, no matter how small, and no matter how small relative to the mortality caused by other human activities, would result in greater exceedance of PBR. PBR is helpful in informing the analysis of the effects of mortality on a species or stock because it is important from a biological perspective to be able to consider how the total mortality in a given year may affect the population. However, section 101(a)(5)(A) of the MMPA indicates that NMFS shall authorize the requested incidental take from a specified activity if we find that ''the total of such taking [*i.e.,* from the specified activity] will have a negligible impact on such species or stock.'' In other words, the task under the statute is to evaluate the applicant's anticipated take in relation to their take's impact on the species or stock, not other entities' impacts on the species or stock. Neither the MMPA nor NMFS' implementing regulations call for consideration of other unrelated activities and their impacts on the species or stock. In fact, in response to public comments on the implementing regulations NMFS explained that such effects are not considered in making negligible impact findings under section 101(a)(5), although the extent to which a species or stock is being impacted by other anthropogenic activities is not ignored. Such effects are reflected in the baseline of existing impacts as reflected in the species' or stock's abundance, distribution, reproductive rate, and other biological indicators.

NMFS guidance for commercial fisheries provides insight when evaluating the effects of an applicant's incidental take as compared to the incidental take caused by other entities. Parallel to section 101(a)(5)(A), section 101(a)(5)(E) of the MMPA provides that NMFS shall allow the incidental take of ESA-listed endangered or threatened marine mammals by commercial fisheries if, among other things, the incidental M/SI from the commercial fisheries will have a negligible impact on the species or stock. As discussed earlier, the authorization of incidental take resulting from commercial fisheries and authorization for activities other than commercial fisheries are under two separate regulatory frameworks. However, when it amended the statute in 1994 to provide a separate incidental take authorization process for commercial fisheries, Congress kept the requirement of a negligible impact determination for this one category of species, thereby applying the standard to both programs. Therefore, while the structure and other standards of the two programs differ such that evaluation of negligible impact under one program may not be fully applicable to the other program, guidance on determining negligible impact for commercial fishing take authorizations can be informative when considering incidental take outside the commercial fishing context. In 1999, NMFS published criteria for making a negligible impact determination pursuant to section 101(a)(5)(E) of the MMPA in a notice of proposed permits for certain fisheries (64 FR 28800; May 27, 1999). Criterion 2 stated if total human-related serious injuries and mortalities are greater than PBR, and fisheries-related mortality is less than 0.1 PBR, individual fisheries may be permitted if management measures are being taken to address non-fisheries-related serious injuries and mortalities. Those criteria further stated that when fisheries-related serious injury and mortality is less than 10 percent of the total, the appropriate management action is to address components that account for the major portion of the total. Criterion 2 addresses when total human-caused mortality is exceeding PBR, but the activity being assessed is responsible for only a small portion of the mortality. The analytical framework we use here incorporates elements of the 1999 criteria developed for use under section 101(a)(5)(E), and because the negligible impact determination under section 101(a)(5)(A) focuses on the activity being evaluated, it is appropriate to utilize this parallel concept from the framework for section 101(a)(5)(E).

Accordingly, we are using a similar criterion in our negligible impact analysis under section 101(a)(5)(A) to evaluate the relative role of an applicant's incidental take when other sources of take are causing PBR to be exceeded, but the take of the specified activity is comparatively small. Where this occurs, we may find that the impacts of the taking from the specified activity may (alone) be negligible even

when total human-caused mortality from all activities exceeds PBR if (in the context of a particular species or stock): The authorized mortality or serious injury would be less than or equal to 10 percent of PBR and management measures are being taken to address serious injuries and mortalities from the other activities (*i.e.,* other than the specified activities covered by the incidental take authorization under consideration). In addition, we must also still determine that any impacts on the species or stock from other types of take (*i.e.,* harassment) caused by the applicant do not combine with the impacts from mortality or serious injury addressed here to result in adverse effects on the species or stock through effects on annual rates of recruitment or survival.

As discussed above, while PBR is useful in informing the evaluation of the effects of M/SI in section 101(a)(5)(A) determinations, it is just one consideration to be assessed in combination with other factors and is not determinative. For example, as explained above, the accuracy and certainty of the data used to calculate PBR for the species or stock must be considered. And we reiterate the considerations discussed above for why it is not appropriate to consider PBR an absolute cap in the application of this guidance. Accordingly, we use PBR as a trigger for concern while also considering other relevant factors to provide a reasonable and appropriate means of evaluating the effects of potential mortality on rates of recruitment and survival, while acknowledging that it is possible to exceed PBR (or exceed 10 percent of PBR in the case where other human-caused mortality is exceeding PBR but the specified activity being evaluated is an incremental contributor, as described in the last paragraph) by some small amount and still make a negligible impact determination under section 101(a)(5)(A).

We note that on June 17, 2020 NMFS finalized new Criteria for Determining Negligible Impact under MMPA section 101(a)(5)(E). The guidance explicitly notes the differences in the negligible impact determinations required under section 101(a)(5)(E), as compared to sections 101(a)(5)(A) and 101(a)(5)(D), and specifies that the procedure in that document is limited to how the agency conducts negligible impact analyses for commercial fisheries under section 101(a)(5)(E). In the proposed rule (and above), NMFS has described its method for considering PBR to evaluate the effects of potential mortality in the negligible impact analysis. NMFS has reviewed the 2020 guidance and determined that our consideration of PBR in the evaluation of mortality as described above and in the proposed rule remains appropriate for use in the negligible impact analysis for the Navy's activities in the NWTT Study Area under section 101(a)(5)(A).

Our evaluation of the M/SI for each of the species and stocks for which mortality or serious injury could occur follows. No M/SI are anticipated from the Navy's sonar activities or use of explosives.

We first consider maximum potential incidental M/SI from the Navy and NMFS' ship strike analysis for the affected mysticetes and sperm whales (see Table 51; updated from the proposed rule) in consideration of NMFS' threshold for identifying insignificant M/SI take. By considering the maximum potential incidental M/SI in relation to PBR and ongoing sources of anthropogenic mortality, we begin our evaluation of whether the incremental addition of M/SI through the Navy's potential ship strikes may affect the species' or stock's annual rates of recruitment or survival. We also consider the interaction of those mortalities with incidental taking of that species or stock by harassment pursuant to the specified activity.

Based on the methods discussed previously, NMFS believes that mortal takes of three large whales could occur over the course of the seven-year rule. Of the three total M/SI takes, the rule authorizes no more than two from any of the following species/stocks over the seven-year period: Fin whale (which may come from either the Northeast Pacific or CA/OR/WA stock) and humpback whale (which may come from either the Central North Pacific or CA/OR/WA stock). Of the three total M/SI takes, the rule also authorizes no more than one mortality from any of the following species/stocks over the seven-year period: Sperm whale (CA/OR/WA stock), minke whale (CA/OR/WA stock), and gray whale (Eastern North Pacific stock). We do not anticipate, nor authorize, M/SI takes from ship strikes for blue whale (Eastern North Pacific stock), minke whale (Alaska stock), or sei whale (Eastern North Pacific stock). This means an annual average of 0.14 whales from each species or stock where one mortality may occur and an annual average of 0.29 whales from each species or stock where two mortalities may occur, as described in Table 51 (*i.e.,* 1 or 2 takes over 7 years divided by 7 to get the annual number).

TABLE 51—SUMMARY INFORMATION RELATED TO MORTALITIES REQUESTED FOR SHIP STRIKE, 2020–2027

Species (stock)	Stock abundance (Nbest) *	Annual authorized take by serious injury or mortality [1]	Total annual M/SI * [2]	Fisheries interactions (Y/N); annual rate of M/SI from fisheries interactions *	Vessel collisions (Y/N); annual rate of M/SI from vessel collision *	Annual navy HSTT authorized take (2018–2025) [5]	PBR *	Residual PBR–PBR minus annual M/SI and HSTT authorized take [3]	Stock trend * [4]	Recent UME (Y/N); number and year (since 2007)
Fin whale (Northeast Pacific)	3,168	0.29	0.4	N; 0	Y; 0.4	0	5.1	4.7	↑	N
Fin whale (CA/OR/WA)	9,029	0.29	≥ 43.5	Y; ≥ 0.5	Y; 43	0.29	81	37.2	↑	N
Humpback whale (Central North Pacific)	10,103	0.29	25	Y; 9.5	[6] Y; 3.9	0.29	83	57.7	↑	N
Humpback whale (CA/OR/WA)	2,900	0.29	≥ 42.1	Y; ≥ 17.3	Y; 22	0.14	33.4	-8.8	Stable (↑ (historically)	N
Sperm whale (CA/OR/WA)	1,997	0.14	0.6	Y; 0.6	N; 0	0	2.5	1.8	Unknown	N
Minke whale (CA/OR/WA)	636	0.14	≥ 1.3	Y; ≥ 1.3	N; 0	0	3.5	2.2	Unknown	N
Gray whale (Eastern North Pacific)	26,960	0.14	139	Y; 9.6	Y; 0.8	0.29	801	661.6	↑	Y, 384, 2019

*Presented in the 2019 SARs or most recent SAR.

[1]This column represents the annual take by serious injury or mortality by vessel collision and was calculated by the number of mortalities authorized divided by seven years (the length of the rule and LOAs).

[2]This column represents the total number of incidents of M/SI that could potentially accrue to the specified species or stock. This number comes from the SAR, but deducts the takes accrued from either NMFS Science Center research activities or Navy strikes authorized for training and testing activities. No NMFS Science Center or Navy M/SI takes for these stocks are recorded in the SARs and no NMFS Science Center M/SI incidental takes have been authorized.

[3]This value represents the calculated PBR minus the average annual estimate of ongoing anthropogenic mortalities (*i.e.,* total annual human-caused M/SI column and the annual authorized take from the HSTT column). This value represents the total PBR for the stock in the stock's entire range.

[4]See relevant SARs for more information regarding stock status and trends.

[5] This column represents annual M/SI take authorized through NMFS' current HSTT regulations/LOAs (85 FR 41780). On July 10, 2020, NMFS effectively extended the current HSTT regulations by two years, replacing the five-year HSTT regulations with seven-year regulations. These regulations authorized the same number of M/SI for the same species/stocks, but over a seven-year period rather than a five-year period (resulting in slightly lower annual authorized take for each species/stock). See the 2020 HSTT final rule for more details (85 FR 41780, July 10, 2020).

[6] This value represents average annual observed M/SI from ship strikes in Alaska (2.5) and Hawaii (1.4). For the purposes of analysis of potential ship strikes (see the Estimated Take of Marine Mammals section) we incorporated only Alaska ship strikes as only these ship strikes have the potential to overlap with the NWTT Study Area.

Stocks With M/SI Below the Insignificance Threshold

As noted above, for a species or stock with incidental M/SI less than 10 percent of residual PBR, we consider M/SI from the specified activities to represent an insignificant incremental increase in ongoing anthropogenic M/SI that alone (*i.e.,* in the absence of any other take and barring any other unusual circumstances) will clearly not adversely affect annual rates of recruitment and survival. In this case, as shown in Table 51, the following species or stocks have potential M/SI from ship strike authorized below their insignificance threshold: Fin whale (both the Northeast Pacific and CA/OR/WA stocks), humpback whale (Central North Pacific stock), sperm whale (CA/OR/WA stock), minke whale (CA/OR/WA stock), and gray whale (Eastern North Pacific stock). While the authorized M/SI of gray whales (Eastern North Pacific stock) is below the insignificance threshold, because of the recent UME, we further address how the authorized M/SI and the UME inform the negligible impact determination immediately below. For the other five stocks with authorized M/SI below the insignificance threshold, there are no other known factors, information, or unusual circumstances that indicate anticipated M/SI below the insignificance threshold could have adverse effects on annual rates of recruitment or survival and they are not discussed further. For the remaining one stock (CA/OR/WA stock of humpback whales) with potential M/SI above the insignificance threshold, how that M/SI compares to residual PBR, as well as additional factors, are discussed below as well.

Gray Whales (Eastern North Pacific stock)

For this stock, PBR is currently set at 801. The total annual M/SI from other sources of anthropogenic mortality is estimated to be 139. In addition, 0.29 annual mortalities have been authorized for this same stock in the current incidental take regulations for Navy testing and training activities in the HSTT Study Area (85 FR 41780; July 10, 2020). This yields a residual PBR of 661.6. The additional 0.29 annual mortalities that are authorized in this rule are well below the insignificance threshold (10 percent of residual PBR, in this case 66.2). Nonetheless, since January 2019, gray whale strandings along the west coast of North America have been significantly higher than the previous 18-year average. Preliminary findings from necropsies have shown evidence of poor to thin body condition. The seasonal pattern of elevated strandings in the spring and summer months is similar to that of the previous gray whale UME in 1999–2000, and the current UME is continuing to follow a similar pattern with a decrease in strandings in late summer and fall. However, combined with other annual human-caused mortalities, and viewed through the PBR lens (for human-caused mortalities), total human-caused mortality (inclusive of the potential for additional UME deaths) would still fall well below residual PBR and the insignificance threshold. Because of the abundance, population trend (increasing, despite the UME in 1999–2000), and residual PBR (661.6) of this stock, this UME is not expected to have impacts on the population rate that, in combination with the effects of the authorized mortality, would affect annual rates of recruitment or survival.

Stocks with M/SI above the Insignificance Threshold

The CA/OR/WA stock of humpback whales is the only stock with M/SI above the insignificance threshold. For this stock, PBR is currently set at 16.7 for U.S. waters and 33.4 for the stock's entire range. The total annual M/SI is estimated at greater than or equal to 42.1. Combined with 0.14 annual mortalities that have been authorized for this same stock in the current incidental take regulations for Navy testing and training activities in the HSTT Study Area (85 FR 41780; July 10, 2020), this yields a residual PBR of –8.8. NMFS is authorizing up to 2 M/SI takes over the seven-year duration of this rule, which is 0.29 M/SI takes annually for the purposes of comparing to PBR and considering other possible effects on annual rates of recruitment and survival. This means that with the additional 0.29 M/SI annual takes authorized in this rule, residual PBR would be exceeded by 9.1.

In the commercial fisheries setting for ESA-listed marine mammals (which can be informative for the non-fisheries incidental take setting, in that a negligible impact determination is required that is based on the assessment of take caused by the activity being analyzed), NMFS may find the impact of the authorized take from a specified activity to be negligible even if total human-caused mortality exceeds PBR, if the authorized mortality is less than 10 percent of PBR and management measures are being taken to address serious injuries and mortalities from the other activities causing mortality (*i.e.,* other than the specified activities covered by the incidental take authorization under consideration). When those considerations are applied in the section 101(a)(5)(A) context here, the authorized lethal take (0.29 annually) of humpback whales from the CA/OR/WA stock is significantly less than 10 percent of PBR (in fact less than 1 percent of 33.4) and there are management measures in place to address M/SI from activities other than those the Navy is conducting (as discussed below).

Based on identical simulations as those conducted to identify Recovery Factors for PBR in Wade *et al.* (1998), but where values less than 0.1 were investigated (P. Wade, pers. comm.), we predict that where the mortality from a specified activity does not exceed Nmin * ½ Rmax * 0.013, the contemplated mortality for the specific activity will not delay the time to recovery by more than 1 percent. For this stock of humpback whales, Nmin * ½ Rmax * 0.013 = 1.45 and the annual mortality authorized is 0.29 (*i.e.,* less than 1.45). This means that the mortality authorized in this rule for NWTT activities will not delay the time to recovery to OSP by more than 1 percent.

NMFS must also ensure that impacts by the applicant on the species or stock from other types of take (*i.e.,* harassment) do not combine with the impacts from M/SI to adversely affect the species or stock via impacts on annual rates of recruitment or survival, which is discussed further below in the species- and stock-specific section.

In August 2020, NMFS published 2019 SARs in which PBR is reported as 33.4 with the predicted average annual mortality greater than or equal to 42.1 (including 22 estimated from vessel collisions and greater than 17.3 observed fisheries interactions). While the observed M/SI from vessel strikes remains low at 2.2 per year, the 2018 and 2019 SARs rely on a new method to estimate annual deaths by ship strike utilizing an encounter theory model that combined species distribution models of whale density, vessel traffic characteristics, and whale movement patterns obtained from satellite-tagged animals in the region to estimate encounters that would result in mortality (Rockwood *et al.,* 2017). The model predicts 22 annual mortalities of humpback whales from this stock from vessel strikes. The authors (Rockwood *et al.,* 2017) do not suggest that ship strikes suddenly increased to 22. In fact, the model is not specific to a year, but rather offers a generalized prediction of ship strikes off the U.S. West Coast. Therefore, if the Rockwood *et al.* (2017) model is an accurate representation of vessel strike, then similar levels of ship

strike have been occurring in past years as well. Put another way, if the model is correct, for some number of years total human-caused mortality has been significantly underestimated, and PBR has been similarly exceeded by a notable amount, and yet the CA/OR/WA stock of humpback whales is considered stable nevertheless.

The CA/OR/WA stock of humpback whales experienced a steady increase from the 1990s through approximately 2008, and more recent estimates through 2014 indicate a leveling off of the population size. This stock is comprised of the feeding groups of three DPSs. Two DPSs associated with this stock are listed under the ESA as either endangered (Central America DPS) or threatened (Mexico DPS), while the third (Hawaii DPS) is not listed. Humpback whales from the Hawaii DPS are anticipated to be rare in the NWTT Study Area with a probability of the DPS foraging in the waters of the Study Area of 1.6 percent (including summer areas of Oregon/California and Southern British Columbia/Washington from Wade (2017)). Humpback whales from the Mexico DPS and Central America DPS are anticipated to be more prevalent in the Study Area with probabilities of the DPSs foraging in the waters of the Study Area of 31.7 and 100 percent, respectively (including summer areas of Oregon/California and Southern British Columbia/Washington from Wade (2017)). As described in the final rule Identifying 14 DPSs of the Humpback Whale and Revision of Species-Wide Listing (81 FR 62260, September 8, 2016), the Mexico DPS was initially proposed not to be listed as threatened or endangered, but the final decision was changed in consideration of a new abundance estimate using a new methodology that was more accurate (less bias from capture heterogeneity and lower coefficient of variation) and resulted in a lower abundance than was previously estimated. To be clear, the new abundance estimate did not indicate that the numbers had decreased, but rather, the more accurate new abundance estimate (3,264), derived from the same data but based on an integrated spatial multi-strata mark recapture model (Wade *et al.,* 2016), was simply notably lower than earlier estimates, which were 6,000–7,000 from the SPLASH project (Calambokidis *et al.,* 2008) or higher (Barlow *et al.,* 2011). The updated abundance was still higher than 2,000, which is the Biological Review Team's (BRT) threshold between ''not likely to be at risk of extinction due to low abundance alone'' and ''increasing risk from factors associated with low abundance.'' Further, the BRT concluded that the DPS was unlikely to be declining because of the population growth throughout most of its feeding areas, in California/Oregon and the Gulf of Alaska, but they did not have evidence that the Mexico DPS was actually increasing in overall population size.

As discussed earlier, we also take into consideration management measures in place to address M/SI caused by other activities. Commercial fisheries such as crab pot, gillnet, and prawn fisheries are a significant source of mortality and serious injury for humpback whales and other large whales and, unfortunately, have increased mortalities and serious injuries over recent years (Carretta *et al.,* 2019). However, the 2019 draft SAR notes that a recent increase in disentanglement efforts has resulted in an increase in the fraction of cases that are reported as non-serious injuries as a result of successful disentanglement. More importantly, since 2015, NMFS has engaged in a multi-stakeholder process in California (including California State resource managers, fishermen, non-governmental organizations (NGOs), and scientists) to identify and develop solutions and make recommendations to regulators and the fishing industry for reducing whale entanglements (see *http://www.opc.ca.gov/whale-entanglement-working-group/*), referred to as the Whale Entanglement Working Group. The Whale Entanglement Working Group has made significant progress since 2015 and is tackling the problem from multiple angles, including:

- Development of Fact Sheets and Best Practices (BMPs) for specific Fisheries issues (*e.g.,* California Dungeness Crab Fishing BMPs and the 2018–2019 Best Fishing Practices Guide);
- A Risk Assessment and Mitigation Program (RAMP) to support the state of California in working collaboratively with experts (fishermen, researchers, NGOs, *etc.*) to identify and assess elevated levels of entanglement risk and determine the need for management options to reduce risk of entanglement; and
- Support of pilot studies to test new fisheries technologies to reduce take (*e.g.,* exploring Ropeless Fishing Technologies for the California Dungeness Crab Fishery).

The Working Group meets regularly, posts reports and annual recommendations, and makes all of their products and guidance documents readily accessible for the public (*https://opc.ca.gov/risk-assessment-and-mitigation-program-ramp/*).

In early 2019, as a result of a litigation settlement agreement, the California Department of Fish and Wildlife (CDFW) closed the Dungeness crab fishery three months early for the year, which is expected to reduce the number of likely entanglements. The agreement also limits the fishery duration over the next couple of years and has different triggers to reduce or close it further. Further, pursuant to the settlement, CDFW is required to apply for a Section 10 Incidental Take Permit under the ESA to address protected species interactions with fishing gear and crab fishing gear (pots). Any request for such a permit must include a Conservation Plan that specifies, among other things, what steps the applicant will take to minimize and mitigate the impacts, and the funding that will be available to implement such steps. On May 15, 2020, CDFW submitted a draft Conservation Plan to NMFS and CDFW's development of this plan continues. The May 2020 draft plan may be viewed here: *https://nrm.dfg.ca.gov/FileHandler.ashx?DocumentID=179066&inline.* Additional information about CDFWs planned application for an ITP can be accessed at the CDFW Whale Safe Fisheries web page (*https://wildlife.ca.gov/Conservation/Marine/Whale-Safe-Fisheries*). A critical element of CDFW's approach to reducing the risk of entanglement includes the implementation of RAMP regulations. These proposed regulations may be found at: *https://wildlife.ca.gov/Notices/Regulations/RAMP.*

Regarding measures in place to reduce mortality from other sources, the Channel Islands NMS staff coordinates, collects, and monitors whale sightings in and around a Whale Advisory Zone and the Channel Islands NMS region, which is within the area of highest vessel strike mortality (90th percentile) for humpback whales on the U.S. West Coast (Rockwood *et al.,* 2017). The seasonally established Whale Advisory Zone spans from Point Arguello to Dana Point, including the Traffic Separation Schemes in the Santa Barbara Channel and San Pedro Channel. Vessels transiting the area from June through November are recommended to exercise caution and voluntarily reduce speed to 10 kn or less for blue, humpback, and fin whales. Channel Island NMS observers collect information from aerial surveys conducted by NOAA, the U.S. Coast Guard, California Department of Fish and Game, and Navy chartered aircraft. Information on seasonal presence, movement, and general

distribution patterns of large whales is shared with mariners, NMFS' Office of Protected Resources, the U.S. Coast Guard, the California Department of Fish and Game, the Santa Barbara Museum of Natural History, the Marine Exchange of Southern California, and whale scientists. Although well south of the NWTT Study Area, reduced vessel strikes in this area benefit humpback whales throughout the stock's range. Real time and historical whale observation data collected from multiple sources can be viewed on the Point Blue Whale Database.

More recently, similar efforts to reduce entanglement risk and severity have also been initiated in Oregon and Washington. Both Oregon and Washington are developing applications for ESA Incidental Take Permits for their commercial crab fisheries, and all three West Coast states regularly coordinate on their Conservation Plan proposals and schedules. Both states advocate similar best practices for their fishermen as California, and they are taking regulatory steps related to gear marking and pot limits. For example, they have recently implemented or proposed regulations intended to reduce entanglement risk or increase the identification of fishing gear entangling whales. Additional information about Oregon's efforts may be found at *https://www.dfw.state.or.us/MRP/shellfish/commercial/crab/whale_entanglement.asp.* A summary of WDFW whale entanglement risk reduction information may be found at: *https://wdfw.wa.gov/sites/default/files/2020-01/5_whale_ent_in_coastal_crab_fishery_jan_2020_revised.pdf* .

In this case, 0.29 M/SI annually means the potential for two mortalities in one or two of the seven years and zero mortalities in five or six of those seven years. Therefore, the Navy will not be contributing to the total human-caused mortality at all in at least five of the seven, or 71.4 percent, of the years covered by this rule. That means that even if a humpback whale from the CA/OR/WA stock were to be struck, in at least five of the seven years there could be no effect on annual rates of recruitment or survival from Navy-caused M/SI. Additionally, the loss of a male would have far less, if any, of an effect on population rates than the loss of a reproductive female (as males are known to mate with multiple females), and absent any information suggesting that one sex is more likely to be struck than another, we can reasonably assume that there is a 50 percent chance that the strikes authorized by this rule would be males, thereby further decreasing the likelihood of impacts on the population rate. In situations like this where potential M/SI is fractional, consideration must be given to the lessened impacts anticipated due to the absence of any M/SI in five or six of the years and due to the fact that strikes could be males.

Lastly, we reiterate that PBR is a conservative metric and also not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based. Wade *et al.* (1998), authors of the paper from which the current PBR equation is derived, note that ''Estimating incidental mortality in one year to be greater than the PBR calculated from a single abundance survey does not prove the mortality will lead to depletion; it identifies a population worthy of careful future monitoring and possibly indicates that mortality-mitigation efforts should be initiated.''

The information included here illustrates that this humpback whale stock is currently stable, the potential (and authorized) mortality is well below 10 percent (0.87 percent) of PBR, and management actions are in place to minimize both fisheries interactions and ship strike from other vessel activity in one of the highest-risk areas for strikes. More specifically, although the total human-caused mortality exceeds PBR, the authorized mortality for the Navy's specified activities would incrementally contribute less than 1 percent of that and, further, given the fact that it would occur in only one or two of the seven years with a 50 percent chance of the take involving males (far less impactful to the population), the potential impacts on population rates are even less. Based on all of the considerations described above, including consideration of the fact that the authorized M/SI of 0.29 will not delay the time to recovery by more than 1 percent, the potential lethal take from Navy activities, alone, are unlikely to adversely affect the CA/OR/WA stock of humpback whales through effects on annual rates of recruitment or survival. Nonetheless, the fact that total human-caused mortality exceeds PBR necessitates close attention to the remainder of the impacts (*i.e.,* harassment) on the CA/OR/WA stock of humpback whales from the Navy's activities to ensure that the total authorized takes will have a negligible impact on the species and stock. Therefore, this information will be considered in combination with our assessment of the impacts of authorized harassment takes in the *Group and Species-Specific Analyses* section that follows.

Group and Species-Specific Analyses

In this section, we build on the general analysis that applies to all marine mammals in the NWTT Study Area from the previous section, and include first information and analysis that applies to mysticetes or, separately, odontocetes, or pinnipeds, and then within those three sections, more specific information that applies to smaller groups, where applicable, and the affected species or stocks. The specific authorized take numbers are also included in the analyses below, and so here we provide some additional context and discussion regarding how we consider the authorized take numbers in those analyses.

The maximum amount and type of incidental take by harassment of marine mammals reasonably likely to occur from exposures to sonar and other active acoustic sources and explosions and therefore authorized during the seven-year training and testing period are shown in Tables 32 and 33. The vast majority of predicted exposures (greater than 99 percent) are expected to be Level B harassment (TTS and behavioral reactions) from acoustic and explosive sources during training and testing activities at relatively low received levels.

In the discussions below, the estimated takes by Level B harassment represent instances of take, not the number of individuals taken (the much lower and less frequent Level A harassment takes are far more likely to be associated with separate individuals), and in some cases individuals may be taken more than one time. Below, we compare the total take numbers (including PTS, TTS, and behavioral disturbance) for species or stocks to their associated abundance estimates to evaluate the magnitude of impacts across the species or stock and to individuals. Generally, when an abundance percentage comparison is below 100, it suggests the following: (1) That not all of the individuals will be taken; (2) that, barring specific circumstances suggesting repeated takes of individuals (such as in circumstances where all activities resulting in take are focused in one area and time where the same individual marine mammals are known to congregate, such as pinnipeds at a haulout), the average or expected number of days for those individuals taken is one per year; and (3) that we would not expect any individuals to be taken more than a few times in a year, or for those days to be sequential. When it is more than 100 percent, it means there will definitely be some number of repeated takes of individuals. For

example, if the percentage is 300, the average would be each individual is taken on three days in a year if all were taken, but it is more likely that some number of individuals will be taken more than three times and some number of individuals fewer or not at all. While it is not possible to know the maximum number of days across which individuals of a stock might be taken, in acknowledgement of the fact that it is more than the average, for the purposes of this analysis, we assume a number approaching twice the average. For example, if the percentage of take compared to the abundance is 800, we estimate that some individuals might be taken as many as 16 times. Those comparisons are included in the sections below.

To assist in understanding what this analysis means, we clarify a few issues related to estimated takes and the analysis here. An individual that incurs a PTS or TTS take may sometimes, for example, also be subject to behavioral disturbance at the same time. As described above in this section, the degree of PTS, and the degree and duration of TTS, expected to be incurred from the Navy's activities are not expected to impact marine mammals such that their reproduction or survival could be affected. Similarly, data do not suggest that a single instance in which an animal accrues PTS or TTS and is also subjected to behavioral disturbance would result in impacts to reproduction or survival. Alternately, we recognize that if an individual is subjected to behavioral disturbance repeatedly for a longer duration and on consecutive days, effects could accrue to the point that reproductive success is jeopardized, although those sorts of impacts are generally not expected to result from these activities. Accordingly, in analyzing the number of takes and the likelihood of repeated and sequential takes, we consider the total takes, not just the takes by Level B harassment by behavioral disturbance, so that individuals potentially exposed to both threshold shift and behavioral disturbance are appropriately considered. The number of Level A harassment takes by PTS are so low (and zero in most cases) compared to abundance numbers that it is considered highly unlikely that any individual would be taken at those levels more than once.

Use of sonar and other transducers would typically be transient and temporary. The majority of acoustic effects to marine mammals from sonar and other active sound sources during testing and training activities would be primarily from ASW events. It is important to note that unlike other Navy Training and Testing Study Areas, there are no MTEs planned for the NWTT Study Area. On the less severe end, exposure to comparatively lower levels of sound at a detectably greater distance from the animal, for a few or several minutes, could result in a behavioral response such as avoiding an area that an animal would otherwise have moved through or fed in, or breaking off one or a few feeding bouts. More severe behavioral effects could occur when an animal gets close enough to the source to receive a comparatively higher level of sound, is exposed continuously to one source for a longer time, or is exposed intermittently to different sources throughout a day. Such effects might result in an animal having a more severe flight response and leaving a larger area for a day or more, or potentially losing feeding opportunities for a day. However, such severe behavioral effects are expected to occur infrequently.

Occasional, milder behavioral reactions are unlikely to cause long-term consequences for individual animals or populations, and even if some smaller subset of the takes are in the form of a longer (several hours or a day) and more severe response, if they are not expected to be repeated over sequential days, impacts to individual fitness are not anticipated. Nearly all studies and experts agree that infrequent exposures of a single day or less are unlikely to impact an individual's overall energy budget (Farmer *et al.,* 2018; Harris *et al.,* 2017; King *et al.,* 2015; NAS 2017; New *et al.,* 2014; Southall *et al.,* 2007; Villegas-Amtmann *et al.,* 2015).

If impacts to individuals are of a magnitude or severity such that either repeated and sequential higher severity impacts occur (the probability of this goes up for an individual the higher total number of takes it has) or the total number of moderate to more severe impacts occurs across sequential days, then it becomes more likely that the aggregate effects could potentially interfere with feeding enough to reduce energy budgets in a manner that could impact reproductive success via longer cow-calf intervals, terminated pregnancies, or calf mortality. It is important to note that these impacts only accrue to females, which only comprise a portion of the population (typically approximately 50 percent). Based on energetic models, it takes energetic impacts of a significantly greater magnitude to cause the death of an adult marine mammal, and females will always terminate a pregnancy or stop lactating before allowing their health to deteriorate. Also, the death of an adult female has significantly more impact on population growth rates than reductions in reproductive success, while the death of an adult male has very little effect on population growth rates. However, as explained earlier, such severe impacts from the Navy's activities would be very infrequent and not likely to occur at all for most species and stocks. Even for the one stock of harbor seals where it is possible for a small number of females to experience reproductive effects, we explain below why there still will be no effect on rates of recruitment or survival.

The analyses below in some cases address species collectively if they occupy the same functional hearing group (*i.e.,* low, mid, and high-frequency cetaceans), share similar life history strategies, and/or are known to behaviorally respond similarly to acoustic stressors. Because some of these groups or species share characteristics that inform the impact analysis similarly, it would be duplicative to repeat the same analysis for each species. In addition, similar species typically have the same hearing capabilities and behaviorally respond in the same manner.

Thus, our analysis below considers the effects of the Navy's activities on each affected species or stock even where discussion is organized by functional hearing group and/or information is evaluated at the group level. Where there are meaningful differences between a species or stock that would further differentiate the analysis, they are either described within the section or the discussion for those species or stocks is included as a separate subsection. Specifically below, we first give broad descriptions of the mysticete, odontocete, and pinniped groups and then differentiate into further groups as appropriate.

Mysticetes

This section builds on the broader discussion above and brings together the discussion of the different types and amounts of take that different species and stocks could potentially or will likely incur, the applicable mitigation, and the status of the species and stocks to support the negligible impact determinations for each species or stock. We have described (above in the *General Negligible Impact Analysis* section) the unlikelihood of any masking having effects that will impact the reproduction or survival of any of the individual marine mammals affected by the Navy's activities. We have also described in the *Potential Effects of Specified Activities on Marine*

Mammals and their Habitat section of the proposed rule that the specified activities would not have adverse or long-term impacts on marine mammal habitat, and therefore the unlikelihood of any habitat impacts affecting the reproduction or survival of any individual marine mammals affected by the Navy's activities. No new information has been received that affects this analysis and conclusion, although additional mitigation further reducing impacts to Mysticetes and their habitat has been added, as described in the *Mitigation Measures* section. For mysticetes, there is no predicted PTS from sonar or explosives and no predicted tissue damage from explosives for any species or stock. Much of the discussion below focuses on the behavioral effects and the mitigation measures that reduce the probability or severity of effects. Because there are species-specific and stock-specific considerations as well as M/SI take authorized for several stocks, at the end of the section we break out our findings on a species-specific and, for one species, stock-specific basis.

In Table 52 below for mysticetes, we indicate for each species and stock the total annual numbers of take by mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundane.

TABLE 52—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR MYSTICETES AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF SPECIES ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes	Abundance (NMFS SARs)*	Instances of total take as percentage of abundance
		Level B harassment		Level A harassment		Mortality			
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage				
Suborder Mysticeti (baleen whales) Family Balaenopteridae (roquals)									
Blue whale	Eastern North Pacific	6	4	0	0	0	10	1,496	<1
Fin whale	Northeast Pacific	1	1	0	0	0.29	2.29	3,168	<1
	CA/OR/WA	91	44	0	0	0.29	135.29	9,029	2
Humpback whale	Central North Pacific	47	68	0	0	0.29	115.29	10,103	1
	CA/OR/WA	40	53	0	0	0.29	93.29	2,900	3
Minke whale	Alaska	1	1	0	0	0	2	[1] 389	<1
	CA/OR/WA	111	191	0	0	0.14	302.14	636	48
Sei whale	Eastern North Pacific	33	50	0	0	0	83	519	16
Family Eschrichtiidae									
Gray whale	Eastern North Pacific	28	15	0	0	0.14	43.14	26,960	<1

* Presented in the 2019 SARs or most recent SAR.

[1] The 2018 final SAR (most recent SAR) for the Alaska stock of minke whales reports the stock abundance as unknown because only a portion of the stock's range has been surveyed. To be conservative, for this stock we report the smallest estimated abundance produced during recent surveys.

The majority of takes by harassment of mysticetes in the NWTT Study Area are caused by anti-submarine warfare (ASW) activities in the Offshore portion of the Study Area. Anti-submarine activities include sources from the MFAS bin (which includes hull-mounted sonar) because they are high level, narrowband sources in the 1–10 kHz range, which intersect what is estimated to be the most sensitive area of hearing for mysticetes. They also are used in a large portion of exercises (see Tables 3 and 4). Most of the takes (90 percent) from the MF1 bin in the NWTT Study Area would result from received levels between 160 and 178 dB SPL, while another 9 percent would result from exposure between 178 and 184 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF4 = 97 percent between 124 and 142 dB SPL, MF4 = 95 percent between 136 and 148 dB SPL, MF5 = 97 percent between 112 and 142 dB SPL, and HF4 = 91 percent between 100 and 154 dB SPL. For mysticetes, explosive training activities do not result in any take. Explosive testing activities result in a small number of takes by Level B harassment by behavioral disturbance (0–6 per stock) and TTS takes (0–2 per stock). Based on this information, the majority of the Level B harassment by behavioral disturbance is expected to be of moderate and sometimes lower severity and of a relatively shorter duration. As noted above, no PTS or tissue damage from training and testing activities is anticipated or authorized for any species or stock.

Research and observations show that if mysticetes are exposed to sonar or other active acoustic sources they may react in a number of ways depending on the characteristics of the sound source, their experience with the sound source, and whether they are migrating or on seasonal feeding or breeding grounds. Behavioral reactions may include alerting, breaking off feeding dives and surfacing, diving or swimming away, or no response at all (DOD, 2017; Nowacek, 2007; Richardson, 1995; Southall *et al.,* 2007). Overall, mysticetes have been observed to be more reactive to acoustic disturbance when a noise source is located directly on their migration route. Mysticetes disturbed while migrating could pause their migration or route around the disturbance, while males en route to breeding grounds have been shown to be less responsive to disturbances. Although some may pause temporarily, they will resume migration shortly after the exposure ends. Animals disturbed while engaged in other activities such as feeding or reproductive behaviors may be more likely to ignore or tolerate the disturbance and continue their natural behavior patterns.

Alternately, adult female mysticetes with calves may be more responsive to stressors. An increase in the disturbance level from noise-generating human activities (such as sonar or explosives) may increase the risk of mother–calf pair separation (reducing the time available for suckling) or require that louder contact calls are made which, in turn, increases the possibility of detection. In either case, increased ambient noise could have negative consequences for calf fitness (Cartwright and Sullivan 2009; Craig *et al.,* 2014). However, given the low number of

predicted mysticete exposures and the absence of known calving areas, exposure of younger, more vulnerable calves is considered to be unlikely in the NWTT Study Area.

As noted in the *Potential Effects of Specified Activities on Marine Mammals and Their Habitat* section of the proposed rule, while there are multiple examples from behavioral response studies of odontocetes ceasing their feeding dives when exposed to sonar pulses at certain levels, alternately, blue whales (mysticetes) were less likely to show a visible response to sonar exposures at certain levels when feeding than when traveling. However, Goldbogen *et al.* (2013) indicated some horizontal displacement of deep foraging blue whales in response to simulated MFAS. Southall *et al.* (2019b) observed that after exposure to simulated and operational mid-frequency active sonar, more than 50 percent of blue whales in deep-diving states responded to the sonar, while no behavioral response was observed in shallow-feeding blue whales. Southall *et al.* (2019b) noted that the behavioral responses they observed were generally brief, of low to moderate severity, and highly dependent on exposure context (behavioral state, source-to-whale horizontal range, and prey availability). Most Level B harassment by behavioral disturbance of mysticetes is likely to be short-term and of low to sometimes moderate severity, with no anticipated effect on reproduction or survival.

Richardson *et al.* (1995) noted that avoidance (temporary displacement of an individual from an area) reactions are the most obvious manifestations of disturbance in marine mammals. Avoidance is qualitatively different from the startle or 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. Some mysticetes may avoid larger activities as they move through an area, although the Navy's activities do not typically use the same training locations day-after-day during multi-day activities, except periodically in instrumented ranges. Therefore, displaced animals could return quickly after a large activity is completed. In the ocean, the use of Navy sonar and other active acoustic sources is transient and is unlikely to expose the same population of animals repeatedly over a short period of time, especially given the broader-scale movements of mysticetes.

The implementation of procedural mitigation and the sightability of mysticetes (especially given their large size) further reduces the potential for a significant behavioral reaction or a threshold shift to occur (*i.e.,* shutdowns are expected to be successfully implemented), which is reflected in the amount and type of incidental take that is anticipated to occur and authorized.

As noted previously, when an animal incurs a threshold shift, it occurs in the frequency from that of the source up to one octave above. This means that the vast majority of threshold shifts caused by Navy sonar sources will typically occur in the range of 2–20 kHz (from the 1–10 kHz MF1 bin, though in a specific narrow band within this range as the sources are narrowband), and if resulting from hull-mounted sonar, will be in the range of 3.5–7 kHz. The majority of mysticete vocalizations occur in frequencies below 1 kHz, which means that TTS incurred by mysticetes will not interfere with conspecific communication. Additionally, many of the other critical sounds that serve as cues for navigation and prey (*e.g.,* waves, fish, invertebrates) occur below a few kHz, which means that detection of these signals will not be inhibited by most threshold shift either. When we look in ocean areas where the Navy has been intensively training and testing with sonar and other active acoustic sources for decades, there is no data suggesting any long-term consequences to reproduction or survival rates of mysticetes from exposure to sonar and other active acoustic sources.

All the mysticete species discussed in this section will benefit from the procedural mitigation measures described earlier in the *Mitigation Measures* section. Additionally, the Navy will limit activities and employ other measures in mitigation areas that will avoid or reduce impacts to mysticetes utilizing those areas. Where these mitigation areas are designed to mitigate impacts to particular species or stocks (gray whales and humpback whales), they are discussed in detail below. Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect any species or stock through effects on annual rates of recruitment or survival for any of the affected mysticete stocks.

Blue Whale (Eastern North Pacific Stock)

Blue whales are listed as endangered under the ESA throughout their range, but there is no ESA designated critical habitat or biologically important area identified for this species in the NWTT Study Area. The SAR identifies this stock as ''stable.'' We further note that this stock was originally listed under the ESA as a result of the impacts from commercial whaling, which is no longer affecting the species. Blue whales are anticipated to be present in summer and winter months and only in the Offshore Area of the Study Area. No mortality from either explosives or vessel strike and no Level A harassment is anticipated or authorized.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance is less than 1 percent. Given the range of blue whales, this information indicates that only a very small portion of individuals in the stock are likely impacted and repeated exposures of individuals are not anticipated (*i.e.,* individuals are not expected to be taken on more than one day within a year). Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB with a small portion up to 184 dB (*i.e.,* of a moderate or sometimes lower level). Regarding the severity of TTS takes, we have explained that they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with blue whale communication or other important low-frequency cues and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, although the species is listed as endangered under the ESA, this population is stable, only a very small portion of the stock is anticipated to be impacted, and any individual blue whale is likely to be disturbed at a low-moderate level. No mortality and no Level A harassment is anticipated or authorized. The low magnitude and moderate-lower severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals, let alone have impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Eastern North Pacific stock of blue whales.

Fin Whale (Northeast Pacific Stock and California/Oregon/Washington Stock)

Fin whales are listed as endangered under the ESA throughout their range,

but no ESA designated critical habitat or biologically important areas are identified for this species in the NWTT Study Area. The SAR identifies these stocks as ''increasing.'' NMFS is authorizing two mortalities of fin whales over the seven years covered by this rule, but because it is not possible to determine from which stock these potential takes would occur, that is 0.29 mortality annually for each stock. The addition of this 0.29 annual mortality still leaves the total annual human-caused mortality well under residual PBR (37.2 for the CA/OR/WA stock and 4.7 for the Northeast Pacific stock) and below the insignificance threshold for both stocks. No mortality from explosives and no Level A harassment is anticipated or authorized.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance is less than 1 percent for the Northeast Pacific stock and 1.5 percent for the CA/OR/WA stock. This information indicates that only a very small portion of individuals in each stock are likely impacted and repeated exposures of individuals are not anticipated (*i.e.,* individuals are not expected to be taken on more than one day within a year). Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB with a small portion up to 184 dB (*i.e.,* of a moderate or sometimes lower level). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with fin whale communication or other important low-frequency cues—and the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, although the species is listed as endangered under the ESA, these populations are increasing, only a very small portion of each stock is anticipated to be impacted, and any individual fin whale is likely to be disturbed at a low-moderate level. No Level A harassment is anticipated or authorized. This low magnitude and moderate-lower severity of harassment effects is not expected to result in impacts on individual reproduction or survival for any individuals, nor are these harassment takes combined with the authorized mortality expected to adversely affect these stocks through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on both the Northeast Pacific and CA/OR/WA stocks of fin whales.

Humpback Whale (Central North Pacific Stock)

The Central North Pacific stock of humpback whales consists of winter/spring humpback whale populations of the Hawaiian Islands which migrate primarily to foraging habitat in northern British Columbia/Southeast Alaska, the Gulf of Alaska, and the Bering Sea/Aleutian Islands (Muto *et al.* 2019). Three Feeding Area biologically important areas for humpback whales overlap with the NWTT Study Area: Northern Washington Feeding Area for humpback whales (May-November); Stonewall and Heceta Bank Feeding Area for humpback whales (May–November); and Point St. George Feeding Area for humpback whales (July-November) (Calambokidis *et al.,* 2015). The Marine Species Coastal, Olympic Coast National Marine Sanctuary, Stonewall and Heceta Bank Humpback Whale, and Point St. George Humpback Whale Mitigation Areas overlap with these important foraging areas. The Marine Species Coastal Mitigation Area 50 nmi from shore zone includes the entirety of all three BIAs. The Stonewall and Heceta Bank Humpback Whale Mitigation Area includes the entire Stonewall and Heceta Bank Feeding Area for humpback whales. The Point St. George Humpback Whale Mitigation Area and the 20 nmi from shore zone in the Marine Species Coastal Mitigation Area both include the entire Point St. George Feeding Area for humpback whales. Additionally, the new Juan de Fuca Eddy Marine Species Coastal Mitigation area will also benefit humpback whale feeding. The full extent of the Juan de Fuca Eddy is not incorporated into the Northern Washington humpback whale biologically important feeding area because the development of biologically important areas was restricted to U.S. waters only. Therefore, the Northern Washington biologically important humpback whale feeding area extends northward to the boundary of the U.S. Exclusive Economic Zone (Calambokidis *et al.,* 2015; Ferguson *et al.,* 2015a; Ferguson *et al.,* 2015b). However, humpback whale aggregations feed across this political boundary in the nutrient rich waters throughout the Juan de Fuca Eddy from May to November. Therefore, waters within the Juan de Fuca Eddy between the Northern Washington humpback whale biologically important area and the northern boundary of the NWTT Offshore Area are included in the Juan de Fuca Eddy Marine Species Mitigation Area. The mitigation measures implemented in each of these areas, including but not limited to, no MF1 MFAS use seasonally or limited MFAS use year round, no explosive training, and no explosive testing or restrictions on explosive testing (see details of all mitigation measures for each area in the Mitigation Measures section), will reduce the severity of impacts to humpback whales by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities.

The SAR identifies this stock as ''increasing'' and the associated Hawaii DPS is not listed as endangered or threatened under the ESA. No mortality from explosives and no Level A harassment is anticipated or authorized. NMFS is authorizing two mortalities of humpback whales over the seven years covered by this rule, but because it is not possible to determine from which stock these potential takes would occur, that is 0.29 mortality annually for both this stock and the CA/OR/WA stock (discussed separately below). The addition of this 0.29 annual mortality still leaves the total annual human-caused mortality well under both the insignificance threshold and residual PBR (57.7).

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated instances of take compared to the abundance is 1 percent. This information and the far-ranging nature of the stock structure indicates that only a very small portion of the stock is likely impacted and repeated exposures of individuals are not anticipated (*i.e.,* individuals are not expected to be taken on more than one day within a year). Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB with a small portion up to 184 dB (*i.e.,* of a moderate or sometimes lower level). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with humpback whale communication or other important low-frequency cues, and that the associated lost

opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, this population is increasing and the associated DPS is not listed as endangered or threatened under the ESA. Only a very small portion of the stock is anticipated to be impacted and any individual humpback whale is likely to be disturbed at a low-moderate level. No Level A harassment is anticipated or authorized. This low magnitude and moderate-lower severity of harassment effects is not expected to result in impacts on individual reproduction or survival, nor are these harassment takes combined with the authorized mortality expected to adversely affect this stock through effects on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Central North Pacific stock of humpback whales.

Humpback Whale (California/Oregon/Washington Stock)

The CA/OR/WA stock of humpback whales includes individuals from three ESA DPSs: Central America (endangered), Mexico (threatened), and Hawaii (not listed). There is no ESA-designated critical habitat for humpback whales, however NMFS has proposed to designate critical habitat for humpback whales (84 FR 54354; October 9, 2019). Three Feeding Area biologically important areas for humpback whales overlap with the NWTT Study Area: Northern Washington Feeding Area for humpback whales (May–November); Stonewall and Heceta Bank Feeding Area for humpback whales (May–November); and Point St. George Feeding Area for humpback whales (July–November) (Calambokidis *et al.,* 2015). The Marine Species Coastal, Olympic Coast National Marine Sanctuary, Stonewall and Heceta Bank Humpback Whale, and Point St. George Humpback Whale Mitigation Areas overlap with these important foraging areas. The Marine Species Coastal Mitigation Area 50 nmi from shore zone includes the entirety of all three BIAs. The Stonewall and Heceta Bank Humpback Whale Mitigation Area includes the entire Stonewall and Heceta Bank Feeding Area for humpback whales. The Point St. George Humpback Whale Mitigation Area and the 20 nmi from shore zone in the Marine Species Coastal Mitigation Area both include the entire Point St. George Feeding Area for humpback whales. Additionally, the new Juan de Fuca Eddy Marine Species Coastal Mitigation area will also benefit humpback whale feeding. The full extent of the Juan de Fuca Eddy is not incorporated into the Northern Washington humpback whale biologically important feeding area because the development of biologically important areas was restricted to U.S. waters only. Therefore, the Northern Washington biologically important humpback whale feeding area extends northward to the boundary of the U.S. Exclusive Economic Zone (Calambokidis *et al.,* 2015; Ferguson *et al.,* 2015a; Ferguson *et al.,* 2015b). However, humpback whale aggregations feed across this political boundary in the nutrient rich waters throughout the Juan de Fuca Eddy from May to November. Therefore, waters within the Juan de Fuca Eddy between the Northern Washington humpback whale biologically important area and the northern boundary of the NWTT Offshore Area are included in the Juan de Fuca Eddy Marine Species Mitigation Area. The mitigation measures implemented in each of these areas, including but not limited to, no MF1 MFAS use seasonally or limited MFAS use year round, no explosive training, and no explosive testing or restrictions on explosive testing (see details of all mitigation measures for each area in the *Mitigation Measures* section), will reduce the severity of impacts to humpback whales by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities.

The SAR identifies this stock as stable (having shown a long-term increase from 1990 and then leveling off between 2008 and 2014). NMFS is authorizing two mortalities over the seven years covered by this rule, or 0.29 mortality annually. With the addition of this 0.29 annual mortality, the total annual human-caused mortality exceeds residual PBR by 9.1. However, as described in more detail in the *Serious Injury or Mortality* subsection, when total human-caused mortality exceeds PBR, we consider whether the incremental addition of a small amount of mortality from the specified activity may still result in a negligible impact, in part by identifying whether it is less than 10 percent of PBR, which is 3.3. In this case, the authorized mortality is well below 10 percent of PBR (less than one percent, in fact) and management measures are in place to reduce mortality from other sources. More importantly, as described above in the *Serious Injury or Mortality* section, the authorized mortality of 0.29 will not delay the time to recovery by more than 1 percent. Given these factors, the incremental addition of two mortalities over the course of the seven-year Navy rule is not expected to, alone (*i.e.,* in the absence of any other take and barring any other unusual circumstances), lead to adverse impacts on the stock through effects on annual rates of recruitment or survival. No mortality from explosives and no Level A harassment is anticipated or authorized.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance is 3 percent (Table 52). Given the range of humpback whales, this information suggests that only a small portion of individuals in the stock are likely impacted and repeated exposures of individuals are not anticipated (*i.e.,* individuals are not expected to be taken on more than one day within a year). Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB with a small portion up to 184 dB (*i.e.,* of a moderate or sometimes lower level). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with humpback whale communication or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, this population is stable and even though two of the three associated DPSs are listed as endangered or threatened under the ESA, only a small portion of the stock is anticipated to be impacted, and any individual humpback whale is likely to be disturbed at a low-moderate level. No Level A harassment is anticipated or authorized. This low magnitude and moderate-lower severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals and, therefore, when combined with the authorized mortality (which our earlier analysis indicated will not, alone, have more than a negligible impact on this stock of humpback whales), is not expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities

combined, that the authorized take will have a negligible impact on the CA/OR/WA stock of humpback whales.

Minke Whale (Alaska and California/Oregon/Washington Stocks)

The status of these stocks is unknown and the species is not listed under the ESA. No biologically important areas have been identified for this species in the NWTT Study Area. NMFS is authorizing one mortality over the seven years covered by this rule, or 0.14 mortality annually, for the CA/OR/WA stock, and no mortality is anticipated or authorized for the Alaska stock. The addition of this 0.14 annual mortality still leaves the total annual human-caused mortality well under the residual PBR (2.2) and below the insignificance threshold. No mortality from explosives and no Level A harassment is anticipated or authorized for either stock.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance is less than 1 percent for the Alaska stock (based on, to be conservative, the smallest available provisional estimate in the SAR, which is derived from surveys that cover only a portion of the stock's range) and 47.5 percent for the CA/OR/WA stock. Given the range of minke whales, this information indicates that only a very small portion of individuals in the Alaska stock are likely to be impacted and repeated exposures of individuals are not anticipated (*i.e.,* individuals are not expected to be taken on more than one day within a year). For the CA/OR/WA stock, fewer than half of the individuals in the stock will likely be taken, with those individuals disturbed on likely one, but not more than a few non-sequential days within a year. Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB with a small portion up to 184 dB (*i.e.,* of a moderate or sometimes lower level). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with minke whale communication or other important low-frequency cues—and the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, although the status of the stocks is unknown, the species is not listed under the ESA as endangered or threatened, only a smaller portion of these stocks is anticipated to be impacted, and any individual minke whale is likely to be disturbed at a low-moderate level. No Level A harassment is anticipated or authorized. This low magnitude and moderate-lower severity of harassment effects is not expected to result in impacts on individual reproduction or survival for either stock, nor are these harassment takes combined with the authorized mortality expected to adversely affect the CA/OR/WA stock through effects on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Alaska and CA/OR/WA stocks of minke whales.

Sei Whale (Eastern North Pacific Stock)

The status of this stock is unknown, however sei whales are listed as endangered under the ESA throughout their range. There is no ESA designated critical habitat or biologically important areas identified for this species in the NWTT Study Area. No mortality from either explosives or vessel strikes and no Level A harassment is anticipated or authorized.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance is 16 percent (Table 52). This information and the large range of sei whales suggests that only a small portion of individuals in the stock are likely impacted and repeated exposures of individuals are not anticipated (*i.e.,* individuals are not expected to be taken on more than one day within a year). Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB with a small portion up to 184 dB (*i.e.,* of a moderate or sometimes lower level). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with sei whale communication or other important low-frequency cues. Therefore the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, the status of the stock is unknown and the species is listed as endangered, but only a small portion of the stock is anticipated to be impacted and any individual sei whale is likely to be disturbed at a low-moderate level. No mortality and no Level A harassment is anticipated or authorized. This low magnitude and moderate-lower severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals, let alone have impacts on annual rates of recruitment or survival. Therefore, the total take will not adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Eastern North Pacific stock of sei whales.

Gray Whale (Eastern North Pacific Stock)

The SAR identifies this stock as ''increasing'' and the associated DPS is not listed under the ESA. The NWTT Study Area overlaps with the offshore Northwest Feeding Area for gray whales and the Northern Puget Sound Feeding Area for gray whales, both identified as biologically important areas. In addition, a portion of the Northwest coast of Washington, approximately from Pacific Beach (WA) and extending north to the Strait of Juan de Fuca, overlaps with the gray whale migration corridor biologically important areas (Northbound and Southbound). The Marine Species Coastal, Olympic Coast National Marine Sanctuary, Stonewall and Heceta Bank Humpback Whale, Point St. George Humpback Whale, Puget Sound and Strait of Juan de Fuca, and Northern Puget Sound Gray Whale Mitigation Areas overlap with these important foraging and migration areas. The Marine Species Coastal Mitigation Area (all distances—50 nmi, 20 nmi, and 12 nmi from shore) include the entire offshore Northwest Feeding Area for gray whales as well as the Northbound Phase A, Northbound Phase B, and Southbound gray whale migration corridor BIAs. The Olympic Coast National Marine Sanctuary Mitigation Area overlaps with each of these BIAs by 96–100 percent. The Stonewall and Heceta Bank Humpback Whale Mitigation Area and the Point St. George Humpback Whale Mitigation Area overlap minimally with the gray whale potential presence migration BIA (5 percent overlap or less). The Puget Sound and Strait of Juan de Fuca Mitigation Area and the Northern Puget Sound Gray Whale Mitigation Area both include the entire Northern Puget Sound Feeding Area for gray whales. The mitigation measures implemented

in each of these areas, including but not limited to, no MF1 MFAS use seasonally or limited MFAS use year round, no explosive training, and no explosive testing or restrictions on explosive testing (see details of all mitigation measures for each area in the *Mitigation Measures* section), will reduce the severity of impacts to gray whales by reducing interference in feeding and migration that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good foraging opportunities or move migration routes.

NMFS is authorizing one mortality over the seven years covered by this rule, or 0.14 mortality annually. The addition of this 0.14 annual mortality still leaves the total annual human-caused mortality well under both the insignificance threshold and residual PBR (661.6). No mortality from explosives and no Level A harassment is anticipated or authorized.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance is less than 1 percent. This information indicates that only a very small portion of individuals in the stock are likely to be impacted and repeated exposures of individuals are not anticipated (*i.e.,* individuals are not expected to be taken on more than one day within a year). Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB with a small portion up to 184 dB (*i.e.,* of a moderate or sometimes lower level). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with gray whale communication or other important low-frequency cues and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, while we have considered the impacts of the gray whale UME, this population of gray whales is not endangered or threatened under the ESA and the stock is increasing. No Level A harassment is anticipated or authorized. Only a very small portion of the stock is anticipated to be impacted by Level B harassment and any individual gray whale is likely to be disturbed at a low-moderate level. This low magnitude and moderate-lower severity of harassment effects is not expected to result in impacts to reproduction or survival for any individuals, nor are these harassment takes combined with the authorized mortality of one whale over the seven-year period expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Eastern North Pacific stock of gray whales.

Odontocetes

This section builds on the broader discussion above and brings together the discussion of the different types and amounts of take that different species and stocks could potentially or will likely incur, the applicable mitigation, and the status of the species and stock to support the negligible impact determinations for each species or stock. We have described (above in the *General Negligible Impact Analysis* section) the unlikelihood of any masking having effects that will impact the reproduction or survival of any of the individual marine mammals affected by the Navy's activities. We have also described in the *Potential Effects of Specified Activities on Marine Mammals and their Habitat* section of the proposed rule that the specified activities would not have adverse or long-term impacts on marine mammal habitat, and therefore the unlikelihood of any habitat impacts affecting the reproduction or survival of any individual marine mammals affected by the Navy's activities. No new information has been received that affects this analysis and conclusion, although mitigation measures have been added that will further reduce impacts to Southern Resident killer whales, other odontocetes, and their habitat. For odontocetes, there is no anticipated M/SI or tissue damage from sonar or explosives for any species or stock. Here, we include information that applies to all of the odontocete species, which are then further divided and discussed in more detail in the following subsections: Sperm whales, dwarf sperm whales, and pygmy sperm whales; beaked whales; dolphins and small whales; and porpoises. These subsections include more specific information about the groups, as well as conclusions for each species or stock represented.

The majority of takes by harassment of odontocetes in the NWTT Study Area are caused by sources from the MFAS bin (which includes hull-mounted sonar) because they are high level, typically narrowband sources at a frequency (in the 1–10 kHz range) that overlaps a more sensitive portion (though not the most sensitive) of the MF hearing range and they are used in a large portion of exercises (see Tables 3 and 4). For odontocetes other than beaked whales and porpoises (for which these percentages are indicated separately in those sections), most of the takes (96 percent) from the MF1 bin in the NWTT Study Area would result from received levels between 160 and 172 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF4 = 99 percent between 124 and 154 dB SPL, MF4 = 99 percent between 136 and 166 dB SPL, MF5 = 98 percent between 112 and 148 dB SPL, and HF4 = 95 percent between 100 and 160 dB SPL. Based on this information, the majority of the takes by Level B harassment by behavioral disturbance are expected to be low to sometimes moderate in nature, but still of a generally shorter duration.

For all odontocetes, takes from explosives (Level B harassment by behavioral disturbance, TTS, or PTS) comprise a very small fraction (and low number) of those caused by exposure to active sonar. For the following odontocetes, zero takes from explosives are expected to occur: Common bottlenose dolphins, killer whales, short-beaked common dolphins, short-finned pilot whales, the Alaska stock of Dall's porpoises, Southeast Alaska stock of harbor porpoises, sperm whales, Baird's beaked whale, Cuvier's beaked whale, and *Mesoplodon* species. For Level B harassment by behavioral disturbance from explosives, with the exception of porpoises, one take is anticipated for the remaining species/stocks. For the CA/OR/WA stock of Dall's porpoise and the remaining three harbor porpoise stocks, 1–91 takes by Level B harassment by behavioral disturbance from explosives are anticipated. Similarly the instances of TTS and PTS expected to occur from explosives for all remaining species/stocks, with the exception of porpoises, are anticipated to be low (1–3 for TTS and 1 for PTS). Because of the lower TTS and PTS thresholds for HF odontocetes, for the CA/OR/WA stock of Dall's porpoise and the remaining three harbor porpoise stocks, TTS takes range from 61–214 and PTS takes range from 27–86.

Because the majority of harassment takes of odontocetes result from the sources in the MFAS bin, the vast majority of threshold shift would occur upon receipt of a single frequency within the 1–10 kHz range and, therefore, the vast majority of threshold shift caused by Navy sonar sources

would be at a single frequency within the range of 2–20 kHz. The frequency range within which any of the anticipated narrowband threshold shift would occur would fall directly within the range of most odontocete vocalizations (2–20 kHz). For example, the most commonly used hull-mounted sonar has a frequency around 3.5 kHz, and any associated threshold shift would be expected to be at around 7 kHz. However, odontocete vocalizations typically span a much wider range than this, and alternately, threshold shift from active sonar will often be in a narrower band (reflecting the narrower band source that caused it), which means that TTS incurred by odontocetes would typically only interfere with communication within a portion of their range (if it occurred during a time when communication with conspecifics was occurring) and, as discussed earlier, it would only be expected to be of a short duration and relatively small degree. Odontocete echolocation occurs predominantly at frequencies significantly higher than 20 kHz, though there may be some small overlap at the lower part of their echolocating range for some species, which means that there is little likelihood that threshold shift, either temporary or permanent, would interfere with feeding behaviors. Many of the other critical sounds that serve as cues for navigation and prey (*e.g.,* waves, fish, invertebrates) occur below a few kHz, which means that detection of these signals will not be inhibited by most threshold shift either. The low number of takes by threshold shift that might be incurred by individuals exposed to explosives would likely be lower frequency (5 kHz or less) and spanning a wider frequency range, which could slightly lower an individual's sensitivity to navigational or prey cues, or a small portion of communication calls, for several minutes to hours (if temporary) or permanently. There is no reason to think that any of the individual odontocetes taken by TTS would incur these types of takes over more than one day, or over a few days at most, and therefore they are unlikely to incur impacts on reproduction or survival. The number of PTS takes from these sources are very low, and while spanning a wider frequency band, are still expected to be of a low degree (*i.e.,* low amount of hearing sensitivity loss) and unlikely to affect reproduction or survival.

The range of potential behavioral effects of sound exposure on marine mammals generally, and odontocetes specifically, has been discussed in detail previously. There are behavioral patterns that differentiate the likely impacts on odontocetes as compared to mysticetes. First, odontocetes echolocate to find prey, which means that they actively send out sounds to detect their prey. While there are many strategies for hunting, one common pattern, especially for deeper diving species, is many repeated deep dives within a bout, and multiple bouts within a day, to find and catch prey. As discussed above, studies demonstrate that odontocetes may cease their foraging dives in response to sound exposure. If enough foraging interruptions occur over multiple sequential days, and the individual either does not take in the necessary food, or must exert significant effort to find necessary food elsewhere, energy budget deficits can occur that could potentially result in impacts to reproductive success, such as increased cow/calf intervals (the time between successive calving). Second, while many mysticetes rely on seasonal migratory patterns that position them in a geographic location at a specific time of the year to take advantage of ephemeral large abundances of prey (*i.e.,* invertebrates or small fish, which they eat by the thousands), odontocetes forage more homogeneously on one fish or squid at a time. Therefore, if odontocetes are interrupted while feeding, it is often possible to find more prey relatively nearby.

All the Odontocete species discussed in this section will benefit from the procedural mitigation measures described earlier in the *Mitigation Measures* section. Additionally, the Navy will limit activities and employ other measures in mitigation areas that will avoid or reduce impacts to Odonticetes utilizing those areas, as discussed in more detail below.

Sperm Whale, Dwarf Sperm Whale, and Pygmy Sperm Whale

This section builds on the broader odontocete discussion above and brings together the discussion of the different types and amounts of take that different species and stocks could potentially or will likely incur, any additional applicable mitigation, and the status of the species and stocks to support the negligible impact determinations for each species or stock. For sperm whales, there is no predicted PTS from sonar or explosives and no predicted tissue damage from explosives. For dwarf sperm whales and pygmy sperm whales (described as *Kogia* species for the reasons explained below) no mortality or tissue damage from sonar or explosives is anticipated or authorized and only one PTS take is predicted.

In Table 53 below for sperm whales and *Kogia* species, we indicate the total annual numbers of take by mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

TABLE 53—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR SPERM WHALES AND KOGIA SPP. (DWARF SPERM WHALES, AND PYGMY SPERM WHALES) IN THE NWTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes	Abundance (NMFS SARs)*	Instances of total take as percentage of abundance
		Level B harassment		Level A harassment		Mortality			
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage				
Suborder Odontoceti (toothed whales) Family Physeteridae (sperm whale)									
Sperm whale*	CA/OR/WA	834	5	0	0	0.14	839	1,997	42
Family Kogiidae (sperm whales)									
Kogia Species	CA/OR/WA	365	517	2	0	0	884	4,111	22

*Presented in the 2019 SARs or most recent SAR.

Note: As indicated in Table 32 and Table 33, the *Kogia* Spp. take estimates were updated to reflect clarifications due to rounding errors in the proposed rule.

As discussed above, the majority of takes by Level B harassment by behavioral disturbance of odontocetes, and thereby sperm whales and *Kogia* species, is expected to be in the form of low to occasionally moderate severity of a generally shorter duration. As discussed earlier in this section, we anticipate more severe effects from takes when animals are exposed to higher received levels or for longer durations. Occasional milder Level B harassment by behavioral disturbance, as is expected here, is unlikely to cause long-term consequences for either individual animals or populations, even if some smaller subset of the takes are in the form of a longer (several hours or a day) and more moderate response.

We note that *Kogia* species (dwarf and pygmy sperm whales), as HF-sensitive species, have a lower PTS threshold than all other groups and therefore are generally likely to experience larger amounts of TTS and PTS, and NMFS accordingly has evaluated and authorized higher numbers. Also, however, regarding PTS from sonar exposure, *Kogia* whales are still likely to avoid sound levels that would cause higher levels of TTS (greater than 20 dB) or PTS. Therefore, even though the number of TTS takes are higher than for other odontocetes, any PTS is expected to be at a lower level and for all of the reasons described above, TTS and PTS are not expected to impact reproduction or survival of any individual.

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect sperm whales and pygmy and dwarf sperm whales through effects on annual rates of recruitment or survival.

Sperm Whale (California/Oregon/Washington Stock)

The SAR identifies the CA/OR/WA stock of sperm whales as ''stable'' although the species is listed as endangered under the ESA. No critical habitat has been designated for sperm whales under the ESA and no biologically important areas have been identified for sperm whales in the NWTT Study Area. NMFS is authorizing one mortality for the CA/OR/WA stock of sperm whales over the seven years covered by this rule, or 0.14 mortality annually. The addition of this 0.14 annual mortality still leaves the total human-caused mortality under residual PBR (1.8) and below the insignificance threshold. No mortality from explosives and no Level A harassment is anticipated or authorized.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance is 42 percent for sperm whales. Given the range of this stock (which extends the entire length of the U.S. West Coast, as well as beyond the U.S. EEZ boundary), this information indicates that notably fewer than half the individuals in the stock are likely to be taken annually and with those individuals disturbed on likely one, but not more than a few non-sequential days within a year. Additionally, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity. Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower, to occasionally moderate, level and less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with sperm whale communication or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, this population is stable (even though the species is listed under the ESA), only a portion (notably less than half) of the stock is anticipated to be impacted, and any individual sperm whale is likely to be disturbed at a low-moderate level. No Level A harassment is anticipated or authorized. This low magnitude and low-moderate severity of harassment effects is not expected to result in impacts on the reproduction or survival for any individuals, nor are these harassment takes combined with the authorized mortality expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the CA/OR/WA stock of sperm whales.

Kogia Species (California/Oregon/Washington Stocks)

The status of the CA/OR/WA stocks of pygmy and dwarf sperm whales (*Kogia* species) is unknown and neither are listed under the ESA. No biologically important areas have been identified for *Kogia* species in the NWTT Study Area. No mortality or Level A harassment from tissue damage are anticipated or authorized, and two PTS Level A harassment takes are expected and authorized.

Due to their pelagic distribution, small size, and cryptic behavior, pygmy sperm whales and dwarf sperm whales (*Kogia* species) are rarely sighted during at-sea surveys and are difficult to distinguish between when visually observed in the field. Many of the relatively few observations of *Kogia* species off the U.S. West Coast were not identified to species. All at-sea sightings of Kogia species have been identified as pygmy sperm whales or *Kogia* species generally. Stranded dwarf sperm and pygmy sperm whales have been found on the U.S. West Coast, however dwarf sperm whale strandings are rare. NMFS SARs suggest that the majority of *Kogia* sighted off the U.S. West Coast were likely pygmy sperm whales. As such, the stock estimate in the NMFS SAR for pygmy sperm whales is the estimate derived for all *Kogia* species in the region (Barlow, 2016), and no separate abundance estimate can be determined for dwarf sperm whales, though some low number likely reside in the U.S. EEZ. Due to the lack of an abundance estimate it is not possible to predict the amount of Level A and Level B harassment take of dwarf sperm whales and therefore take estimates are identified as *Kogia* whales (including both pygmy and dwarf sperm whales). We assume only a small portion of those takes are likely to be dwarf sperm whales as the available information indicates that the density and abundance in the U.S. EEZ is low.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance is 21 percent. Given the range of these stocks (which extends the entire length of the West Coast, as well as beyond the U.S. EEZ boundary), this information indicates that only a small portion of the individuals in the stocks are likely to be impacted and repeated exposures of individuals are not anticipated (*i.e.,* individuals are not expected to be taken on more than one day within a year). Additionally, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity. Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower, to

occasionally moderate, level and less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with dwarf or pygmy sperm whale communication or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. A small permanent loss of hearing sensitivity (PTS) may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, but at the expected degree the estimated two Level A harassment takes by PTS are unlikely to impact behaviors, opportunities, or detection capabilities to a degree that will interfere with reproductive success or survival of the affected individuals, let alone affect annual rates of recruitment or survival for the stock.

Altogether, although the status of the stocks is unknown, these species are not listed under the ESA as endangered or threatened, only a small portion of these stocks are anticipated to be impacted, and any individual *Kogia* whale is likely to be disturbed at a low-moderate level. This low magnitude and low-moderate severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals, let alone have impacts on annual rates of recruitment or survival. Two individuals could be taken by PTS annually of likely low severity, the impact of which also is not expected to affect reproduction or survival, alone or in combination with the authorized Level B harassment. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the CA/OR/WA stocks of *Kogia* whales.

Beaked Whales

This section builds on the broader odontocete discussion above (*i.e.,* that information applies to beaked whales as well), and brings together the discussion of the different types and amounts of take that different beaked whale species and stocks will likely incur, any additional applicable mitigation, and the status of the species and stocks to support the negligible impact determinations for each species or stock. For beaked whales, there is no anticipated Level A harassment by PTS or tissue damage from sonar or explosives, and no mortality is anticipated or authorized.

In Table 54 below for beaked whales, we indicate the total annual numbers of take by mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

TABLE 54—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR BEAKED WHALES IN THE NWTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes	Abundance (NMFS SARs)*	Instances of total take as percentage of abundance
		Level B harassment		Level A harassment		Mortality			
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage				
Suborder Odontoceti (toothed whales) Family Ziphiidae (beaked whales)									
Baird's beaked whale	CA/OR/WA	976	0	0	0	0	976	2,697	36
Cuvier's beaked whale.	CA/OR/WA	2,535	4	0	0	0	2,539	3,274	78
Mesoplodont beaked whales.	CA/OR/WA	1,119	3	0	0	0	1,122	3,044	37

*Presented in the 2019 SARs or most recent SAR.

This first paragraph provides specific information that is in lieu of the parallel information provided for odontocetes as a whole. The majority of takes by harassment of beaked whales in the NWTT Study Area are caused by sources from the MFAS bin (which includes hull-mounted sonar) because they are high level narrowband sources that fall within the 1–10 kHz range, which overlap a more sensitive portion (though not the most sensitive) of the MF hearing range. Also, of the sources expected to result in take, they are used in a large portion of exercises (see Tables 3 and 4). Most of the takes (95 percent) from the MF1 bin in the NWTT Study Area would result from received levels between 142 and 160 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF4 = 99 percent between 118 and 148 dB SPL, MF4 = 97 percent between 124 and 148 dB SPL, MF5 = 99 percent between 100 and 148 dB SPL, and HF4 = 97 percent between 100 and 154 dB SPL. Given the levels they are exposed to and their sensitivity, some responses would be of a lower severity, but many would likely be considered moderate, but still of generally short duration.

Research has shown that beaked whales are especially sensitive to the presence of human activity (Pirotta *et al.,* 2012; Tyack *et al.,* 2011) and therefore have been assigned a lower harassment threshold, with lower received levels resulting in a higher percentage of individuals being harassed and a more distant distance cutoff (50 km for high source level, 25 km for moderate source level).

Beaked whales have been documented to exhibit avoidance of human activity or respond to vessel presence (Pirotta *et al.,* 2012). Beaked whales were observed to react negatively to survey vessels or low altitude aircraft by quick diving and other avoidance maneuvers, and none were observed to approach vessels (Wursig *et al.,* 1998). It has been speculated for some time that beaked whales might have unusual sensitivities to sonar sound due to their likelihood of stranding in conjunction with MFAS use, although few definitive causal relationships between MFAS use and strandings have been documented (see *Potential Effects of Specified Activities on Marine Mammals and their Habitat* section in the proposed rule). However, as described in the *Estimated Take of Marine Mammals* section of this final rule and further addressed in the response to Comment 19, NMFS neither

anticipates nor authorizes the mortality of beaked whales (or other species or stocks) resulting from exposure to active sonar.

Research and observations show that if beaked whales are exposed to sonar or other active acoustic sources, they may startle, break off feeding dives, and avoid the area of the sound source to levels of 157 dB re: 1 μPa, or below (McCarthy *et al.,* 2011). For example, after being exposed to 1–2 kHz upsweep naval sonar signals at a received SPL of 107 dB re 1 μPa, Northern bottlenose whales began moving in an unusually straight course, made a near 180° turn away from the source, and performed the longest and deepest dive (94 min, 2339 m) recorded for this species (Miller *et al.* 2015). Wensveen *et al.* (2019) also documented avoidance behaviors in Northern bottlenose whales exposed to 1–2 kHz tonal sonar signals with SPLs ranging between 117–126 dB re: 1 μPa, including interrupted diving behaviors, elevated swim speeds, directed movements away from the sound source, and cessation of acoustic signals throughout exposure periods. Acoustic monitoring during actual sonar exercises revealed some beaked whales continuing to forage at levels up to 157 dB re: 1 μPa (Tyack *et al.,* 2011). Stimpert *et al.* (2014) tagged a Baird's beaked whale, which was subsequently exposed to simulated MFAS. Changes in the animal's dive behavior and locomotion were observed when received level reached 127 dB re: 1 μPa. However, Manzano-Roth *et al.* (2013) found that for beaked whale dives that continued to occur during MFAS activity, differences from normal dive profiles and click rates were not detected with estimated received levels up to 137 dB re: 1 μPa while the animals were at depth during their dives. In research done at the Navy's fixed tracking range in the Bahamas, animals were observed to leave the immediate area of the anti-submarine warfare training exercise (avoiding the sonar acoustic footprint at a distance where the received level was ''around 140 dB SPL'', according to Tyack *et al.* (2011)), but return within a few days after the event ended (Claridge and Durban, 2009; McCarthy *et al.,* 2011; Moretti *et al.,* 2009, 2010; Tyack *et al.,* 2010, 2011). Joyce *et al.* (2019) found that Blainville's beaked whales moved up to 68 km away from an Atlantic Undersea Test and Evaluation Center site and reduced time spent on deep dives after the onset of mid-frequency active sonar exposure; whales did not return to the site until 2–4 days after the exercises ended. Changes in acoustic activity have also been documented. For example, Blainville's beaked whales showed decreased group vocal periods after biannual multi-day Navy training activities (Henderson *et al.*2016). Tyack *et al.* (2011) report that, in reaction to sonar playbacks, most beaked whales stopped echolocating, made long slow ascent to the surface, and moved away from the sound. A similar behavioral response study conducted in Southern California waters during the 2010–2011 field season found that Cuvier's beaked whales exposed to MFAS displayed behavior ranging from initial orientation changes to avoidance responses characterized by energetic fluking and swimming away from the source (DeRuiter *et al.,* 2013b). However, the authors did not detect similar responses to incidental exposure to distant naval sonar exercises at comparable received levels, indicating that context of the exposures (*e.g.,* source proximity, controlled source ramp-up) may have been a significant factor. The study itself found the results inconclusive and meriting further investigation. Falcone *et al.* (2017) however, documented that Cuvier's beaked whales had longer dives and surface durations after exposure to mid-frequency active sonar, with the longer surface intervals contributing to a longer interval between deep dives, a proxy for foraging disruption in this species. Cuvier's beaked whale responses suggested particular sensitivity to sound exposure consistent with results for Blainville's beaked whale.

Populations of beaked whales and other odontocetes on the Bahamas and other Navy fixed ranges that have been operating for decades appear to be stable. Behavioral reactions (avoidance of the area of Navy activity) seem likely in most cases if beaked whales are exposed to anti-submarine sonar within a few tens of kilometers, especially for prolonged periods (a few hours or more) since this is one of the most sensitive marine mammal groups to anthropogenic sound of any species or group studied to date and research indicates beaked whales will leave an area where anthropogenic sound is present (De Ruiter *et al.,* 2013; Manzano-Roth *et al.,* 2013; Moretti *et al.,* 2014; Tyack *et al.,* 2011). Research involving tagged Cuvier's beaked whales in the SOCAL Range Complex reported on by Falcone and Schorr (2012, 2014) indicates year-round prolonged use of the Navy's training and testing area by these beaked whales and has documented movements in excess of hundreds of kilometers by some of those animals. Given that some of these animals may routinely move hundreds of kilometers as part of their normal pattern, leaving an area where sonar or other anthropogenic sound is present may have little, if any, cost to such an animal. Photo identification studies in the SOCAL Range Complex, a Navy range that is utilized for training and testing, have identified approximately 100 Cuvier's beaked whale individuals with 40 percent having been seen in one or more prior years, with re-sightings up to seven years apart (Falcone and Schorr, 2014). These results indicate long-term residency by individuals in an intensively used Navy training and testing area, which may also suggest a lack of long-term consequences as a result of exposure to Navy training and testing activities. More than eight years of passive acoustic monitoring on the Navy's instrumented range west of San Clemente Island documented no significant changes in annual and monthly beaked whale echolocation clicks, with the exception of repeated fall declines likely driven by natural beaked whale life history functions (DiMarzio *et al.,* 2018). Finally, results from passive acoustic monitoring estimated that regional Cuvier's beaked whale densities were higher than indicated by NMFS' broad scale visual surveys for the U.S. West Coast (Hildebrand and McDonald, 2009).

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect beaked whales through effects on annual rates of recruitment or survival.

Baird's and Cuvier's Beaked Whales and *Mesoplodon* Species

California/Oregon/Washington Stocks

Baird's beaked whale, Cuvier's beaked whale, and the *Mesoplodon* species are not listed as endangered or threatened species under the ESA, and the CA/OR/WA stocks have been identified as ''stable,'' ''decreasing,'' and ''increasing,'' respectively, in the SARs. No biologically important areas have been identified for beaked whales in the NWTT Study Area. No mortality or Level A harassment from sonar or explosives is expected or authorized.

No methods are available to distinguish between the six species of *Mesoplodon* beaked whales from the CA/OR/WA stocks (Blainville's beaked whale (*M. densirostris*), Perrin's beaked whale (*M. perrini*), Lesser beaked whale (*M. peruvianus*), Stejneger's beaked whale (*M. stejnegeri*), Gingko-toothed beaked whale (*M. gingkodens*), and Hubbs' beaked whale (*M. carlhubbsi*)) when observed during at-sea surveys

(Carretta *et al.,* 2019). Bycatch and stranding records from the region indicate that Hubb's beaked whale is the most commonly encountered (Carretta *et al.,* 2008, Moore and Barlow, 2013). As indicated in the SAR, no species-specific abundance estimates are available, the abundance estimate includes all CA/OR/WA *Mesoplodon* species, and the six species/stocks are managed as one unit. Due to the lack of species-specific abundance estimates it is not possible to predict the take of individual species for each stock and take estimates are identified as *Mesoplodon* species. Therefore our analysis considers these *Mesoplodon* species together.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance is 36 to 78 percent. This information indicates that potentially half or more (but no more than 78 percent) of the individuals in these stocks may be impacted, depending on the stock, though the more likely scenario is that a smaller portion than that would be taken, and a subset of them would be taken on a few days, with no indication that these days would be sequential. Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 166 dB, though with beaked whales, which are considered somewhat more sensitive, this could mean that some individuals will leave preferred habitat for a day (*i.e.,* moderate level takes). However, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options nearby. Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with beaked whale communication or other important low-frequency cues, and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. As mentioned earlier in the odontocete overview, we anticipate more severe effects from takes when animals are exposed to higher received levels or sequential days of impacts.

Altogether, none of these species are listed as threatened or endangered under the ESA, only a portion of the stocks are anticipated to be impacted, and any individual beaked whale is likely to be disturbed at a moderate or sometimes low level. This low magnitude and moderate to lower severity of harassment effects is not expected to result in impacts on individual reproduction or survival, let alone annual rates of recruitment or survival. No mortality or Level A harassment is anticipated or authorized. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the CA/OR/WA stocks of beaked whales.

Dolphins and Small Whales

This section builds on the broader odontocete discussion above and brings together the discussion of the different types and amounts of take that different dolphin and small whale species and stocks are likely to incur, any additional applicable mitigation, and the status of the species and stocks to support the negligible impact determinations for each species or stock. For all dolphin and small whale stocks discussed here, no mortality or tissue damage from sonar or explosives is anticipated or authorized. No PTS from sonar or explosives is predicted, except for the CA/OR/WA stocks of Northern right whale dolphin and Pacific white-sided dolphin, for which one Level A harassment by PTS from testing activities is predicted for each stock.

In Table 55 below for dolphins and small whales, we indicate for each species and stock the total annual numbers of take by mortality, Level A harassment and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

TABLE 55—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR DOLPHINS AND SMALL WHALES IN THE NWTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes	Abundance (NMFS SARs)*	Instances of total take as percentage of abundance
		Level B harassment		Level A harassment		Mortality			
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage				
Family Delphinidae (dolphins) Family Ziphiidae (beaked whales)									
Common bottlenose dolphin.	CA/OR/WA Offshore	8	0	0	0	0	8	1,924	<1
Killer whale	Eastern North Pacific Alaska Resident.	34	0	0	0	0	34	2,347	1
	West Coast Transient.	210	22	0	0	0	232	243	95
	Eastern North Pacific Offshore.	152	5	0	0	0	157	300	52
	Eastern North Pacific Southern Resident.	49	2	0	0	0	51	75	68
Northern right whale dolphin.	CA/OR/WA	20,671	1,029	1	0	0	21,701	26,556	82
Pacific white-sided dolphin.	North Pacific	101	0	0	0	0	101	26,880	<1
	CA/OR/WA	19,593	1,372	1	0	0	20,966	26,814	78
Risso's dolphin	CA/OR/WA	6,080	275	0	0	0	6,355	6,336	100
Short-beaked common dolphin.	CA/OR/WA	2,103	46	0	0	0	2,149	969,861	<1
Short-finned pilot whale.	CA/OR/WA	87	1	0	0	0	88	836	11

TABLE 55—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR DOLPHINS AND SMALL WHALES IN THE NWTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE—Continued

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes	Abundance (NMFS SARs)*	Instances of total take as percentage of abundance
		Level B harassment		Level A harassment		Mortality			
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage				
Striped dolphin	CA/OR/WA	763	20	0	0	0	783	29,211	3

*Presented in the 2019 SARs or most recent SAR.

As described above, the large majority of Level B harassment by behavioral disturbance to odontocetes, and thereby dolphins and small whales, from hull-mounted sonar (MFAS) in the NWTT Study Area would result from received levels between 160 and 172 dB SPL. Therefore, the majority of takes by Level B harassment for dolphins and small whales are expected to be in the form of low to occasionally moderate responses of a generally shorter duration. As mentioned earlier in this section, we anticipate more severe effects from takes when animals are exposed to higher received levels or for longer durations. Occasional milder occurrences of Level B harassment by behavioral disturbance, as is expected here, are unlikely to cause long-term consequences for individual animals or populations that have any effect on reproduction or survival.

Research and observations show that if delphinids are exposed to sonar or other active acoustic sources they may react in a number of ways depending on their experience with the sound source and what activity they are engaged in at the time of the acoustic exposure. Delphinids may not react at all until the sound source is approaching within a few hundred meters to within a few kilometers depending on the environmental conditions and species. Some dolphin species (the more surface-dwelling taxa—typically those with ''dolphin'' in the common name, such as bottlenose dolphins, spotted dolphins, spinner dolphins, rough-toothed dolphins, *etc.,* but not Risso's dolphin), especially those residing in more industrialized or busy areas, have demonstrated more tolerance for disturbance and loud sounds and many of these species are known to approach vessels to bow-ride. These species are often considered generally less sensitive to disturbance. Dolphins and small whales that reside in deeper waters and generally have fewer interactions with human activities are more likely to demonstrate more typical avoidance reactions and foraging interruptions as described above in the odontocete overview.

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect dolphins and small whales through effects on annual rates of recruitment or survival.

Killer Whales (Eastern North Pacific Southern Resident Stock)

The Eastern North Pacific Southern Resident stock (Southern Resident killer whale DPS) is listed as endangered under the ESA. ESA-designated critical habitat for the Southern Resident killer whale DPS overlaps with the NWTT Study Area in the Strait of Juan de Fuca and Washington inland waters. No other biologically important areas for killer whales have been identified in the NWTT Study Area. The Eastern North Pacific Southern Resident stock is small (75 individuals) and has been decreasing in recent years. No mortality or Level A harassment is anticipated or authorized for the Eastern North Pacific Southern Resident stock of killer whales.

The Marine Species Coastal, Olympic Coast National Marine Sanctuary, Stonewall and Heceta Bank Humpback Whale, Point St. George Humpback Whale, and Puget Sound and Strait of Juan de Fuca Mitigation Areas overlap with important Eastern North Pacific Southern Resident (Southern Resident DPS) killer whale foraging and migration habitat, as described in the proposed rule and this final rule. The mitigation measures implemented in each of these areas include, but are not limited to, no MF1 MFAS use seasonally or limited MFAS use year round, no explosive training or restrictions on explosive training, and no explosive testing or restrictions on explosive testing. For complete details on mitigation measures for each area, see Table 50 and discussion in the *Mitigation Measures* section of this rule. As stated in the *Mitigation Areas* section of this final rule, new mitigation in the Puget Sound and Strait of Juan de Fuca Mitigation Area is designed to help avoid any potential impacts from training and testing on Southern Resident killer whales in NWTT Inland Waters. With implementation of these new mitigation measures, we do not anticipate any take of Southern Resident killer whales in NWTT Inland Waters due to NWTT training and testing activities.

Additionally, this final rule includes a new mitigation area, the Juan de Fuca Eddy Marine Species Mitigation Area, in which MF1 MFAS will be restricted and explosives prohibited. Waters within the Juan de Fuca Eddy Marine Species Mitigation Area (including areas off Cape Flattery) are important migration habitat for Eastern North Pacific Southern Resident killer whales as they transit between Inland Waters and the Offshore Area. In addition, Eastern North Pacific Southern Resident killer whales will benefit from the procedural mitigation measures described earlier in the *Mitigation Measures* section. All of these measures will reduce the severity of impacts to Eastern North Pacific Southern Resident (Southern Resident DPS) killer whales by reducing interference in feeding and migration that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good foraging opportunities or migration routes. Altogether, the mitigation measures in this final rule result in a significant reduction in activities likely to disturb Eastern North Pacific Southern Resident killer whales across a large portion of their range within the NWTT Study Area, and especially within inland waters.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance for the Eastern North Pacific Southern Resident stock is 68 percent. This information indicates that potentially half or more of the individuals in this stock may be impacted, though the more likely scenario is that a smaller portion than

that will be taken, and a subset of them will be taken multiple days with no indication that these days will be sequential.

Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower, to occasionally moderate, level and less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with killer whale communication or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, the Eastern North Pacific Southern Resident killer whale stock is listed as endangered under the ESA. Only a portion of this killer whale stock is anticipated to be impacted, and any individual is likely to be disturbed at a low-moderate level, with those individuals likely not disturbed on more than a few non-sequential days within a year. Even acknowledging the small and declining stock size of the Eastern North Pacific Southern Resident stock, this low magnitude and severity of harassment effects is unlikely to result in impacts on individual reproduction or survival, let alone have impacts on annual rates of recruitment or survival of the stock. No mortality or Level A harassment is anticipated or authorized for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Eastern North Pacific Southern Resident killer whale stock.

Killer Whales (Eastern North Pacific Alaska Resident, West Coast Transient, and Eastern North Pacific Offshore Stocks)

None of these killer whale stocks are listed under the ESA. No biologically important areas for killer whales have been identified in the NWTT Study Area, other than the Southern Resident ESA-designated critical habitat discussed above. The Eastern North Pacific Offshore stock is reported as ''stable,'' while the Eastern North Pacific Alaska Resident and West Coast Transient stocks have unknown population trends. No mortality or Level A harassment is anticipated or authorized for any of these stocks.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance ranges from 1 percent (Eastern North Pacific Alaska Resident) to 95 percent (West Coast Transient). This information indicates that only a very small portion of the Eastern North Pacific Alaska Resident stock is likely impacted and repeated exposures of individuals are not anticipated (*i.e.,* individuals are not expected to be taken on more than one day within a year). This information also indicates that potentially half or more of the individuals in the other two stocks may be impacted, though the more likely scenario is that a smaller portion than that will be taken, and a subset of them will be taken multiple days with no indication that these days will be sequential.

Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower, to occasionally moderate, level and less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with killer whale communication or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, these killer whale stocks are not listed under the ESA. Only a portion of each killer whale stock is anticipated to be impacted, and any individual is likely to be disturbed at a low-moderate level, with the taken individuals likely not disturbed on more than a few non-sequential days within a year. This low magnitude and severity of harassment effects is unlikely to result in impacts on individual reproduction or survival, let alone have impacts on annual rates of recruitment or survival of any of the stocks. No mortality or Level A harassment is anticipated or authorized for any of the stocks. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on these killer whale stocks.

All Other Dolphin and Small Whale Stocks

None of these stocks is listed under the ESA and their stock statuses are considered ''unknown,'' except for the CA/OR/WA stock of short-beaked common dolphin which is described as ''increasing.'' No biologically important areas for these stocks have been identified in the NWTT Study Area. No mortality or serious injury is anticipated or authorized. With the exception of one Level A harassment PTS take each for the CA/OR/WA stocks of Northern right whale dolphin and Pacific white-sided dolphin, no Level A harassment by PTS or tissue damage is expected or authorized for these stocks.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance ranges from less than 1 percent (North Pacific stock of Pacific white-sided dolphins, CA/OR/WA Offshore stock of common bottlenose dolphins, and CA/OR/WA stock of short-beaked common dolphins) to 100 percent (CA/OR/WA stock of Risso's dolphins). All stocks except for the CA/OR/WA stocks of Risso's dolphin, Pacific white-sided dolphin, and Northern right whale dolphin have estimated total instances of take compared to the abundances less than or equal to 11 percent. This information indicates that only a small portion of these stocks is likely impacted and repeated exposures of individuals are not anticipated. The CA/OR/WA stocks of Risso's dolphins, Pacific white-sided dolphin, and Northern right whale dolphin have estimated total instances of take compared to the abundances that range from 78 to 100 percent. This information indicates that up to half or more of the individuals of these stocks could be impacted, though the more likely scenario is that a smaller portion than that will be taken, and a subset of them will be taken on a few days, with no indication that these days will be sequential.

Regarding the severity of those individual takes by Level B harassment by behavioral disturbance, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower, to occasionally moderate, level and less likely to evoke a severe response). However, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options nearby. Regarding the severity

of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with dolphin and small whale communication or other important low-frequency cues, and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity (PTS) may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale the estimated one Level A harassment take by PTS for the CA/OR/WA stocks of Northern right whale dolphin and Pacific white-sided dolphin is unlikely to impact behaviors, opportunities, or detection capabilities to a degree that will interfere with reproductive success or survival of that individual. Thus the one Level A harassment take by PTS for these stocks is unlikely to affect rates of recruitment and survival for the stock.

Altogether, though the status of these stocks is largely unknown, none of these stocks is listed under the ESA and any individual is likely to be disturbed at a low to occasionally moderate level, with the taken individuals likely exposed on one to a few days. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival. One individual each from the CA/OR/WA stocks of Northern right whale dolphin and Pacific white-sided dolphin could be taken by PTS annually of likely low severity. A small permanent loss of hearing sensitivity (PTS) may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, but at the expected scale the estimated Level A harassment takes by PTS for the CA/OR/WA stocks of Northern right whale dolphin and Pacific white-sided dolphin is unlikely to impact behaviors, opportunities, or detection capabilities to a degree that will interfere with reproductive success or survival of those individuals, let alone annual rates of recruitment or survival, either alone, or in combination with the authorized Level B harassment. No mortality is anticipated or authorized. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on these stocks of small whales and dolphins.

Porpoises

This section builds on the broader odontocete discussion above and brings together the discussion of the different types and amounts of take that different porpoise species or stocks will likely incur, any additional applicable mitigation, and the status of the species and stocks to support the negligible impact determinations for each species or stock. For porpoises, there is no anticipated M/SI or tissue damage from sonar or explosives for any species.

In Table 56 below for porpoises, we indicate the total annual numbers of take by mortality, Level A harassment and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

TABLE 56—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR PORPOISES IN THE NWTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes	Abundance (NMFS SARs)*	Instances of total take as percentage of abundance
		Level B harassment		Level A harassment		Mortality			
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage				
Family Phocoenidae (porpoises)									
Dall's porpoise	Alaska	179	459	0	0	0	638	83,400	<1
	CA/OR/WA	13,407	20,290	98	0	0	33,795	25,750	131
Harbor porpoise	Southeast Alaska	92	38	0	0	0	130	1,354	10
	Nothern OR/WA Coast.	31,602	20,810	103	0	0	52,515	21,487	244
	Northern CA/Southern OR.	1,691	348	86	0	0	2,125	24,195	9
	Washington Inland Waters.	15,146	14,397	180	0	0	29,723	11,233	265

*Presented in the 2019 SARs or most recent SAR, including updates since publication of the proposed rule.

The majority of takes by harassment of harbor porpoises in the NWTT Study Area are caused by sources from the MFAS bin (which includes hull-mounted sonar) because they are high level sources at a frequency (1–10 kHz) which overlaps a more sensitive portion (though not the most sensitive) of the HF hearing range, and of the sources expected to result in take, they are used in a large portion of exercises (see Tables 3 and 4). Most of the takes (90 percent) from the MF1 bin in the NWTT Study Area would result from received levels between 148 and 166 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF4 = 99 percent between 124 and 142 dB SPL, MF4 = 97 percent between 124 and 148 dB SPL, MF5 = 97 percent between 118 and 142 dB SPL, and HF4 = 97 percent between 118 and 160 dB SPL. Given the levels they are exposed to and harbor porpoise sensitivity, some responses would be of a lower severity, but many would likely be considered moderate, but still of generally short duration.

Harbor porpoises have been shown to be particularly sensitive to human activity (Tyack *et al.,* 2011; Pirotta *et al.,* 2012). The information currently available regarding harbor porpoises suggests a very low threshold level of response for both captive (Kastelein *et al.,* 2000; Kastelein *et al.,* 2005) and wild (Johnston, 2002) animals. Southall *et al.* (2007) concluded that harbor porpoises are likely sensitive to a wide range of anthropogenic sounds at low received levels (approximately 90 to 120 dB). Research and observations of harbor porpoises for other locations show that this species is wary of human activity and will display profound avoidance behavior for anthropogenic

sound sources in many situations at levels down to 120 dB re: 1 μPa (Southall, 2007). Harbor porpoises routinely avoid and swim away from large motorized vessels (Barlow *et al.,* 1988; Evans *et al.,* 1994; Palka and Hammond, 2001; Polacheck and Thorpe, 1990). Harbor porpoises may startle and temporarily leave the immediate area of the training or testing until after the event ends. Accordingly, harbor porpoises have been assigned a lower behavioral harassment threshold, *i.e.,* a more distant distance cutoff (40 km for high source level, 20 km for moderate source level) and, as a result, the number of harbor porpoise taken by Level B harassment by behavioral disturbance through exposure to LFAS/MFAS/HFAS in the NWTT Study Area is generally higher than the other species. As mentioned earlier in the odontocete overview, we anticipate more severe effects from takes when animals are exposed to higher received levels or sequential days of impacts; occasional low to moderate behavioral reactions are unlikely to affect reproduction or survival. Some takes by Level B harassment by behavioral disturbance could be in the form of a longer (several hours or a day) and more moderate response, but unless they are repeated over more than several sequential days, impacts to reproduction or survival are not anticipated.

While harbor porpoises have been observed to be especially sensitive to human activity, the same types of responses have not been observed in Dall's porpoises. Dall's porpoises are typically notably longer than, and weigh more than twice as much as, harbor porpoises, making them generally less likely to be preyed upon and likely differentiating their behavioral repertoire somewhat from harbor porpoises. Further, they are typically seen in large groups and feeding aggregations, or exhibiting bow-riding behaviors, which is very different from the group dynamics observed in the more typically solitary, cryptic harbor porpoises, which are not often seen bow-riding. For these reasons, Dall's porpoises are not treated as an especially sensitive species (versus harbor porpoises which have a lower behavioral harassment threshold and more distant cutoff) but, rather, are analyzed similarly to other odontocetes (with takes from the sonar bin in the NWTT Study Area resulting from the same received levels reported in the *Odontocete* section above). Therefore, the majority of Level B harassment by behavioral disturbance is expected to be in the form of milder responses compared to higher level exposures. As mentioned earlier in this section, we anticipate more severe effects from takes when animals are exposed to higher received levels.

We note that both Dall's and harbor porpoises, as HF-sensitive species, have a lower PTS threshold than other groups and therefore are generally likely to experience larger amounts of TTS and PTS, and NMFS accordingly has evaluated and authorized higher numbers. Also, however, regarding PTS from sonar exposure, porpoises are still likely to avoid sound levels that would cause higher levels of TTS (greater than 20 dB) or PTS. Therefore, even though the number of TTS takes are higher than for other odontocetes, any PTS is expected to be at a lower level and for all of the reasons described above, TTS and PTS takes are not expected to impact reproduction or survival of any individual.

All Porpoise Stocks

These Dall's and harbor porpoise stocks are not listed under the ESA and the status of these stocks is considered ''unknown.'' No biologically important areas have been identified for Dall's and harbor porpoises in the NWTT Study Area. However, a known important feeding area for harbor porpoises overlaps with the Stonewall and Heceta Bank Humpback Whale Mitigation Area. No MF1 MFAS or explosives will be used in this mitigation area from May 1—November 30, which will reduce the severity of impacts to harbor porpoises by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities. No mortality or Level A harassment from tissue damage is expected or authorized for any of these stocks.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), the number of estimated total instances of take compared to the abundance ranges from less than 1 percent for the Alaska stock of Dall's porpoises to 265 percent for the Washington Inland Waters stock of harbor porpoises. The Alaska stock of Dall's porpoises, and the Southeast Alaska and Northern California/Southern Oregon stocks of harbor porpoises have estimated total instances of take compared to the abundances less than or equal to 10 percent. This information indicates that only a small portion of these stocks is likely impacted and repeated exposures of individuals are not anticipated (*i.e.,* individuals are not expected to be disturbed on more than one day a year). The CA/OR/WA stock of Dall's porpoises and the Northern Washington/Oregon Coast and Washington Inland Waters stocks of harbor porpoises have estimated total instances of take compared to the abundances that range from 131 to 265 percent. This information indicates that likely half or more, and potentially the majority of the individuals of these stocks could be impacted, though the more likely scenario is that a smaller portion will be taken, and a subset of those will be taken on up to 5 or 6 days, with no indication that these days will be sequential. In the proposed rule, we stated that due to the potential number of repeated takes of some individuals it was possible that some small number of females could forego reproduction for a year. Since the proposed rule, we have reevaluated the estimated number of harassment takes, where the potential number of repeated takes annually is limited to 5 or 6 days with no indication of take on sequential days, and determined that foregone reproduction is unlikely to occur.

Regarding the severity of those individual takes by Level B harassment by behavioral disturbance for harbor porpoises, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 166 dB, which for harbor porpoise (which have a lower threshold for Level B harassment by disturbance) would be considered a moderate level. Regarding the severity of those individual takes by Level B harassment by behavioral disturbance for Dall's porpoises, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower, to occasionally moderate, level and less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-moderate level, of short duration, and mostly not in a frequency band that would be expected to interfere with communication or other important low-frequency cues. The associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

No Level A harassment by PTS is anticipated or authorized for the Southeast Alaska stock of harbor porpoise or the Alaska stock of Dall's porpoise. For the remaining porpoise stocks, for the same reasons explained above for TTS (low level and the likely frequency band), while a small permanent loss of hearing sensitivity

may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the estimated annual Level A harassment takes by PTS for these three stocks of harbor porpoises and one stock of Dall's porpoises (86 to 180) will be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that will interfere with reproductive success or survival. In the proposed rule, we stated that due to the estimated number of PTS takes it was possible that some small number of females could incur a higher degree of PTS that could interfere with their successful reproduction and growth. Since the proposed rule, we have reevaluated the likelihood of PTS impacts of a higher degree and determined that they are unlikely to occur, given the anticipated avoidance of loud sounds at the distances and durations necessary to incur more severe PTS.

Altogether, the status of the harbor porpoise stocks is unknown, however harbor porpoises are not listed as endangered or threatened under the ESA. Because harbor porpoises are particularly sensitive, it is likely that a fair number of the Level B harassment behavioral responses of individuals will be of a moderate nature. Additionally, as noted, some portion of the stocks may be taken repeatedly on up to 5 or 6 non-sequential days within a year, however this is not anticipated to affect the stocks' annual rates of recruitment or survival. Some individuals (86 to 180) from the Northern Oregon/Washington Coast, Northern California/Southern Oregon, and Washington Inland Waters stocks of harbor porpoises could be taken by PTS annually of likely low severity. A small permanent loss of hearing sensitivity (PTS) may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, but at the expected scale the estimated Level A harassment takes by PTS for these stocks is unlikely, alone or in combination with the Level B harassment take by behavioral disturbance, to impact behaviors, opportunities, or detection capabilities to a degree that will interfere with reproductive success or survival of any individuals, let alone annual rates of recruitment or survival. No mortality is anticipated or authorized. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on all four stocks of harbor porpoises.

Altogether, the status of the Dall's porpoise stocks is unknown, however Dall's porpoises are not listed as endangered or threatened under the ESA. Any individual Dall's porpoise is likely to be disturbed at a low-moderate level, with the taken individuals likely exposed on one to a few days. This low magnitude and low-moderate severity of Level B harassment effects is not expected to result in impacts on individual reproduction or survival, much less annual rates of recruitment or survival. Some individuals (98) from the CA/OR/WA stock of Dall's porpoises could be taken by PTS annually of likely low severity. A small permanent loss of hearing sensitivity (PTS) may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, but at the expected scale the estimated Level A harassment takes by PTS for this stock are unlikely, alone or in combination with the Level B harassment take by behavioral disturbance, to impact behaviors, opportunities, or detection capabilities to a degree that will interfere with reproductive success or survival of any individuals, let alone annual rates of recruitment or survival. No mortality is anticipated or authorized. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on these two stocks of Dall's porpoises.

Pinnipeds

This section builds on the broader discussion above and brings together the discussion of the different types and amounts of take that different species and stocks of pinnipeds will likely incur, the applicable mitigation, and the status of the species and stocks to support the negligible impact determinations for each species or stock. We have described (above in the *General Negligible Impact Analysis* section) the unlikelihood of any masking having effects that will impact the reproduction or survival of any of the individual marine mammals affected by the Navy's activities. We have also described in the *Potential Effects of Specified Activities on Marine Mammals and their Habitat section* of the proposed rule that the specified activities would not have adverse or long-term impacts on marine mammal habitat, and therefore the unlikelihood of any habitat impacts affecting the reproduction or survival of any individual marine mammals affected by the Navy's activities. For pinnipeds, there is no mortality or serious injury and no Level A harassment from tissue damage from sonar or explosives anticipated or authorized for any species. Here, we include information that applies to all of the pinniped species and stocks.

In Table 57 below for pinnipeds, we indicate the total annual numbers of take by mortality, Level A harassment and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

This final rule reflects an updated abundance estimate for the Washington Northern Inland Waters stock, Hood Canal stock, and Southern Puget Sound stock of harbor seal. The Navy derived an in-water harbor seal abundance of 3,116 for Washington Northern Inland Waters by summing abundances for Admiralty Inlet (516), East Whidbey (1,926), and South Whidbey (674) from Smultea *et al.,* (2017). Smultea *et al.* (2017) did not provide an abundance or correction factor for animals hauled out of the water in these locations. Therefore, the Navy utilized a correction factor of 1.53 (Huber *et al.,* 2001), but it is important to note that this correction factor applies for counts of hauled-out animals (*e.g.,* animals hauled out multiplied by the correction factor for animals in-water = total abundance). Therefore, the Navy applied a ''reverse'' correction factor (3,116/0.53 = 5,879) to account for hauled-out animals. In addition, Smultea *et al.* (2017) did not survey the Strait of Juan de Fuca and San Juan Islands for harbor seals. However, NMFS includes the Strait and San Juan Islands as part of the WA Northern Inland Waters stock in the SAR. Thus, the abundance (13,775 seals) calculated to estimate a density, based on haul-out counts by S. Jeffries in summer 2013 and 2014, is added to the Smultea *et al.* total abundance. Therefore, the total stock abundance estimate is equal to the sum of the in-water abundance plus the estimated abundance of hauled-out animals, plus the abundance for the Strait of Juan de Fuca and San Juan Islands, (3,116 + 5,879 + 13,775 = 22,770 total harbor seals in Washington Northern Inland Waters). NMFS concurs with this assessment and uses 22,770 as the abundance estimate for the Washington Northern Inland Waters stock of harbor seal in this final rule.

Regarding the Hood Canal stock, Jefferson *et al.* (2017) estimates an in-water abundance of 2,009 harbor seals in the Hood Canal study region. The in-water abundance provided in Jefferson *et al.* (2017) did not provide an abundance or correction factor for animals hauled out of the water. Therefore, the Navy utilized a correction

factor of 1.53 (Huber *et al.,* 2001), but, as explained above, this correction factor applies for counts of hauled-out animals (*e.g.,* animals hauled out multiplied by the correction factor for animals in-water = total abundance). Therefore, the Navy applied the same ''reverse'' correction factor (2,009/0.53 = 3,791) to account for animals hauled out. Therefore, the total stock abundance estimate is equal to the sum of the in-water abundance plus the estimated abundance of hauled-out animals (2,009 + 3,791 = 5,800 total Hood Canal harbor seals). NMFS concurs with this assessment and uses 5,800 as the abundance estimate for the Hood Canal stock of harbor seal in this final rule.

The Navy derived an in-water harbor seal abundance estimate of 4,042 for the Southern Puget Sound stock by summing in-water abundances for Bainbridge (301), Seattle (252), Southern Puget Sound (2,905), and Vashon (584) included in Smultea *et al.* (2017). Smultea *et al.* (2017) did not provide an abundance or correction factor for animals hauled out of the water in these locations. Therefore, the Navy utilized the same correction factor of 1.53 (Huber *et al.,* 2001). But as with the two stocks discussed above, the correction factor applies for counts of hauled-out animals (*e.g.,* animals hauled out × the correction factor for animals in-water = total abundance). Therefore, the Navy applied the same ''reverse'' correction factor (4,042/0.53 = 7,626), to account for hauled-out animals. Therefore, the total stock abundance estimate is equal to the sum of the in-water abundance plus the estimated abundance of hauled-out animals (4,042 + 7,626 = 11,668 total harbor seals in WA Southern Puget Sound). NMFS concurs with this assessment and uses 11,668 as the abundance estimate for the Southern Puget Sound stock of harbor seal in this final rule.

TABLE 57—ANNUAL ESTIMATED TAKES BY LEVEL B HARASSMENT, LEVEL A HARASSMENT, AND MORTALITY FOR PINNIPEDS IN THE NWTT STUDY AREA AND NUMBER INDICATING THE INSTANCES OF TOTAL TAKE AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes	Abundance (NMFS SARs)*	Instances of total take as percentage of abundance
		Level B harassment		Level A harassment		Mortality			
		Behavioral disturbance	TTS (may also include disturbance)	PTS	Tissue damage				
Suborder Pinnipedia									
Family Phocidae (eared seals and sea lions)									
California sea lion	U.S.	23,756	342	1	0	0	24,099	257,606	9
Guadelupe fur seal	Mexico to California	1,482	13	0	0	0	1,495	34,187	4
Northern fur seal	Eastern Pacific	11,462	130	0	0	0	11,592	620,660	2
	California	231	1	0	0	0	232	14,050	2
Steller sea lion	Eastern U.S.	2,231	7	0	0	0	2,238	43,201	5
Family Phocidae (true seals)									
Harbor seal	Southeast Alaska (Clarence Strait).	2,077	275	0	0	0	2,352	27,659	9
	OR/WA Coast	540	640	2	0	0	1,182	24,732	5
	Washington Northern Inland Waters.	870	377	5	0	0	1,252	[1] 22,770	5
	Hood Canal	38,430	23,040	1	0	0	61,471	[1] 5,800	1,060
	Southern Puget Sound.	3,274	3,564	4	0	0	6,842	[1] 11,668	59
Northern Elephant seal.	California	4,134	710	4	0	0	4,848	179,000	3

* Presented in the 2019 SARs or most recent SAR except where noted otherwise.

[1] Recent survey data in the inland waters has not been incorporated into the SARs for these specific stocks, therefore we have used recent Navy abundance estimates for these stocks for the negligible impact analysis. These abundance estimates are described in detail in this section of the rule.

As described above, the majority of takes by harassment of pinnipeds in the NWTT Study Area are caused by sources from the MFAS bin (which includes hull-mounted sonar) because they are high level sources at a frequency (1–10 kHz) which overlaps the most sensitive portion of the pinniped hearing range, and of the sources expected to result in take, they are used in a large portion of exercises (see Tables 3 and 4). Most of the takes (97 percent) from the MF1 bin in the NWTT Study Area would result from received levels between 166 and 178 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF4 = 97 percent between 130 and 160 dB SPL, MF4 = 99 percent between 142 and 172 dB SPL, MF5 = 97 percent between 130 and 160 dB SPL, and HF4 = 99 percent between 100 and 172 dB SPL. Given the levels they are exposed to and pinniped sensitivity, most responses will be of a lower severity, with only occasional responses likely to be considered moderate, but still of generally short duration.

As mentioned earlier in this section, we anticipate more severe effects from takes when animals are exposed to higher received levels. Occasional milder takes by Level B harassment by behavioral disturbance are unlikely to cause long-term consequences for individual animals or populations, especially when they are not expected to be repeated over multiple sequential days. For all pinnipeds, harassment takes from explosives (behavioral disturbance, TTS, or PTS if present) comprise a very small fraction of those caused by exposure to active sonar.

Because the majority of harassment take of pinnipeds results from narrowband sources in the range of 1–10 kHz, the vast majority of threshold shift caused by Navy sonar sources will typically occur in the range of 2–20 kHz. This frequency range falls within the range of pinniped hearing, however, pinniped vocalizations typically span a somewhat lower range than this (<0.2 to 10 kHz) and threshold shift from active sonar will often be in a narrower band (reflecting the narrower band source that caused it), which means that TTS

incurred by pinnipeds will typically only interfere with communication within a portion of a pinniped's range (if it occurred during a time when communication with conspecifics was occurring). As discussed earlier, it would only be expected to be of a short duration and relatively small degree. Many of the other critical sounds that serve as cues for navigation and prey (*e.g.,* waves, fish, invertebrates) occur below a few kHz, which means that detection of these signals will not be inhibited by most threshold shifts either. The very low number of takes by threshold shifts that might be incurred by individuals exposed to explosives will likely be lower frequency (5 kHz or less) and spanning a wider frequency range, which could slightly lower an individual's sensitivity to navigational or prey cues, or a small portion of communication calls, for several minutes to hours (if temporary) or permanently.

Regarding behavioral disturbance, research and observations show that pinnipeds in the water may be tolerant of anthropogenic noise and activity (a review of behavioral reactions by pinnipeds to impulsive and non-impulsive noise can be found in Richardson *et al.* (1995) and Southall *et al.* (2007)). Available data, though limited, suggest that exposures between approximately 90 and 140 dB SPL do not appear to induce strong behavioral responses in pinnipeds exposed to non-pulse sounds in water (Costa *et al.,* 2003; Jacobs and Terhune, 2002; Kastelein *et al.,* 2006c). Based on the limited data on pinnipeds in the water exposed to multiple pulses (small explosives, impact pile driving, and seismic sources), exposures in the approximately 150 to 180 dB SPL range generally have limited potential to induce avoidance behavior in pinnipeds (Blackwell *et al.,* 2004; Harris *et al.,* 2001; Miller *et al.,* 2004). If pinnipeds are exposed to sonar or other active acoustic sources they may react in a number of ways depending on their experience with the sound source and what activity they are engaged in at the time of the acoustic exposure. Pinnipeds may not react at all until the sound source is approaching within a few hundred meters and then may alert, ignore the stimulus, change their behaviors, or avoid the immediate area by swimming away or diving. Effects on pinnipeds in the NWTT Study Area that are taken by Level B harassment, on the basis of reports in the literature as well as Navy monitoring from past activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring). Most likely, individuals will simply move away from the sound source and be temporarily displaced from those areas, or not respond at all, both of which will have no effect on reproduction or survival of the individuals. In areas of repeated and frequent acoustic disturbance, some animals may habituate or learn to tolerate the new baseline or fluctuations in noise level. 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). While some animals may not return to an area, or may begin using an area differently due to training and testing activities, most animals are expected to return to their usual locations and behavior. Given their documented tolerance of anthropogenic sound (Richardson *et al.,* 1995 and Southall *et al.,* 2007), repeated exposures of individuals of any of these species to levels of sound that may cause Level B harassment are unlikely to result in permanent hearing impairment or to significantly disrupt (through direct disturbance or opportunities lost during TTS) foraging, resting, or reproductive behaviors in a manner that would reduce reproductive success or health. Thus, even repeated Level B harassment of some subset of individuals of an overall stock is unlikely to result in any significant realized decrease in fitness to those individuals that would result in any effect on rates of recruitment or survival for the stock as a whole.

Of these stocks, only Guadalupe fur seals are listed under the ESA (as threatened), with the SAR indicating the stock is ''increasing.'' No critical habitat is designated under the ESA for the Guadalupe fur seal. The other stocks are not ESA-listed. There is an active UME for Guadalupe fur seals. Since 2015 there have been 400 strandings of Guadalupe fur seals (including live and dead seals). The California sea lion UME was recently closed as elevated strandings occurred from 2013–2016. All of the other pinniped stocks are considered ''increasing,'' ''stable,'' or ''unknown'' except for Northern fur seals (Eastern Pacific stock), which is considered to be ''declining.'' There are no known biologically important areas for any of the pinniped stocks. No mortality or Level A harassment from tissue damage is anticipated or authorized. All the pinniped species and stocks discussed in this section will benefit from the procedural mitigation measures described earlier in the *Mitigation Measures* section.

Regarding the magnitude of takes by Level B harassment (TTS and behavioral disturbance), with the exception of the Hood Canal and Southern Puget Sound stocks of harbor seals, the number of estimated total instances of take compared to the abundance is 2–9 percent. Given this information and the ranges of these stocks (*i.e.,* large ranges, but with individuals often staying in the vicinity of haulouts), only a small portion of individuals in the stock are likely impacted and repeated exposures of individuals are not anticipated (*i.e.,* individuals are not expected to be taken on more than one day within a year). For the Southern Puget Sound stock of harbor seals, the number of estimated total instances of take compared to the abundance is 59 percent. This information indicates that fewer than half of the individuals in this stock are likely impacted, with those individuals likely not disturbed on more than a few non-sequential days a year.

For the Hood Canal stock of harbor seals, the number of estimated total instances of take compared to the abundance is 1,060 percent. This information indicates that all individuals of this stock could be impacted, though the more likely scenario is that some individuals may not be taken at all, some may be taken on 10 or fewer days per year, and some could be taken on more than 10 and up to 21 days a year. For those individuals taken on a higher number of days, some of those days may be sequential. Though the majority of impacts are expected to be of a lower to sometimes moderate severity, the repeated takes over some number of sequential days for some individuals in the Hood Canal stock of harbor seals makes it more likely that some small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year (energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal). We note, though, that there is documented evidence of an increasing population for Hood Canal harbor seals, despite high levels of acoustic activity in their habitat, including pile driving, pierside sonar maintenance/testing, and testing activities in Dabob Bay. This documented expansion includes, for

example, pupping on the Naval Base Kitsap Bangor waterfront in recent years. As noted previously, however, foregone reproduction (especially for only one year within seven, which is the maximum predicted because the small number anticipated in any one year makes the probability that any individual will be impacted in this way twice in seven years very low) has far less of an impact on population rates than mortality and the relatively small number of instances of foregone reproduction that could occur are not expected to adversely affect the stock through effects on annual rates of recruitment or survival. Regarding the severity of those individual takes by Level B harassment by behavioral disturbance for all pinniped stocks, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 178 dB, which is considered a relatively low to occasionally moderate level for pinnipeds. However, as noted, for the Hood Canal stock of harbor seals, some of these takes could occur on some number of sequential days.

Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with pinniped communication or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the 1–5 estimated takes by Level A harassment by PTS for California sea lions, Northern elephant seals, and the Washington Northern Inland Waters, Hood Canal, OR/WA Coast, and Southern Puget Sound stocks of harbor seals is unlikely to impact behaviors, opportunities, or detection capabilities to a degree that will interfere with reproductive success or survival of any individuals.

Altogether, all pinniped stocks are considered ''increasing,'' ''stable,'' or ''unknown'' except for Northern fur seals (Eastern Pacific stock), which is considered ''declining'' but is not listed under the ESA. Only the Guadalupe fur seal is listed under the ESA, with a population that is considered increasing. No mortality for pinnipeds is anticipated or authorized. No more than five individuals from any pinniped stock are estimated to be taken by PTS, of likely low severity, annually. Additionally, no PTS is expected for Guadalupe fur seal, Northern fur seal, Steller sea lion, and the Southeast Alaska (Clarence Strait) stock of harbor seal. A small permanent loss of hearing sensitivity (PTS) may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, but at the expected scale the estimated Level A harassment takes by PTS for these stocks are unlikely, alone or in combination with the Level B harassment take, to impact behaviors, opportunities, or detection capabilities to a degree that will interfere with reproductive success or survival of any individuals, let alone annual rates of recruitment or survival. For nearly all pinniped stocks (with the exception of the Hood Canal stock of harbor seals) only a portion of the stocks are anticipated to be taken by Level B harassment and any individual is likely to be disturbed at a low-moderate level on no more than a few non-sequential days per year. Even considering the effects of the UME on the Guadalupe fur seal, this low magnitude and severity of harassment effects will not result in impacts on individual reproduction or survival, much less annual rates of recruitment or survival. For the Hood Canal stock of harbor seals, a fair portion of individuals will be taken by Level B harassment (at a moderate or sometimes low level) over a comparatively higher number of days within a year, and some smaller portion of those individuals may be taken on sequential days. However, we do not anticipate the relatively small number of individual harbor seals that might be taken over repeated days within the year in a manner that results in one year of foregone reproduction to adversely affect the stock through effects on rates of recruitment or survival, given the status of the stock. For these reasons, in consideration of all of the effects of the Navy's activities combined, we have determined that the authorized take will have a negligible impact on all stocks of pinnipeds.

Determination

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 monitoring and mitigation measures, NMFS finds that the total marine mammal take from the specified activities will have a negligible impact on all affected marine mammal species or stocks.

Subsistence Harvest of Marine Mammals

In order to issue an incidental take authorization, NMFS must find that the total estimated take will not have an ''unmitigable adverse impact'' on the availability of the affected marine mammal species or stocks for taking for subsistence uses 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.

When applicable, NMFS must prescribe means of effecting the least practicable adverse impact on the availability of the species or stocks for subsistence uses. As discussed in the *Mitigation Measures* section, evaluation of potential mitigation measures includes consideration of two primary factors: (1) The manner in which, and the degree to which, implementation of the potential measure(s) is expected to reduce adverse impacts on the availability of species or stocks for subsistence uses, and (2) the practicability of the measure(s) for applicant implementation.

Subsistence harvest in Southeast Alaska is primarily focused on harbor seals, with occasional harvest of sea lions (Wolfe *et al.* 2013). To our knowledge, no whaling occurs in the NWTT Study Area. Testing activities in Western Behm Canal are the only activities within the NWTT Study Area that have the potential to overlap with subsistence uses of marine mammals.

Four Alaskan Native communities are located in the Behm Canal area: Central Council of the Tlingit and Haida Indian Tribes, Ketchikan Indian Corporation, Organized Village of Saxman, and Metlakatla Indian Community, Annette Island Reserve.

The Tlingit and Haida people retain a life that is strongly based on subsistence, including the use of harbor seals and sea lions for food and raw materials (Wolfe *et al.* 2013). Harbor seals are taken during all months; peak harvests occur during spring and during fall/early winter. The lowest harvest occurs in the summer months (Wolfe *et al.* 2013). In most communities, hunters

use the waters and coastlines adjacent to their home to harvest seals, with travel ranging from 5 to 32.6 mi (8 to 52.5 km) (Davis 1999). While there is large overlap in the core use areas of the Ketchikan and Saxman communities, harvest of seals within Western Behm Canal is more common from the Ketchikan community (Davis 1999). Hunters from the Ketchikan community primarily take seals off Revillagigedo Island. They also harvest seals in areas north of Ketchikan into the northern mouth of Western Behm Canal near Betton Island (Davis, 1999). The Metlakatla Indian Community is located on Annette Island, in the Clarence Strait opposite of Ketchikan. NMFS is unaware of any harvest of harbor seals within Western Behm Canal from hunters in Metlakatla Indian Community.

No information has been provided by these communities regarding how the Navy's activities may impact the availability of marine mammals for Alaskan Native subsistence uses. The Navy sent communications to the four tribes at both the regional and community level at multiple stages throughout the NWTT rulemaking and SEIS/OEIS processes, including an invitation to initiate government to government consultation. Additionally, the Installation Environmental Director for Naval Base Kitsap, who oversees natural resources management at the Navy's Southeast Alaska Acoustic Facility (SEAFAC), met with representatives from the Ketchikan Indian Corporation and the Organized Village of Saxman to discuss the Facility and its operations in March 2019. During this face to face meeting and tour of the facility, the Tribes did not raise concern regarding their ability to harvest marine mammals.

In addition to these communications, the Navy followed up in April 2020 with a specific request to the four communities for any concerns regarding potential impacts of the Navy's proposed activities in the Western Behm Canal on the availability of marine mammal species or stocks for Alaska Native subsistence use. The Navy again contacted the tribes in May 2020, following up on their request. To date, neither the Navy nor NMFS have received correspondence from Alaska Native groups regarding subsistence use, or any other concern with the MMPA rulemaking and authorizations.

In Western Behm Canal, seals and sea lions are estimated to be taken by Level B harassment by behavioral disturbance and TTS only. Given the minor and temporary nature of the takes, and the temporary nature of the activity, we do not expect these impacts to cause the animals to avoid or abandon an area where subsistence harvest typically occurs.

The Navy's testing area in Western Behm Canal includes five restricted areas (see Figure 2–4 in the Navy's rulemaking/LOA application); the largest, Area 5, spans the width of Western Behm Canal and encompasses Areas 1, 2, and 3. During operations, the Navy can close the restricted areas to all vessel traffic. Typically, such closures do not exceed 20 minutes. Public notifications (Notices to Mariners) announcing restricted access have been issued 10 times per year on average; about 8–12 events occur annually that require restrictions on vessel traffic to ensure that the Navy vessel (usually a submarine, which is out of the visual observation of small boat operators) has a clear sea space to navigate safely. Notices to Mariners usually extend for a period of four or five days, but limitations on vessel traffic typically last for 20 minutes and occur up to twice per hour. During these times, small vessels (30 ft or less) transiting through Western Behm Canal are required to stay within 1,000 yd. of the shoreline, maintain a maximum speed of 5 knots, and be in radio contact with SEAFAC. The Navy uses the radio contact to ensure that all vessels comply with the navigation rules during these critical periods. On occasion, the engine of a transiting vessel may create noise that interferes with data collection during a test. When this occurs, SEAFAC may request that the vessel operator voluntarily turn off the engine during the period of data collection. Alternatively, SEAFAC may delay data collection until the vessel has cleared the area. When testing is not being conducted, vessel traffic is not restricted, but permanent restrictions on anchors, nets, towing, and dumping remain in force. Additional information on transiting the restricted areas in Western Behm Canal is provided in 33 CFR 334.1275 (Western Behm Canal, Ketchikan, Alaska, restricted areas).

NMFS does not expect that these occasional 20-minute closures and associated restrictions will displace subsistence users, as the closures are limited, short term, and affect a limited portion of Western Behm Canal.

The Notice to Mariners notifying government agencies and the public that the Navy will conduct operations and restrict access in Western Behm Canal will be provided at least 72 hours in advance to the Central Council of the Tlingit and Haida Indian Tribes, Ketchikan Indian Corporation, Organized Village of Saxman, and Metlakatla Indian Community, Annette Island Reserve, as well as the U.S. Coast Guard, Ketchikan Gateway Borough Planning Department, Harbor Master, Alaska Department of Fish and Game, KRBD radio, KTKN radio, and the Ketchikan Daily News.

NMFS expects that subsistence harvest activities would most likely occur close to the shoreline along Betton Island, as well as some of the neighboring smaller islands (including Back Island), when receding tidal waters expose the shoreline, and animals haulout. There are no Navy activities that would create a physical barrier between subsistence users and marine mammals in nearshore areas. In the offshore area, the temporary presence of vessels (boats, submarines, *etc.*) and operational equipment needed to conduct the testing activities may block preferred navigational paths; however, the presence of vessels and equipment will be temporary, and easy to navigate around. Therefore, we do not expect the presence of these vessels and equipment to create a physical barrier between subsistence hunters and marine mammals.

Further offshore within Western Behm Canal, the Navy has in-water structures which include two sites: the underway site and the static site, located in the five restricted areas discussed above. The underway site and static site are existing testing structures that are required for conducting testing operations. The in-water structures located at the underway site and static site are easy to navigate around, and we do not expect their presence to impact subsistence harvests.

Overall, physical barriers associated with the Navy's activities will be limited to the temporary presence of additional vessels (boats, submarines, *etc.*) and other operational equipment needed to conduct the testing activities, including the reading of those vessels' acoustic signatures. Vessels will only be present temporarily and are easy to navigate around and avoid. Therefore, we do not expect the Navy's action to create a physical barrier that will limit the ability of subsistence harvest by Alaskan Natives.

Based on NMFS having no information indicating that the Navy's activity in Western Behm Canal will affect Alaskan Native subsistence activities and the location and nature of the Navy's activity, NMFS has determined that the total taking of affected species or stocks will not have an unmitigable adverse impact on the availability of the species or stocks for taking for subsistence uses.

Classification

Endangered Species Act

There are seven marine mammal species under NMFS jurisdiction that are listed as endangered or threatened under the ESA (16 U.S.C. 1531 *et seq.*) with confirmed or possible occurrence in the NWTT Study Area: blue whale, fin whale, humpback whale (Mexico and Central America DPSs), sei whale, sperm whale, killer whale (Southern Resident killer whale DPS), and Guadalupe fur seal. The Southern Resident killer whale has critical habitat designated under the ESA in the NWTT Study Area. On September 19, 2019, NMFS proposed to revise ESA-designated critical habitat for Southern Resident killer whales (84 FR 49214). In addition, on October 9, 2019, NMFS published a proposed rule to designate ESA critical habitat for the Central America, Mexico, and Western North Pacific DPSs of humpback whales (84 FR 54354). Neither ESA critical habitat rule has been finalized.

The Navy consulted with NMFS pursuant to section 7 of the ESA for NWTT activities, and NMFS also consulted internally on the promulgation of this rule and the issuance of LOAs under section 101(a)(5)(A) of the MMPA. NMFS issued a biological opinion concluding that the promulgation of the rule and issuance of subsequent LOAs are not likely to jeopardize the continued existence of threatened and endangered species under NMFS' jurisdiction and are not likely to result in the destruction or adverse modification of designated or proposed critical habitat in the NWTT Study Area. The biological opinion is available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

National Marine Sanctuaries Act

Federal agency actions that are likely to injure sanctuary resources are subject to consultation with NOAA's Office of National Marine Sanctuaries (ONMS) under section 304(d) of the National Marine Sanctuaries Act (NMSA; 16 U.S.C. 1431 *et seq.*).

On April 29, 2020, NMFS and the Navy jointly requested consultation with ONMS and submitted a Sanctuary Resource Statement (SRS), as the Navy concluded that their training and testing activities in the NWTT Study Area may incidentally expose sanctuary resources that reside within Olympic Coast National Marine Sanctuary (NMS) to sound and other environmental stressors, and NMFS concluded that proposed MMPA regulations and associated LOAs that would allow the Navy to incidentally take marine mammals include a subset of those impacts that could occur to NMS resources.

After discussions with the ONMS, NMFS and the Navy submitted a revised SRS on July 8, 2020. ONMS reviewed the SRS, and on July 15, 2020, ONMS found the SRS sufficient for the purposes of making an injury determination and developing recommended alternatives as required by the NMSA. On August 28, 2020, ONMS provided its injury determination and three recommended alternatives to minimize injury and to protect sanctuary resources. NMFS and the Navy submitted a joint response to the ONMS recommended alternatives. Consultation under the NMSA is now concluded.

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 evaluate our proposed actions and alternatives with respect to potential impacts on the human environment. NMFS participated as a cooperating agency on the 2020 NWTT FSEIS/OEIS, which was published on September 18, 2020, and is available at *https://nwtteis.com/.* In accordance with 40 CFR 1506.3, NMFS independently reviewed and evaluated the 2020 NWTT FSEIS/OEIS and determined that it is adequate and sufficient to meet our responsibilities under NEPA for the issuance of this rule and associated LOAs. NOAA therefore, has adopted the 2020 NWTT FSEIS/OEIS. NMFS has prepared a separate Record of Decision. NMFS' Record of Decision for adoption of the 2020 NWTT FSEIS/OEIS and issuance of this final rule and subsequent LOAs can be found at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

Regulatory Flexibility Act

The Office of Management and Budget has determined that this rule is not significant for purposes of Executive Order 12866.

Pursuant to the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), the Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

Waiver of Delay in Effective Date

NMFS has determined that there is good cause under the Administrative Procedure Act (APA; 5 U.S.C. 553(d)(3)) to waive the 30-day delay in the effective date of this final rule. No individual or entity other than the Navy is affected by the provisions of these regulations. The Navy has requested that this final rule take effect on or before November 9, 2020, to accommodate the Navy's LOAs that expire on November 8, 2020, so as to not cause a disruption in training and testing activities. The waiver of the 30-day delay of the effective date of the final rule will ensure that the MMPA final rule and LOAs are in place by the time the previous authorizations expire. Any delay in effectiveness of the final rule would result in either: (1) A suspension of planned naval training and testing, which would disrupt vital training and testing essential to national security; or (2) the Navy's procedural non-compliance with the MMPA (should the Navy conduct training and testing without LOAs), thereby resulting in the potential for unauthorized takes of marine mammals. Moreover, the Navy is ready to implement the regulations immediately. For these reasons, NMFS finds good cause to waive the 30-day delay in the effective date. In addition, the rule authorizes incidental take of marine mammals that would otherwise be prohibited under the statute. Therefore, by granting an exception to the Navy, the rule relieves restrictions under the MMPA, which provides a separate basis for waiving the 30-day effective date for the rule under section 553(d)(1) of the APA.

List of Subjects in 50 CFR Part 218

Exports, Fish, Imports, Incidental take, Indians, Labeling, Marine mammals, Navy, Penalties, Reporting and recordkeeping requirements, Seafood, Sonar, Transportation.

Dated: October 20, 2020.

Samuel D. Rauch, III,

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

For reasons set forth in the preamble, 50 CFR part 218 is amended as follows:

PART 218—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 218 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.,* unless otherwise noted.

■ 2. Revise subpart O to part 218 to read as follows:

Subpart O—Taking and Importing Marine Mammals; U.S. Navy's Northwest Training and Testing (NWTT)

Sec.
218.140 Specified activity and geographical region.
218.141 Effective dates.
218.142 Permissible methods of taking.
218.143 Prohibitions.
218.144 Mitigation requirements.
218.145 Requirements for monitoring and reporting.
218.146 Letters of Authorization.
218.147 Renewals and modifications of Letters of Authorization.
218.148 [Reserved]

Subpart O—Taking and Importing Marine Mammals; U.S. Navy's Northwest Training and Testing (NWTT)

§ 218.140 Specified activity and geographical region.

(a) Regulations in this subpart apply only to the U.S. Navy (Navy) for the taking of marine mammals that occurs in the area described in paragraph (b) of this section and that occurs incidental to the activities listed in paragraph (c) of this section.

(b) The taking of marine mammals by the Navy under this subpart may be authorized in Letters of Authorization (LOAs) only if it occurs within the NWTT Study Area. The NWTT Study Area is composed of established maritime operating and warning areas in the eastern North Pacific Ocean region, including areas of the Strait of Juan de Fuca, Puget Sound, and Western Behm Canal in southeastern Alaska. The Study Area includes air and water space within and outside Washington state waters, and outside state waters of Oregon and Northern California. The eastern boundary of the Offshore Area portion of the Study Area is 12 nautical miles (nmi) off the coastline for most of the Study Area starting south of W–237, including southern Washington, Oregon, and Northern California. The Offshore Area includes the ocean all the way to the coastline only along that part of the Washington coast that lies beneath the airspace of W–237 and the Olympic Military Operations Area. The Quinault Range Site is a defined area of sea space where training and testing is conducted. The Quinault Range Site coincides with the boundaries of W–237A and also includes a surf zone component. The surf zone component extends north to south 5 nmi along the eastern boundary of W–237A, extends approximately 3 nmi to shore along the mean lower low water line, and encompasses 1 mile (1.6 kilometers) of shoreline at Pacific Beach, Washington. The Study Area includes four existing range complexes and facilities: the Northwest Training Range Complex (NWTRC), the Keyport Range Complex, the Carr Inlet Operations Area, and the Southeast Alaska Acoustic Measurement Facility (SEAFAC). In addition to these range complexes, the Study Area also includes Navy pierside locations where sonar maintenance and testing occurs as part of overhaul, modernization, maintenance, and repair activities at Naval Base Kitsap, Bremerton; Naval Base Kitsap, Bangor; and Naval Station Everett.

(c) The taking of marine mammals by the Navy is only authorized if it occurs incidental to the Navy conducting training and testing activities, including:

(1) Anti-submarine warfare;

(2) Mine warfare;

(3) Surface warfare;

(4) Unmanned systems;

(5) Vessel evaluation; and

(6) Other training and testing activities.

§ 218.141 Effective dates.

Regulations in this subpart are effective from November 9, 2020, through November 8, 2027.

§ 218.142 Permissible methods of taking.

(a) Under LOAs issued pursuant to §§ 216.106 of this chapter and 218.146, the Holder of the LOAs (hereinafter ''Navy'') may incidentally, but not intentionally, take marine mammals within the area described in § 218.140(b) by Level A harassment and Level B harassment associated with the use of active sonar and other acoustic sources and explosives, as well as serious injury or mortality associated with vessel strikes, provided the activity is in compliance with all terms, conditions, and requirements of this subpart and the applicable LOAs.

(b) The incidental take of marine mammals by the activities listed in § 218.140(c) is limited to the following species:

TABLE 1 TO PARAGRAPH (b)

Species	Stock
Blue whale	Eastern North Pacific.
Fin whale	Northeast Pacific.
Fin whale	California/Oregon/Washington.
Sei whale	Eastern North Pacific.
Minke whale	Alaska.
Minke whale	California/Oregon/Washington.
Humpback whale	Central North Pacific.
Humpback whale	California/Oregon/Washington.
Gray whale	Eastern North Pacific.
Bottlenose dolphin	California/Oregon/Washington Offshore.
Killer whale	Alaska Resident.
Killer whale	Eastern North Pacific Offshore.
Killer whale	West Coast Transient.
Killer whale	Southern Resident.
Northern right whale dolphin	California/Oregon/Washington.
Pacific white-sided dolphin	North Pacific.
Pacific white-sided dolphin	California/Oregon/Washington.
Risso's dolphin	California/Oregon/Washington.
Short-beaked common dolphin	California/Oregon/Washington.
Short-finned pilot whale	California/Oregon/Washington.
Striped dolphin	California/Oregon/Washington.
Pygmy sperm whale	California/Oregon/Washington.
Dwarf sperm whale	California/Oregon/Washington.

TABLE 1 TO PARAGRAPH (b)—Continued

Species	Stock
Dall's porpoise	Alaska.
Dall's porpoise	California/Oregon/Washington.
Harbor porpoise	Southeast Alaska.
Harbor porpoise	Northern Oregon & Washington Coast.
Harbor porpoise	Northern California/Southern Oregon.
Harbor porpoise	Washington Inland Waters.
Sperm whale	California/Oregon/Washington.
Baird's beaked whale	California/Oregon/Washington.
Cuvier's beaked whale	California/Oregon/Washington.
Mesoplodon species	California/Oregon/Washington.
California sea lion	U.S. Stock.
Steller sea lion	Eastern U.S.
Guadalupe fur seal	Mexico.
Northern fur seal	Eastern Pacific.
Northern fur seal	California.
Harbor seal	Southeast Alaska—Clarence Strait.
Harbor seal	Oregon & Washington Coastal.
Harbor seal	Washington Northern Inland Waters.
Harbor seal	Hood Canal.
Harbor seal	Southern Puget Sound.
Northern elephant seal	California.

§ 218.143 Prohibitions.

(a) Notwithstanding incidental takings contemplated in § 218.142(a) and authorized by LOAs issued under §§ 216.106 of this chapter and 218.146, no person in connection with the activities listed in § 218.140(c) may:

(1) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or an LOA issued under §§ 216.106 of this chapter and 218.146;

(2) Take any marine mammal not specified in § 218.142(b);

(3) Take any marine mammal specified in § 218.142(b) in any manner other than as specified in the LOAs; or

(4) Take a marine mammal specified in § 218.142(b) if NMFS determines such taking results in more than a negligible impact on the species or stock of such marine mammal.

(b) [Reserved]

§ 218.144 Mitigation requirements.

(a) When conducting the activities identified in § 218.140(c), the mitigation measures contained in any LOAs issued under §§ 216.106 of this chapter and 218.146 must be implemented. These mitigation measures include, but are not limited to:

(1) *Procedural mitigation.* Procedural mitigation is mitigation that the Navy must implement whenever and wherever an applicable training or testing activity takes place within the NWTT Study Area for each applicable activity category or stressor category and includes acoustic stressors (*i.e.,* active sonar, weapons firing noise), explosive stressors (*i.e.,* sonobuoys, torpedoes, medium-caliber and large-caliber projectiles, missiles, bombs, Mine Countermeasure and Neutralization activities, mine neutralization involving Navy divers), and physical disturbance and strike stressors (*i.e.,* vessel movement, towed in-water devices, small-, medium-, and large-caliber non-explosive practice munitions, non-explosive missiles, non-explosive bombs and mine shapes).

(i) *Environmental awareness and education.* Appropriate Navy personnel (including civilian personnel) involved in mitigation and training or testing activity reporting under the specified activities will complete the environmental compliance training modules identified in their career path training plan, as specified in the LOAs.

(ii) *Active sonar.* Active sonar includes low-frequency active sonar, mid-frequency active sonar, and high-frequency active sonar. For vessel-based active sonar activities, mitigation applies only to sources that are positively controlled and deployed from manned surface vessels (*e.g.,* sonar sources towed from manned surface platforms). For aircraft-based active sonar activities, mitigation applies only to sources that are positively controlled and deployed from manned aircraft that do not operate at high altitudes (*e.g.,* rotary-wing aircraft). Mitigation does not apply to active sonar sources deployed from unmanned aircraft or aircraft operating at high altitudes (*e.g.,* maritime patrol aircraft).

(A) *Number of Lookouts and observation platform for hull-mounted sources.* For hull-mounted sources, the Navy must have one Lookout for platforms with space or manning restrictions while underway (at the forward part of a small boat or ship) and platforms using active sonar while moored or at anchor (including pierside), and two Lookouts for platforms without space or manning restrictions while underway (at the forward part of the ship).

(B) *Number of Lookouts and observation platform for sources not hull-mounted.* For sources that are not hull-mounted, the Navy must have one Lookout on the ship or aircraft conducting the activity.

(C) *Prior to activity.* Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of active sonar transmission until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(ii)(F) are met for marine mammals.

(D) *During activity for low-frequency active sonar at 200 decibels (dB) and hull-mounted mid-frequency active sonar.* During the activity, for low-frequency active sonar at 200 dB and hull-mounted mid-frequency active sonar, Navy personnel must observe the following mitigation zones for marine mammals.

(*1*) *Powerdowns for marine mammals.* Navy personnel must power down active sonar transmission by 6 dB if marine mammals are observed within 1,000 yard (yd) of the sonar source; Navy personnel must power down an additional 4 dB (10 dB total) if marine mammals are observed within 500 yd of the sonar source.

(*2*) *Shutdowns for marine mammals.* Navy personnel must cease transmission if cetaceans are observed within 200 yd of the sonar source in any location in the Study Area; Navy personnel must cease transmission if pinnipeds in the NWTT Offshore Area or Western Behm Canal are observed within 200 yd of the sonar source and cease transmission if pinnipeds in NWTT Inland Waters are observed within 100 yd of the sonar source (except if hauled out on, or in the water near, man-made structures and vessels).

(E) *During activity for low-frequency active sonar below 200 dB, mid-frequency active sonar not hull-mounted, and high-frequency sonar.* During the activity, for low-frequency active sonar below 200 dB, mid-frequency active sonar sources that are not hull-mounted, and high-frequency sonar, Navy personnel must observe the following mitigation zones for marine mammals. Navy personnel must cease transmission if cetaceans are observed within 200 yd of the sonar source in any location in the Study Area. Navy personnel must cease transmission if pinnipeds in the NWTT Offshore Area or Western Behm Canal are observed within 200 yd of the sonar source. Navy personnel must cease transmission if pinnipeds in NWTT Inland Waters are observed within 100 yd of the sonar source (except if hauled out on, or in the water near, man-made structures and vessels).

(F) Co*mmencement/recommencement conditions after marine mammal sighting before or during activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing or powering up active sonar transmission) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonar source;

(*3*) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 minutes (min) for aircraft-deployed sonar sources or 30 min for vessel-deployed sonar sources;

(*4*) *Sonar source transit.* For mobile activities, the active sonar source has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting; or

(*5*) *Bow-riding dolphins.* For activities using hull-mounted sonar, the Lookout concludes that dolphins are deliberately closing in on the ship to ride the ship's bow wave, and are therefore out of the main transmission axis of the sonar (and there are no other marine mammal sightings within the mitigation zone).

(iii) *Weapons firing noise.* Weapons firing noise associated with large-caliber gunnery activities.

(A) *Number of Lookouts and observation platform.* One Lookout must be positioned on the ship conducting the firing. Depending on the activity, the Lookout could be the same as the one described for ''Explosive medium-caliber and large-caliber projectiles'' or for ''Small-, medium-, and large-caliber non-explosive practice munitions'' in paragraphs (a)(1)(vi)(A) and (a)(1)(xiii)(A) of this section.

(B) *Mitigation zone.* Thirty degrees on either side of the firing line out to 70 yd from the muzzle of the weapon being fired.

(C) *Prior to activity.* Prior to the initial start of the activity, Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of weapons firing until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(iii)(E) of this section are met for marine mammals.

(D) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease weapons firing.

(E) *Commencement/recommencement conditions after marine mammal sighting before or during activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing weapons firing) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the firing ship;

(*3*) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 30 min; or

(*4*) *Firing ship transit.* For mobile activities, the firing ship has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(iv) *Explosive sonobuoys.*

(A) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft or on a small boat. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources, including marine mammals, while performing their regular duties.

(B) *Mitigation zone.* 600 yd around an explosive sonobuoy.

(C) *Prior to activity.* Prior to the initial start of the activity (*e.g.,* during deployment of a sonobuoy field, which typically lasts 20–30 min), Navy personnel must conduct passive acoustic monitoring for marine mammals; personnel must use information from detections to assist visual observations. Navy personnel also must visually observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of sonobuoy or source/receiver pair detonations until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(iv)(E) of this section are met for marine mammals.

(D) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease sonobuoy or source/receiver pair detonations.

(E) *Commencement/recommencement conditions after marine mammal sighting before or during activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonobuoy; or

(*3*) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(F) *After activity.* After completion of the activity (*e.g.,* prior to maneuvering off station), Navy personnel must, when practical (*e.g.,* when platforms are not constrained by fuel restrictions or

mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel on these assets must assist in the visual observation of the area where detonations occurred.

(v) *Explosive torpedoes.*

(A) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources, including marine mammals, while performing their regular duties.

(B) *Mitigation zone.* 2,100 yd around the intended impact location.

(C) *Prior to activity.* Prior to the initial start of the activity (*e.g.,* during deployment of the target), Navy personnel must conduct passive acoustic monitoring for marine mammals; personnel must use the information from detections to assist visual observations. Navy personnel also must visually observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of firing until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(v)(E) of this section are met for marine mammals.

(D) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(E) *Commencement/recommencement conditions after marine mammal sighting before or during activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or

(*3*) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(F) *After activity.* After completion of the activity (*e.g.,* prior to maneuvering off station), Navy personnel must, when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel on these assets must assist in the visual observation of the area where detonations occurred.

(vi) *Explosive medium-caliber and large-caliber projectiles.* Gunnery activities using explosive medium-caliber and large-caliber projectiles. Mitigation applies to activities using a surface target.

(A) *Number of Lookouts and observation platform.* One Lookout must be on the vessel conducting the activity. For activities using explosive large-caliber projectiles, depending on the activity, the Lookout could be the same as the one described for ''Weapons firing noise'' in paragraph (a)(1)(iii)(A) of this section. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources, including marine mammals, while performing their regular duties.

(B) *Mitigation zones.* 600 yd around the intended impact location for explosive medium-caliber projectiles. 1,000 yd around the intended impact location for explosive large-caliber projectiles.

(C) *Prior to activity.* Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of firing until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(vi)(E) of this section are met for marine mammals.

(D) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(E) *Commencement/recommencement conditions after marine mammal sighting before or during activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location;

(*3*) *Clear of additional sightings.* The mitigation zone has been clear from any additional sightings for 30 min for vessel-based firing; or

(*4*) *Impact location transit.* For activities using mobile targets, the intended impact location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(F) *After activity.* After completion of the activity (*e.g.,* prior to maneuvering off station), Navy personnel must, when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel on these assets must assist in the visual observation of the area where detonations occurred.

(vii) *Explosive missiles.* Aircraft-deployed explosive missiles. Mitigation applies to activities using a surface target.

(A) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources, including marine mammals, while performing their regular duties.

(B) *Mitigation zone.* 2,000 yd around the intended impact location.

(C) *Prior to activity.* Prior to the initial start of the activity (*e.g.,* during a fly-over of the mitigation zone), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the

start of firing until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(vii)(E) of this section are met for marine mammals.

(D) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(E) *Commencement/recommencement conditions after marine mammal sighting before or during activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or

(*3*) *Clear of additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(F) *After activity.* After completion of the activity (*e.g.,* prior to maneuvering off station), Navy personnel must, when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel on these assets must assist in the visual observation of the area where detonations occurred.

(viii) *Explosive bombs.*

(A) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft conducting the activity. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources, including marine mammals, while performing their regular duties.

(B) *Mitigation zone.* 2,500 yd around the intended target.

(C) *Prior to activity.* Prior to the initial start of the activity (*e.g.,* when arriving on station), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammals is observed, Navy personnel must relocate or delay the start of bomb deployment until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(viii)(E) of this section are met for marine mammals.

(D) *During activity.* During the activity (*e.g.,* during target approach), Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease bomb deployment.

(E) *Commencement/recommencement conditions after marine mammal sighting before or during activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target;

(*3*) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min; or

(*4*) *Intended target transit.* For activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(F) *After activity.* After completion of the activity (*e.g.,* prior to maneuvering off station), Navy personnel must, when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel on these assets must assist in the visual observation of the area where detonations occurred.

(ix) *Explosive Mine Countermeasure and Neutralization activities.*

(A) *Number of Lookouts and observation platform.* One Lookout must be positioned on a vessel or in an aircraft when implementing the smaller mitigation zone. Two Lookouts must be positioned (one in an aircraft and one on a small boat) when implementing the larger mitigation zone. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources, including marine mammals, while performing their regular duties.

(B) *Mitigation zones.* 600 yd around the detonation site for activities using ≤5 lb net explosive weight. 2,100 yd around the detonation site for activities using >5–60 lb net explosive weight.

(C) *Prior to activity.* Prior to the initial start of the activity (*e.g.,* when maneuvering on station; typically, 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of detonations until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(ix)(E) are met for marine mammals.

(D) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease detonations. Navy personnel must use the smallest practicable charge size for each activity. Navy personnel must conduct activities in daylight hours only and in Beaufort Sea state number 3 conditions or less.

(E) *Commencement/recommencement conditions after marine mammal sighting before or during activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the detonation site; or

(*3*) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(F) *After activity.* After completion of the activity (typically 10 min when the

activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel on these assets must assist in the visual observation of the area where detonations occurred.

(x) *Explosive mine neutralization activities involving Navy divers.*

(A) *Number of Lookouts and observation platform.*

(*1*) *Lookouts on small boats.* Two Lookouts on two small boats with one Lookout each, one of which must be a Navy biologist.

(*2*) *Divers.* All divers placing the charges on mines must support the Lookouts while performing their regular duties and report applicable sightings to the lead Lookout, the supporting small boat, or the Range Safety Officer.

(*3*) *Additional platforms.* If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources, including marine mammals, while performing their regular duties.

(B) *Mitigation zone.* 500 yd around the detonation site during activities using > 0.5–2.5 lb net explosive weight.

(C) *Prior to activity.* Prior to the initial start of the activity (starting 30 min before the first planned detonation), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of detonations until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(x)(E) are met for marine mammals. A Navy biologist must serve as the lead Lookout and must make the final determination that the mitigation zone is clear of any floating vegetation or marine mammals, prior to the commencement of a detonation. The Navy biologist must maintain radio communication with the unit conducting the event and the other Lookout.

(D) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease detonations. To the maximum extent practicable depending on mission requirements, safety, and environmental conditions, Navy personnel must position boats near the midpoint of the mitigation zone radius (but outside of the detonation plume and human safety zone), must position themselves on opposite sides of the detonation location, and must travel in a circular pattern around the detonation location with one Lookout observing inward toward the detonation site and the other observing outward toward the perimeter of the mitigation zone. Navy personnel must only use positively controlled charges (*i.e.,* no time-delay fuses). Navy personnel must use the smallest practicable charge size for each activity. All activities must be conducted in Beaufort sea state number 2 conditions or better and must not be conducted in low visibility conditions.

(E) *Commencement/recommencement conditions after marine mammal sighting before or during activity.* Navy personnel must allow a sighted animal to leave the mitigation zone prior to the initial start of the activity (by delaying the start to ensure the mitigation zone is clear for 30 min) or during the activity (by not recommencing detonations) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the detonation site; or

(*3*) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 30 min.

(F) *After activity.* After each detonation and completion of an activity, the Navy must observe for marine mammals for 30 min in the vicinity of where detonations occurred and immediately downstream of the detonation location; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), Navy personnel on these assets must assist in the visual observation of the area where detonations occurred.

(xi) *Vessel movement.* The mitigation will not be applied if: The vessel's safety is threatened; the vessel is restricted in its ability to maneuver (*e.g.,* during launching and recovery of aircraft or landing craft, during towing activities, when mooring, and during Transit Protection Program exercises or other events involving escort vessels); the vessel is submerged or operated autonomously; or when impractical based on mission requirements (*e.g.,* during test body retrieval by range craft).

(A) *Number of Lookouts and observation platform.* One Lookout must be on the vessel that is underway.

(B) *Mitigation zones.*

(*1*) *Whales.* 500 yd around whales.

(*2*) *Marine mammals other than whales: Surface vessels.* 200 yd around marine mammals other than whales (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels) for surface vessels (which do not include small boats).

(*3*) *Marine mammals other than whales: Small boats.* 100 yd around marine mammals other than whales (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels) for small boats, such as range craft.

(C) *During activity.* When underway, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must maneuver to maintain distance.

(D) *Incident reporting procedures.* If a marine mammal vessel strike occurs, Navy personnel must follow the established incident reporting procedures.

(xii) *Towed in-water devices.* Mitigation applies to devices that are towed from a manned surface platform or manned aircraft, or when a manned support craft is already participating in an activity involving in-water devices being towed by unmanned platforms. The mitigation will not be applied if the safety of the towing platform or in-water device is threatened.

(A) *Number of Lookouts and observation platform.* One Lookout must be positioned on a manned towing platform or support craft.

(B) *Mitigation zones.*

(*1*) *Mitigation zone: In-water devices towed by aircraft or surface ships.* 250 yd around marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels) for in-water devices towed by aircraft or surface ships.

(*2*) *Mitigation zone: In-water devices towed by small boats.* 100 yd around marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels) for in-water devices towed by small boats, such as range craft.

(C) *During activity.* During the activity (*i.e.,* when towing an in-water device), Navy personnel must observe the

mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must maneuver to maintain distance.

(xiii) *Small-, medium-, and large-caliber non-explosive practice munitions.* Gunnery activities using small-, medium-, and large-caliber non-explosive practice munitions. Mitigation applies to activities using a surface target.

(A) *Number of Lookouts and observation platform.* One Lookout must be positioned on the platform conducting the activity. Depending on the activity, the Lookout could be the same as the one described for ''Weapons firing noise'' in paragraph (a)(1)(iii)(A) of this section.

(B) *Mitigation zone.* 200 yd around the intended impact location.

(C) *Prior to activity.* Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(xiii)(E) are met for marine mammals.

(D) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(E) *Commencement/recommencement conditions after marine mammal sighting before or during activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location;

(*3*) *Clear of additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min for aircraft-based firing or 30 min for vessel-based firing; or

(*4*) *Impact location transit.* For activities using a mobile target, the intended impact location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(xiv) *Non-explosive missiles.* Aircraft-deployed non-explosive missiles. Mitigation applies to activities using a surface target.

(A) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft.

(B) *Mitigation zone.* 900 yd around the intended impact location.

(C) *Prior to activity.* Prior to the initial start of the activity (*e.g.,* during a fly-over of the mitigation zone), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of firing until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(xiv)(E) of this section are met for marine mammals.

(D) *During activity.* During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(E) *Commencement/recommencement conditions after marine mammal sighting prior to or during activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or

(*3*) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(xv) *Non-explosive bombs and mine shapes.* Non-explosive bombs and non-explosive mine shapes during mine laying activities.

(A) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft.

(B) *Mitigation zone.* 1,000 yd around the intended target.

(C) *Prior to activity.* Prior to the initial start of the activity (*e.g.,* when arriving on station), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of bomb deployment or mine laying until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(1)(xv)(E) of this section are met for marine mammals.

(D) *During activity.* During the activity (*e.g.,* during approach of the target or intended minefield location), Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease bomb deployment or mine laying.

(E) *Commencement/recommencement conditions after marine mammal sighting prior to or during activity.* Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment or mine laying) until one of the following conditions has been met:

(*1*) *Observed exiting.* The animal is observed exiting the mitigation zone;

(*2*) *Thought to have exited.* The animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target or minefield location;

(*3*) *Clear from additional sightings.* The mitigation zone has been clear from any additional sightings for 10 min; or

(*4*) *Intended target transit.* For activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(2) *Mitigation areas.* In addition to procedural mitigation, Navy personnel must implement mitigation measures within mitigation areas to avoid or reduce potential impacts on marine mammals.

(i) *Marine Species Coastal Mitigation Area (year round unless specified as seasonal).*

(A) Within 50 nmi from shore in the Marine Species Coastal Mitigation Area.

(*1*) *Prohibited activities.* The Navy must not conduct: Explosive training activities; explosive testing activities (with the exception of explosive Mine Countermeasure and Neutralization Testing activities); and non-explosive missile training activities.

(*2*) *Seasonal awareness notification messages.* The Navy must issue annual seasonal awareness notification messages to alert Navy ships and aircraft to the possible presence of increased concentrations of Southern Resident killer whales from December 1 to June 30, humpback whales from May 1 to December 31, and gray whales from May 1 to November 30. For safe navigation

and to avoid interactions with large whales, the Navy must instruct vessels to remain vigilant to the presence of Southern Resident killer whales, humpback whales, and gray whales that may be vulnerable to vessel strikes or potential impacts from training and testing activities. Platforms must use the information from the awareness notification messages to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation.

(B) Within 20 nmi from shore in the Marine Species Coastal Mitigation Area.

(*1*) *Surface ship hull-mounted MF1 mid-frequency active sonar.* The Navy must not conduct more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined.

(*2*) *Mine Countermeasure and Neutralization Testing from July 1 to September 30.* To the maximum extent practical, the Navy must conduct explosive Mine Countermeasure and Neutralization Testing from July 1 to September 30 when operating within 20 nmi from shore.

(*3*) *Mine Countermeasure and Neutralization Testing from October 1 to June 30.* From October 1 to June 30, the Navy must not conduct more than one explosive Mine Countermeasure and Neutralization Testing event, not to exceed the use of 20 explosives from bin E4 and 3 explosives from bin E7 annually, and not to exceed the use of 60 explosives from bin E4 and 9 explosives from bin E7 over the seven-year period of the rule.

(*4*) *Large-caliber gunnery training activities and non-explosive bombing training.* The Navy must not conduct non-explosive large-caliber gunnery training activities and non-explosive bombing training activities.

(C) Within 12 nmi from shore in the Marine Species Coastal Mitigation Area.

(*1*) *Anti-submarine warfare tracking exercise—helicopter,—maritime patrol aircraft,—ship, or—submarine training and anti-submarine warfare torpedo exercise—submarine training.* The Navy must not conduct Anti-Submarine Warfare Tracking Exercise—Helicopter,—Maritime Patrol Aircraft,—Ship, or—Submarine training activities (which involve the use of mid-frequency or high-frequency active sonar) or non-explosive Anti-Submarine Warfare Torpedo Exercise—Submarine training activities (which involve the use of mid-frequency or high-frequency active sonar).

(*2*) *Unmanned Underwater Vehicle Training.* The Navy must not conduct more than one Unmanned Underwater Vehicle Training event within 12 nmi from shore at the Quinault Range Site. In addition, Unmanned Underwater Vehicle Training events within 12 nmi from shore at the Quinault Range Site must be cancelled or moved to another training location if Southern Resident killer whales are detected at the planned training location during the event planning process, or immediately prior to the event, as applicable.

(*3*) *Explosive use during Mine Countermeasure and Neutralization testing.* During explosive Mine Countermeasure and Neutralization Testing, the Navy must not use explosives in bin E7 closer than 6 nmi from shore in the Quinault Range Site.

(*4*) *Non-explosive small- and medium-caliber gunnery training.* The Navy must not conduct non-explosive small- and medium-caliber gunnery training activities.

(D) *National security exception.* Should national security require that the Navy cannot comply with the restrictions in paragraphs (a)(2)(i)(A)(*1*); (a)(2)(i)(B); or (a)(2)(i)(C) of this section, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(ii) *Olympic Coast National Marine Sanctuary Mitigation Area (year-round).*

(A) *Surface ship hull-mounted MF1 mid-frequency active sonar during training.* The Navy must not conduct more than 32 hours of surface ship hull-mounted MF1 mid-frequency active sonar during training annually.

(B) *Non-explosive bombing training.* The Navy must not conduct non-explosive bombing training activities.

(C) *Surface ship hull-mounted MF1 mid-frequency active sonar during testing.* The Navy must not conduct more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined.

(D) *Explosive Mine Countermeasure and Neutralization testing.* The Navy must not conduct explosive Mine Countermeasure and Neutralization Testing activities.

(E) *National security exception.* Should national security require that the Navy cannot comply with the restrictions in paragraphs (a)(2)(ii)(A), (B), (C), or (D) of this section, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(iii) *Juan de Fuca Eddy Marine Species Mitigation Area (year-round).*

(A) *Surface ship hull-mounted MF1 mid-frequency active sonar during testing.* The Navy must not conduct more than a total of 33 hours of surface ship hull-mounted MF1 mid-frequency active sonar during testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, in the Juan de Fuca Eddy Marine Species Mitigation Area, and in the Olympic Coast National Marine Sanctuary Mitigation Area combined.

(B) *Explosive Mine Countermeasure and Neutralization testing.* The Navy must not conduct explosive Mine Countermeasure and Neutralization Testing activities.

(C) *National security exception.* Should national security require that the Navy cannot comply with the restrictions in paragraphs (a)(2)(iii)(A) or (B) of this section, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(iv) *Stonewall and Heceta Bank Humpback Whale Mitigation Area (May 1–November 30).*

(A) *Surface ship hull-mounted MF1 mid-frequency active sonar.* The Navy must not use surface ship hull-mounted MF1 mid-frequency active sonar during training and testing from May 1 to November 30.

(B) *Explosive Mine Countermeasure and Neutralization testing.* The Navy must not conduct explosive Mine Countermeasure and Neutralization testing from May 1 to November 30.

(C) *National security exception.* Should national security require that the Navy cannot comply with the restrictions in paragraphs (a)(2)(iv)(A) or (B) of this section, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include

information about the event in its annual activity reports to NMFS.

(v) *Point St. George Humpback Whale Mitigation Area (July 1–November 30).*

(A) *Surface ship hull-mounted MF1 mid-frequency active sonar.* The Navy must not use surface ship hull-mounted MF1 mid-frequency active sonar during training or testing from July 1 to November 30.

(B) *Explosive Mine Countermeasure and Neutralization testing.* The Navy must not conduct explosive Mine Countermeasure and Neutralization Testing from July 1 to November 30.

(C) *National security exception.* Should national security require that the Navy cannot comply with the restrictions in paragraphs (a)(2)(v)(A) or (B) of this section, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(vi) *Northern Puget Sound Gray Whale Mitigation Area (March 1–May 31).*

(A) *Civilian port defense—homeland security anti-terrorism/force protection exercises.* The Navy must not conduct Civilian Port Defense–Homeland Security Anti-Terrorism/Force Protection Exercises from March 1 to May 31.

(B) *National security exception.* Should national security require that the Navy cannot comply with the restrictions in paragraph (a)(2)(vi)(A) of this section, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(vii) *Puget Sound and Strait of Juan de Fuca Mitigation Area (year-round unless specified as seasonal).*

(A) *Active sonar use.* The Navy must not use low-frequency, mid-frequency, or high-frequency active sonar during training or testing within the Puget Sound and Strait of Juan de Fuca Mitigation Area, unless a required element (*i.e.,* a criterion necessary for the success of the event) necessitates that the activity be conducted in NWTT Inland Waters during:

(*1*) *Unmanned underwater vehicle training.*

(*2*) *Civilian port defense—homeland security anti-terrorism/force protection exercises.*

(*3*) *Activities conducted by Naval Sea Systems Command at designated locations.*

(*4*) *Pierside sonar maintenance or testing at designated locations.*

(B) *Active sonar source levels.* The Navy must use the lowest active sonar source levels practical to successfully accomplish each event. Naval units must obtain permission from the appropriate designated Command authority prior to commencing pierside maintenance or testing with hull-mounted mid-frequency active sonar.

(C) *Unmanned underwater vehicle training.* The Navy must not conduct more than one Unmanned Underwater Vehicle Training activity annually at the Navy 3 OPAREA, Navy 7 OPAREA, and Manchester Fuel Depot (*i.e.,* a maximum of one event at each location).

(D) *Use of explosives*—(*1*) *Explosives during testing.* The Navy must not use explosives during testing.

(*2*) *Explosives during training.* The Navy must not use explosives during training except at the Hood Canal EOD Range and Crescent Harbor EOD Range during explosive mine neutralization activities involving the use of Navy divers.

(*3*) *Explosives in bin E4 or above.* The Navy must not use explosives in bin E4 (>2.5–5 lb. net explosive weight) or above, and must instead use explosives in bin E0 (< 0.1 lb. net explosive weight) or bin E3 (>0.5–2.5 lb. net explosive weight).

(*4*) *Explosives in bin E3 during February, March, and April at the Hood Canal EOD Range.* During February, March, and April at the Hood Canal EOD Range, the Navy must not use explosives in bin E3 (>0.5–2.5 lb. net explosive weight), and must instead use explosives in bin E0 (< 0.1 lb. net explosive weight).

(*5*) *Explosives in bin E3 during August, September, and October at the Hood Canal EOD Range.* During August, September, and October at the Hood Canal EOD Range, the Navy must not use explosives in bin E3 (>0.5–2.5 lb. net explosive weight) and must instead use explosives in bin E0 (< 0.1 lb. net explosive weight) to the maximum extent practical unless necessitated by mission requirements.

(*6*) *Explosives at the Crescent Harbor EOD Range.* At the Crescent Harbor EOD Range, the Navy must conduct explosive activities at least 1,000 m from the closest point of land.

(E) *Non-explosive live fire events.* The Navy must not conduct non-explosive live fire events in the mitigation area (except firing blank weapons), including gunnery exercises, missile exercises, torpedo exercises, bombing exercises, and Kinetic Energy Weapon Testing.

(F) *Coordination with Navy biologists.* Navy event planners must coordinate with Navy biologists during the event planning process prior to conducting the activities listed in paragraphs (a)(2)(vii)(F)(*1*), (*2*), (*3*), and (*4*) of this section. Navy biologists must work with NMFS and must initiate communication with the appropriate marine mammal detection networks to determine the likelihood of applicable marine mammal species presence in the planned training location. Navy biologists must notify event planners of the likelihood of species presence. To the maximum extent practical, Navy planners must use this information when planning specific details of the event (*e.g.,* timing, location, duration) to avoid planning activities in locations or seasons where species presence is expected. The Navy must ensure environmental awareness of event participants. Environmental awareness will help alert participating crews to the possible presence of applicable species in the training location. Lookouts must use the information to assist visual observation of applicable mitigation zones and to aid in the implementation of procedural mitigation. Unmanned Underwater Vehicle Training events at the Navy 3 OPAREA, Manchester Fuel Depot, Crescent Harbor Explosive Ordnance Disposal Range, and Navy 7 OPAREA must be cancelled or moved to another training location if the presence of Southern Resident killer whales is reported through available monitoring networks during the event planning process, or immediately prior to the event, as applicable.

(*1*) *Unmanned underwater vehicle training.* Unmanned Underwater Vehicle Training at the Navy 3 OPAREA, Manchester Fuel Depot, Crescent Harbor Explosive Ordnance Disposal Range, and Navy 7 OPAREA (for Southern Resident killer whales);

(*2*) *Civilian port defense—homeland security anti-terrorism/force protection exercises.* Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises (for Southern Resident killer whales and gray whales);

(*3*) *Explosive mine neutralization activities involving the use of Navy divers.* Explosive mine neutralization activities involving the use of Navy divers (for Southern Resident killer whales); and

(*4*) *Small boat attack exercises.* Small Boat Attack Exercises, which involve firing blank small-caliber weapons (for Southern Resident killer whales and gray whales).

(G) *Seasonal awareness notification messages.* The Navy must issue annual seasonal awareness notification messages to alert Navy ships and aircraft operating within the Puget Sound and Strait of Juan de Fuca Mitigation Area to the possible presence of concentrations of Southern Resident killer whales from July 1 to November 30 in Puget Sound and the Strait of Juan de Fuca, and concentrations of gray whales from March 1 to May 31 in the Strait of Juan de Fuca and northern Puget Sound. For safe navigation and to avoid interactions with large whales, the Navy must instruct vessels to remain vigilant to the presence of Southern Resident killer whales and gray whales that may be vulnerable to vessel strikes or potential impacts from training and testing activities. Platforms must use the information from the awareness notification messages to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation.

(H) *National security exception.* Should national security require that the Navy cannot comply with the restrictions in paragraphs (a)(2)(vii)(A), (B), (C), (D), or (E) of this section, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(3) *Availability for Subsistence Use.* The Navy must notify the following Alaskan Native communities of the issuance of Notices to Mariners of Navy operations that involve restricting access in the Western Behm Canal at least 72 hours in advance: Central Council of the Tlingit and Haida Indian Tribes, Ketchikan Indian Corporation, Organized Village of Saxman, and Metlakatla Indian Community, Annette Island Reserve.

(b) [Reserved]

§ 218.145 Requirements for monitoring and reporting.

(a) *Notification of take.* Navy personnel must notify NMFS immediately (or as soon as operational security considerations allow) if the specified activity identified in § 218.140 is thought to have resulted in the mortality or serious injury of any marine mammals, or in any Level A harassment or Level B harassment of marine mammals not identified in this subpart.

(b) *Monitoring and reporting under the LOAs.* The Navy must conduct all monitoring and reporting required under the LOAs, including abiding by the U.S. Navy's Marine Species Monitoring Program. Details on program goals, objectives, project selection process, and current projects are available at *www.navymarinespeciesmonitoring.us.*

(c) *Notification of injured, live stranded, or dead marine mammals.* The Navy must consult the Notification and Reporting Plan, which sets out notification, reporting, and other requirements when dead, injured, or live stranded marine mammals are detected. The Notification and Reporting Plan is available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

(d) *Annual NWTT Study Area marine species monitoring report.* The Navy must submit an annual report of the NWTT Study Area monitoring, which will be included in a Pacific-wide monitoring report including results specific to the NWTT Study Area, describing the implementation and results from the previous calendar year. Data collection methods must be standardized across Pacific Range Complexes including the Mariana Islands Training and Testing (MITT), Hawaii-Southern California Training and Testing (HSTT), NWTT, and Gulf of Alaska (GOA) Study Areas to allow for comparison in different geographic locations. The report must be submitted to the Director, Office of Protected Resources, NMFS, either within three months after the end of the calendar year, or within three months after the conclusion of the monitoring year, to be determined by the adaptive management process. NMFS will submit comments or questions on the report, if any, within three months of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or three months after submittal of the draft if NMFS does not provide comments on the draft report. This report will describe progress of knowledge made with respect to intermediate scientific objectives within the NWTT Study Area associated with the Integrated Comprehensive Monitoring Program (ICMP). Similar study questions must be treated together so that progress on each topic can be summarized across all Navy ranges. The report need not include analyses and content that does not provide direct assessment of cumulative progress on the monitoring plan study questions. This will continue to allow the Navy to provide a cohesive monitoring report covering multiple ranges (as per ICMP goals), rather than entirely separate reports for the NWTT, HSTT, GOA, and MITT Study Areas.

(e) *NWTT Annual Training Exercise Report and Annual Testing Activity Report.* Each year, the Navy must submit two preliminary reports (Quick Look Reports) detailing the status of applicable sound sources within 21 days after the anniversary of the date of issuance of each LOA to the Director, Office of Protected Resources, NMFS. The Navy must also submit detailed reports (NWTT Annual Training Exercise Report and Annual Testing Activity Report) to the Director, Office of Protected Resources, NMFS, within three months after the one-year anniversary of the date of issuance of the LOAs. NMFS will submit comments or questions on the reports, if any, within one month of receipt. The reports will be considered final after the Navy has addressed NMFS' comments, or one month after submittal of the draft if NMFS does not provide comments on the draft reports. The NWTT Annual Training Exercise Report and Annual Testing Activity Report can be consolidated with other exercise and activity reports from other range complexes in the Pacific Ocean for a single Pacific Training Exercise and Testing Activity Report, if desired. The annual reports must contain a summary of all sound sources used (total hours or quantity of each bin of sonar or other non-impulsive source; total annual number of each type of explosive; and total annual expended/detonated rounds (missiles, bombs, sonobuoys, *etc.*) for each explosive bin). The annual reports will also contain both the current year's sonar and explosive use data as well as cumulative sonar and explosive use quantity from previous years' reports. Additionally, if there were any changes to the sound source allowance in a given year, or cumulatively, the report must include a discussion of why the change was made and include analysis to support how the change did or did not affect the analysis in the 2020 NWTT FSEIS/OEIS and MMPA final rule. The annual report must also include details regarding specific requirements associated with the mitigation areas listed in § 218.144(a)(2). The final annual/close-out report at the conclusion of the authorization period (year seven) will serve as the comprehensive close-out report and include both the final year annual incidental take compared to annual authorized incidental take as well as cumulative seven-year incidental take compared to seven-year authorized incidental take. The Annual Training Exercise Report and Annual

Testing Activity Report must include the following information.

(1) *Summary of sources used.* This section of the report must include the following information summarized from the authorized sound sources used in all training and testing events:

(i) *Sonar and other transducers.* Total annual hours or quantity (per the LOA) of each bin of sonar or other transducers, and

(ii) *Explosives.* Total annual expended/detonated ordinance (missiles, bombs, sonobuoys, etc.) for each explosive bin.

(2) [Reserved]

(f) *Annual classified reports.* Within the annual classified training exercise and testing activity reports, separate from the unclassified reports described in paragraphs (a) through (e) of this section, the Navy must specifically include the information described in paragraphs (f)(1) and (2) of this section.

(1) *Olympic Coast National Marine Sanctuary Mitigation Area.* Total hours of authorized low-frequency, mid-frequency, and high-frequency active sonar (all bins, by bin) used during training and testing annually within the Olympic Coast National Marine Sanctuary Mitigation Area; and

(2) *Surface ship hull-mounted MF1 mid-frequency active sonar.* Total hours of surface ship hull-mounted MF1 mid-frequency active sonar used in the following mitigation areas:

(i) *Testing annually in three combined areas.* Testing annually within 20 nmi from shore in the Marine Species Coastal Mitigation Area, the Juan de Fuca Eddy Marine Species Mitigation Area, and the Olympic Coast National Marine Sanctuary Mitigation Area combined;

(ii) *Stonewall and Heceta Bank Humpback Whale Mitigation Area.* Training and testing from May 1 to November 30 within the Stonewall and Heceta Bank Humpback Whale Mitigation Area; and

(iii) *Point St. George Humpback Whale Mitigation Area.* Training and testing from July 1 to November 30 within the Point St. George Humpback Whale Mitigation Area.

(g) *Final close-out report.* The final (year seven) draft annual/close-out report must be submitted within three months after the expiration of this subpart to the Director, Office of Protected Resources, NMFS. NMFS will submit comments on the draft close-out report, if any, within three months of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or three months after submittal of the draft if NMFS does not provide comments.

§ 218.146 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to the regulations in this subpart, the Navy must apply for and obtain LOAs in accordance with § 216.106 of this chapter.

(b) An LOA, unless suspended or revoked, may be effective for a period of time not to exceed the expiration date of this subpart.

(c) If an LOA expires prior to the expiration date of this subpart, the Navy may apply for and obtain a renewal of the LOA.

(d) In the event of projected changes to the activity or to mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision of § 218.147(c)(1)) required by an LOA issued under this subpart, the Navy must apply for and obtain a modification of the LOA as described in § 218.147.

(e) Each LOA will set forth:

(1) Permissible methods of incidental taking;

(2) Geographic areas for incidental taking;

(3) Means of effecting the least practicable adverse impact (*i.e.,* mitigation) on the species and stocks of marine mammals and their habitat; and

(4) Requirements for monitoring and reporting.

(f) Issuance of the LOA(s) must be based on a determination that the level of taking is consistent with the findings made for the total taking allowable under the regulations in this subpart.

(g) Notice of issuance or denial of the LOA(s) will be published in the **Federal Register** within 30 days of a determination.

§ 218.147 Renewals and modifications of Letters of Authorization.

(a) An LOA issued under §§ 216.106 of this chapter and 218.146 for the activity identified in § 218.140(c) may be renewed or modified upon request by the applicant, provided that:

(1) The planned specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for the regulations in this subpart (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section); and

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOAs were implemented.

(b) For LOA modification or renewal requests by the applicant that include changes to the activity or to the mitigation, monitoring, or reporting measures (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section) that do not change the findings made for the regulations or result in no more than a minor change in the total estimated number of takes (or distribution by species or stock or years), NMFS may publish a notice of planned LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under §§ 216.106 of this chapter and 218.146 may be modified by NMFS under the following circumstances:

(1) After consulting with the Navy regarding the practicability of the modifications, NMFS may modify (including adding or removing measures) the existing mitigation, monitoring, or reporting measures if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring, as part of an adaptive management process.

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA include:

(A) Results from the Navy's monitoring report and annual exercise reports from the previous year(s);

(B) Results from other marine mammal and/or sound research or studies; or

(C) Any information that reveals marine mammals may have been taken in a manner, extent, or number not authorized by this subpart or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS will publish a notice of planned LOA in the **Federal Register** and solicit public comment.

(2) If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in LOAs issued pursuant to §§ 216.106 of this chapter and 218.146, an LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within 30 days of the action.

§ 218.148 [Reserved]

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Part VI

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Updated Life Expectancy and Distribution Period Tables Used for Purposes of Determining Minimum Required Distributions; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9930]

RIN 1545–BP11

Updated Life Expectancy and Distribution Period Tables Used for Purposes of Determining Minimum Required Distributions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation.

SUMMARY: This document sets forth final regulations providing guidance relating to the life expectancy and distribution period tables that are used to calculate required minimum distributions from qualified retirement plans, individual retirement accounts and annuities, and certain other tax-favored employer-provided retirement arrangements. These regulations affect participants, beneficiaries, and plan administrators of these qualified retirement plans and other tax-favored employer-provided retirement arrangements, as well as owners, beneficiaries, trustees and custodians of individual retirement accounts and annuities.

DATES: *Effective Date:* The final regulations contained in this document are effective on November 12, 2020.

Applicability Date: The final regulations in this document apply to distribution calendar years (as defined in § 1.401(a)(9)–5, Q&A–1(b)), beginning on or after January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Arslan Malik or Linda S.F. Marshall, (202) 317–6700.

SUPPLEMENTARY INFORMATION:

Background

This document includes amendments to the Income Tax Regulations (26 CFR part 1) under section 401(a)(9) of the Internal Revenue Code (Code) regarding the requirement to take required minimum distributions from qualified trusts. These regulations also apply with respect to the corresponding requirements for individual retirement accounts and annuities (IRAs) described in section 408(a) and (b), and eligible deferred compensation plans under section 457, as well as section 403(a) and 403(b) annuity contracts, custodial accounts, and retirement income accounts.

I. Section 401(a)(9) and Related Statutory Provisions

Section 401(a)(9) provides rules regarding minimum required distributions from qualified retirement plans. These rules ensure that the assets of a qualified retirement plan, which are afforded favorable tax treatment, are used primarily to provide retirement income to a participant, while allowing distributions to continue after the participant's death over the lifetime of the participant's surviving spouse or the life expectancy of certain designated beneficiaries. Accordingly, section 401(a)(9) provides that a qualified retirement plan must commence benefits to an employee no later than a specified age (or within a specified number of years after the employee's death) and, under the regulations, once benefits commence, the pattern of payment must meet certain standards to ensure that distributions are not unduly deferred.

Section 401(a)(9)(A) provides rules for distributions during the life of the employee. Section 401(a)(9)(A)(ii) provides that the entire interest of an employee in a qualified retirement plan must be distributed, beginning not later than the employee's required beginning date, in accordance with regulations, over the life of the employee or over the lives of the employee and a designated beneficiary (or over a period not extending beyond the life expectancy of the employee and a designated beneficiary).

Section 401(a)(9)(B) provides rules for distributions that are made after the death of the employee. Section 401(a)(9)(B)(i) provides that, if the employee dies after distributions have begun, the employee's interest must be distributed at least as rapidly as under the method used by the employee. Section 401(a)(9)(B)(ii) provides a general rule that the employee's interest must be distributed within 5 years after the death of the employee if the employee dies before distributions have begun. Section 401(a)(9)(B)(iii) provides an exception to this 5-year rule if the employee has appointed a designated beneficiary. Under this exception, the 5-year rule is treated as satisfied if the employee's interest is distributed, in accordance with regulations, over the life or life expectancy of the designated beneficiary, provided that the distributions generally begin no later than 1 year after the date of the employee's death.[1] In addition, under section 401(a)(9)(B)(iv), if the designated beneficiary is the employee's surviving spouse, the beneficiary may wait until the date the employee would have attained age 72 to begin receiving required minimum distributions.

Section 401(a)(9)(C) defines the term *required beginning date* for employees (other than 5-percent owners and IRA owners) as April 1 of the calendar year following the later of the calendar year in which the employee attains age 72 or the calendar year in which the employee retires. For 5-percent owners and IRA owners, the required beginning date is April 1 of the calendar year following the calendar year in which the employee attains age 72, even if the employee has not retired.

Section 401(a)(9)(D) provides that, except in the case of a life annuity, the life expectancy of an employee and the employee's spouse that is used to determine the period over which payments must be made may be re-determined, but not more frequently than annually.

Section 401(a)(9)(E)(i) provides that the term *designated beneficiary* means any individual designated as a beneficiary by the employee. Section 401(a)(9)(E)(ii) provides that the term *eligible designated beneficiary* means any designated beneficiary who is (1) the surviving spouse of the employee; (2) a child of the employee who has not reached the age of majority; (3) disabled within the meaning of section 72(m)(7); (4) an individual who is disabled under section 7702B(c)(2) with a disability of indefinite length which is expected to be lengthy in nature; or (5) an individual who is not more than 10 years younger than the employee. For this purpose, section 401(a)(9)(E)(ii) provides that the determination of whether a designated beneficiary is an eligible designated beneficiary is made as the date of the death of the employee.

Section 401(a)(9)(G) provides that any distribution required to satisfy the incidental death benefit requirement of section 401(a) is a required minimum distribution. The incidental death benefit requirement, which is set forth in § 1.401–1(b)(1), provides that although a qualified pension or profit-sharing plan may provide for incidental death (or life insurance) benefits, the plan must be established and maintained primarily for the purpose of providing retirement benefits or deferred compensation.

Section 401(a)(9)(H) provides special rules for an eligible retirement plan described in section 402(c)(8)(B) that is

[1] However, section 401(a)(9)(H)(ii) provides that, with respect to an eligible retirement plan defined in section 402(c)(8)(B) other than a defined benefit plan, the section 401(a)(9)(B)(iii) exception is only available in the case of an eligible designated beneficiary defined in section 401(a)(9)(E)(ii).

not a defined benefit plan. Section 401(a)(9)(H)(i) provides that for such a plan, in the case of a designated beneficiary, section 401(a)(9)(B)(ii) is applied (1) by substituting 10 years for 5 years, and (2) without regard to whether distributions have begun prior to an employee's death. Section 401(a)(9)(H)(ii) provides that the section 401(a)(9)(B)(iii) exception to section 401(a)(9)(B)(ii), as modified, only applies in the case of an eligible designated beneficiary. Section 401(a)(9)(H)(iii) provides that if an eligible designated beneficiary dies prior to the distribution of the employee's entire interest, the remaining interest must be distributed within 10 years after the death of the eligible designated beneficiary.

Under sections 403(b)(10), 408(a)(6), 408(b), and 457(d)(2), requirements similar to the requirements of section 401(a)(9) apply to a number of types of retirement arrangements other than qualified retirement plans. However, pursuant to sections 408A(a) and (c)(5), those rules apply to a Roth IRA only after the death of the IRA owner.[2] Pursuant to sections 403(a)(1) and 404(a)(2), qualified annuity plans also must comply with the requirements of section 401(a)(9).

II. Regulations Under Section 401(a)(9)

Sections 1.401(a)(9)–1 through 1.401(a)(9)–8 provide rules regarding the application of section 401(a)(9).[3] In the case of a defined contribution plan, § 1.401(a)(9)–5 provides generally that an individual's required minimum distribution for a distribution calendar year is determined by dividing the individual's account balance determined under § 1.401(a)(9)–5, Q&A–3, by the applicable distribution period. Under § 1.401(a)(9)–5, Q&A–1(b), a distribution calendar year is a calendar year for which a minimum distribution is required. For example, if a 5-percent owner participating in a qualified retirement plan will attain age 72 during August of 2023 (so that the individual's required beginning date is April 1, 2024), then the individual's first distribution calendar year will be 2023, and the required minimum distribution for that year will be based on the applicable distribution period for a 72-year-old individual for 2023 (even though it is permitted to be paid at any time from January 1, 2023, through April 1, 2024).

Pursuant to § 1.401(a)(9)–5, Q&A–4(a), for required minimum distributions during the employee's lifetime (including the year in which the employee dies), the applicable distribution period for an employee is the distribution period for the employee's age under the Uniform Lifetime Table (which is equal to the joint and last survivor life expectancy for the employee and a hypothetical beneficiary 10 years younger). However, pursuant to § 1.401(a)(9)–5, Q&A–4(b), if an employee's sole beneficiary is the employee's surviving spouse and the spouse is more than 10 years younger than the employee, then the applicable distribution period is the joint and last survivor life expectancy of the employee and spouse under the Joint and Last Survivor Table (which is longer than the distribution period that would apply for the employee under the Uniform Lifetime Table).

Pursuant to § 1.401(a)(9)–5, Q&A–5, for distribution calendar years after the calendar year of the employee's death, the applicable distribution period generally is the remaining life expectancy of the designated beneficiary, subject to certain exceptions.[4] Two of these exceptions, which apply if the employee dies after the required beginning date, substitute the employee's remaining life expectancy for the beneficiary's remaining life expectancy. These two exceptions apply to an employee who does not have a designated beneficiary or who is younger than the designated beneficiary.[5]

Section 1.401(a)(9)–5, Q&A–5(c)(1) provides that the remaining life expectancy of the designated beneficiary is calculated as the life expectancy under the Single Life Table for the designated beneficiary's age in the calendar year following the calendar year of the employee's death, reduced by 1 for each subsequent year. However, if one of the two exceptions applies (so that the relevant life expectancy is the remaining life expectancy of the employee), then, pursuant to § 1.401(a)(9)–5, Q&A–5(c)(3), the remaining life expectancy of the employee is calculated as the life expectancy under the Single Life Table for the employee's age in the calendar year of the employee's death, reduced by 1 for each subsequent year.

A special rule applies to determine the designated beneficiary's remaining life expectancy if the employee's sole beneficiary is the employee's surviving spouse. In that case, pursuant to § 1.401(a)(9)–5, Q&A–5(c)(2), the surviving spouse's remaining life expectancy is recalculated each calendar year as the life expectancy under the Single Life Table for the surviving spouse's age in that year. Under § 1.401(a)(9)–5, Q&A–5(c)(2), for calendar years after the year of the spouse's death, the distribution period that applies for the spouse's beneficiary is the spouse's remaining life expectancy from the Single Life Table for the spouse's age for the calendar year of the spouse's death, reduced by 1 for each subsequent year.

Consistent with the policy of section 401(a)(9) to limit deferral of retirement income, § 1.401(a)(9)–6, Q&A–1(a) provides that, except as otherwise provided in § 1.401(a)(9)–6, payments from a defined benefit plan must be non-increasing in order to satisfy section 401(a)(9).[6] Section 1.401(a)(9)–6, Q&A–14(c) provides that, in the case of annuity payments paid from an annuity contract purchased from an insurance company, certain types of increasing payments will not cause an annuity payment stream to fail to satisfy this non-increasing payment requirement. These exceptions apply only if the total future expected payments under the annuity contract (determined in accordance with § 1.401(a)(9)–6, Q&A–14(e)(3)), based on the life expectancy tables of § 1.401(a)(9)–9, exceed the total value being annuitized (determined in accordance with § 1.401(a)(9)–6, Q&A–14(e)(1)).

III. Life Expectancy and Distribution Period Tables of § 1.401(a)(9)–9

Section 1.401(a)(9)–9, as it appears in 26 CFR part 1 (revised as of April 1, 2020), provides life expectancy and distribution period tables that are used to apply the rules of § 1.401(a)(9)–5 and to make the calculations in § 1.401(a)(9)–6, Q&A–14. That regulation, referred to in this preamble as formerly applicable § 1.401(a)(9)–9, was issued in 2002 (67 FR 18988), and the tables in formerly applicable

[2] Note that section 401(a)(9)(H) does not apply to an eligible deferred compensation plan under section 457(b) maintained by an organization that is not an eligible employer described in section 457(e)(1)(A) (because such a plan is not an eligible retirement plan described in section 402(c)(8)(B)).

[3] Sections 1.401(a)(9)–1 through 1.401(a)(9)–8 reflect section 401(a)(9) as in effect in 2003 and have not been updated to reflect statutory changes in 2019 and 2020.

[4] Section 1.401(a)(9)–5, Q&A–5 has not been updated to reflect the enactment of section 401(a)(9)(H) but nonetheless is relevant for the transition rule that is described in the *Effective/Applicability Date* section of this preamble.

[5] Under 401(a)(9)(B)(ii), another exception applies if the employee dies before the required beginning date and has no designated beneficiary. In that case, the employee's entire interest must be distributed by the end of the calendar year that includes the fifth anniversary of the date of the employee's death.

[6] Pursuant to § 1.401(a)(9)–8, Q&A–2(a)(3), the rules of § 1.401(a)(9)–6 also apply to an annuity contract purchased under a defined contribution plan.

§ 1.401(a)(9)–9 were developed using mortality rates for 2003. Those mortality rates were derived by applying mortality improvement through 2003 to the mortality rates from the Annuity 2000 Basic Table (which was the most recent individual annuity mortality table available in 2002).[7] The rates of mortality improvement used for this purpose were the ones that were used in developing the Annuity 2000 Basic Table. The resulting separate mortality rates for males and females were blended using a fixed 50 percent male/50 percent female blend.

The life expectancy tables and mortality rates are also relevant to the application of section 72(t), which imposes an additional income tax on early distributions from qualified retirement plans (including plans qualified under section 401(a) or section 403(a), annuity contracts and other arrangements described in section 403(b), and individual retirement arrangements described in section 408(a) or section 408(b)). Section 72(t)(2)(A)(iv) provides an exception from this additional income tax that applies in the case of a series of substantially equal periodic payments made for the life (or life expectancy) of the employee or the joint lives (or joint life expectancies) of the employee and the designated beneficiary. Revenue Ruling 2002–62, 2002–2 C.B. 710, provides that the life expectancy tables set forth in § 1.401(a)(9)'' may be used for purposes of determining payments that satisfy the exception under section 72(t)(2)(A)(iv). Rev. Rul. 2002–62 also sets forth a fixed annuitization method of determining payments that satisfy this exception. Under the fixed annuitization method, the annual payment for each year (which is determined only for the first year and not reset for subsequent years) is determined by dividing the account balance by an annuity factor that is the present value of an annuity of $1 per year beginning at the taxpayer's age when the payments commence and continuing for the life of the taxpayer (or the joint lives of the taxpayer and his or her beneficiary). The annuity factor is derived using the mortality table used to develop the life expectancy tables set forth in § 1.401(a)(9)–9.

IV. Executive Order 13847 and Proposed Regulations

Executive Order 13847, 83 FR 45321, which was signed on August 31, 2018, directs the Secretary of the Treasury to examine the life expectancy and distribution period tables in the regulations on required minimum distributions from retirement plans and determine whether they should be updated to reflect current mortality data and whether such updates should be made annually or on another periodic basis. The purpose of any updates would be to increase the effectiveness of tax-favored retirement programs by allowing retirees to retain sufficient retirement savings in these programs for their later years.

On November 8, 2019, the Department of the Treasury (Treasury Department) and the IRS published proposed regulations (REG–132210–18) under section 401(a)(9) in the **Federal Register** (84 FR 60812) (the proposed regulations) setting out updated life expectancy and distribution tables. A public hearing on the proposed regulations was held on January 13, 2020. Fifty-five written comments were received, and two speakers provided oral comments at the public hearing. After consideration of the comments, the proposed regulations are adopted as revised by this Treasury decision.

Summary of Comments and Explanation of Provisions

I. Overview

In accordance with Executive Order 13847, the Treasury Department and the IRS have examined the life expectancy and distribution period tables in formerly applicable § 1.401(a)(9)–9 and have reviewed currently available mortality data. As a result of this review, the Treasury Department and the IRS have determined that those tables should be updated to reflect current life expectancies. Accordingly, these regulations update those tables.

The life expectancy tables and applicable distribution period tables in these regulations generally reflect longer life expectancies than the tables in formerly applicable § 1.401(a)(9)–9. For example, a 72-year-old IRA owner who applied the Uniform Lifetime Table under formerly applicable § 1.401(a)(9)–9 to calculate required minimum distributions used a life expectancy of 25.6 years. Applying the Uniform Lifetime Table set forth in these regulations, a 72-year-old IRA owner will use a life expectancy of 27.4 years to calculate required minimum distributions. As another example, a 75-year-old surviving spouse who is the employee's sole beneficiary and applied the Single Life Table under formerly applicable § 1.401(a)(9)–9 to compute required minimum distributions used a life expectancy of 13.4 years. Under these regulations, a 75-year-old surviving spouse will use a life expectancy of 14.8 years. The effect of these changes is to reduce required minimum distributions generally, which will allow participants to retain larger amounts in their retirement plans to account for the possibility they may live longer.

II. Comments

The Treasury Department and the IRS received a number of comments about the updated life expectancy and distribution period tables in the proposed regulations, the effective date for the use of the tables, and how often the tables should be updated. All of the comments received were in favor of the updating of the previously applicable tables.

Two commenters observed that, at some older ages, life expectancies in the proposed regulations were shorter than under formerly applicable § 1.401(a)(9)–9. The life expectancy and distribution period tables in the proposed regulations were developed based on the mortality rates for purchasers of individual annuities, which are set forth in the experience tables used to develop the 2012 Individual Annuity Mortality Basic Table. These commenters recommended that the final regulations should instead provide life expectancy and distribution period tables developed based on the mortality rates set forth in the 2012 Individual Annuity Reserve Table. Those mortality rates were developed based on the same experience tables as the 2012 Individual Annuity Mortality Basic Table but reflect an adjustment to the mortality rates in the 2012 Individual Annuity Mortality Basic Table to provide a margin for conservatism for establishing life insurance company reserves (and therefore the use of those mortality rates would result in longer life expectancies than the life expectancies in the proposed regulations).[8]

The Treasury Department and the IRS reviewed the underlying data and methodology used to develop the mortality tables reflected in formerly applicable § 1.401(a)(9)–9, as well as the 2012 Individual Annuity Mortality Basic Table and the 2012 Individual Annuity Reserve Table. Based on that review, the Treasury Department and the IRS determined that the life expectancies in formerly applicable § 1.401(a)(9)–9 were based on an

[7] The Annuity 2000 Basic Table was developed by projecting mortality rates from the 1983 Individual Annuity Mortality Basic Table.

[8] The 2012 Individual Annuity Mortality Basic Table, the 2012 Individual Annuity Reserve Table, and methodology used to develop these tables can be found at *https://www.actuary.org/sites/default/files/files/publications/Payout_Annuity_Report_09-28-11.pdf.*

overestimate of the rate of mortality improvement, especially for individuals in their nineties. The Treasury Department and IRS also concluded that using a table based on the mortality experience of purchasers of individual annuities for purposes of determining required minimum distributions already applies longer life expectancies than expected for the general population,[9] so that reflecting the extra conservatism added to the mortality table that is used for purposes of determining insurance company reserves is not appropriate. Therefore, these regulations use mortality rates that are derived from the 2012 Individual Annuity Mortality Basic Table because those rates more accurately reflect empirical life expectancy data.

A number of commenters asked for changes in the minimum distribution rules that were not related to the life expectancy and distribution period tables in the proposed regulations, and many of these changes would require legislation. For example, some commenters asked for a change in the tax treatment of minimum distributions or for the elimination of the application of the minimum distribution requirements in certain circumstances. These comments were not adopted either because the Treasury Department and the IRS do not have the authority to make the changes in the absence of a statutory change or because the changes are otherwise beyond the scope of these regulations.

After the proposed regulations were published, the Setting Every Community Up for Retirement Enhancement Act (SECURE Act) was enacted as Division O of the Further Consolidated Appropriations Act, Public Law 116–94. The SECURE Act made two significant changes to section 401(a)(9): (1) It changed the required beginning date for an employee from April 1 of the year following the year the employee attains age 70½ to April 1 of the year following the year the employee attains age 72; and (2) it made adjustments to the required minimum distribution rules that apply after the death of the employee in the case of an eligible retirement plan described in section 402(c)(8)(B) that is not a defined benefit plan. The Treasury Department and the IRS expect to update the regulations under section 401(a)(9) to take into account the amendments to section 401(a)(9) made by the SECURE Act (including new section 401(a)(9)(H))[10] and in doing so will consider any comments on the proposed regulations to the extent that the comments, though beyond the scope of these regulations, are relevant in that context.

A number of commenters also requested that the effective date of the final regulations be delayed to 2022 (instead of 2021). They noted that plan sponsors and IRA providers are currently working to update their systems for the SECURE Act changes to section 401(a)(9) and recommended that the effective date of these regulations be delayed in order to allow administrators sufficient additional time to update systems for these regulations. As described in the *Effective/Applicability Date* section of this preamble, these regulations will apply to distribution calendar years beginning on or after January 1, 2022.

III. Updated Life Expectancy and Distribution Period Tables

The life expectancy and distribution period tables in these regulations have been developed based on mortality rates for 2022. These mortality rates were derived by applying mortality improvement through 2022 to the mortality rates from the experience tables used to develop the 2012 Individual Annuity Mortality Basic Tables (which are the most recent individual annuity mortality tables). As was the case in the proposed regulations, the separate mortality rates for males and females in these experience tables, which were based on the 2000–2004 Payout Annuity Mortality Experience Study,[11] have been projected from the central year of 2002 using the respective mortality improvement rates from the Mortality Improvement Scale MP–2018 for males and females.[12] The mortality table in these regulations was developed by blending the resulting separate mortality rates for males and females using a fixed 50 percent male/50 percent female blend.

The Single Life Table in these regulations sets forth life expectancies for each age, with the life expectancy for an age calculated as the sum of the probabilities of an individual at that age surviving to each future year. The resulting life expectancy is then increased by 11/24[13] to approximate the effect of monthly payments and is subject to a floor of 1.0.

The Uniform Lifetime Table in these regulations sets forth joint and last survivor life expectancies for each age beginning with age 72, based on a hypothetical beneficiary.[14] Pursuant to § 1.401(a)(9)–5, Q&A–4(a), the Uniform Lifetime Table is used for determining the distribution period for lifetime distributions to an employee in situations in which the employee's surviving spouse either is not the sole designated beneficiary or is the sole designated beneficiary but is not more than 10 years younger than the employee. The joint and last survivor life expectancy of an employee is taken from the Joint and Last Survivor Table using a hypothetical beneficiary who is assumed to be 10 years younger than the employee.

The Joint and Last Survivor Table sets forth joint and last survivor life expectancies of an employee and the employee's beneficiary for each combination of ages of those individuals. The joint and last survivor life expectancy for an employee and a beneficiary at a combination of ages is calculated as the sum of the probabilities of the employee surviving to each future year, plus the sum of the probabilities of the beneficiary surviving to each future year, minus the sum of the probabilities of both the employee and beneficiary surviving to each future year. The resulting joint and last survivor life expectancy is then increased by 11/24 to approximate the effect of monthly payments and is subject to a floor of 1.0.

The life expectancy tables in formerly applicable § 1.401(a)(9)–9 are used in several numerical examples in § 1.401(a)(9)–6, Q&A–14(f) that illustrate the availability of the exception described in § 1.401(a)(9)–6, Q&A–14(c) (regarding certain increasing payments under insurance company annuity contracts). These regulations do not

[9] Using a table based on the mortality experience of purchasers of individual annuities generates longer life expectancies than expected for the general population because of anti-selection in that purchasers of individual annuities have chosen to purchase a product that rewards long life (and therefore are expected to have greater longevity than the general population).

[10] No interpretive inferences should be drawn from the references to section 401(a)(9)(H) included in this preamble and the regulations.

[11] Information about the 2000–2004 Payout Annuity Mortality Experience Study and the experience tables, can be found at *https://www.actuary.org/sites/default/files/files/publications/Payout_Annuity_Report_09-28-11.pdf.*

[12] The Mortality Improvement Scale MP–2018 can be found at *https://www.soa.org/experience-studies/2018/mortality-improvement-scale-mp-2018/.*

[13] Assuming an equal distribution of deaths throughout the year, if a retiree is scheduled to receive monthly payments on the last day of each month then, in the year of death, on average, the retiree would receive 11/24th of a full year's worth of payments.

[14] The proposed regulations included Uniform Lifetime Table entries beginning with age 70. These regulations do not include Uniform Lifetime Table entries for ages 70 and 71 because section 114 of the SECURE Act changed the minimum age for receiving required minimum distributions from age 70½ to age 72.

include revisions to these examples to reflect the life expectancy tables in these regulations. However, it is expected that the examples will be updated as part of the broader update of the regulations under section 401(a)(9) to take into account the SECURE Act.

In the preamble to the proposed regulations, the Treasury Department and the IRS asked for comments about how frequently to update the life expectancy and distribution period tables. A number of commenters cited the need to strike an appropriate balance between the benefit of providing updated tables and the administrative burden of frequent updates and suggested that life expectancy and distribution period tables not be updated annually. The frequency of updates suggested by commenters ranged from 4 to 10 years.

These regulations do not provide for automatic updates to the life expectancy and distribution period tables. The Treasury Department and the IRS currently anticipate that they will review the tables at the earlier of: (1) 10 years or (2) whenever a new study of individual annuity mortality experience is published.

IV. Effective/Applicability Date

The life expectancy tables and Uniform Lifetime Table under these regulations apply for distribution calendar years beginning on or after January 1, 2022. Thus, for example, for an IRA owner who attained age 70½ in February of 2020 (so that the individual attains age 72 in August of 2021 and the individual's required beginning date is April 1, 2022), these regulations do not apply to the minimum required distribution for the individual's 2021 distribution calendar year (which is due April 1, 2022) but will apply to the minimum required distribution for the individual's 2022 distribution calendar year (which is due December 31, 2022).

These regulations include a transition rule that applies if an employee died before January 1, 2022, and, under the rules of § 1.401(a)(9)–5, Q&A–5, the distribution period that applies for calendar years following the calendar year of the employee's death is equal to a single life expectancy calculated as of the calendar year of the employee's death (or if applicable, the year after the employee's death), reduced by 1 for each subsequent year. Under this transition rule, the initial life expectancy used to determine the distribution period is reset by using the new Single Life Table for the age of the relevant individual in the calendar year for which life expectancy was set under § 1.401(a)(9)–5, Q&A–5(c). For distribution calendar years beginning on or after January 1, 2022, the distribution period is determined by reducing that initial life expectancy by 1 for each year subsequent to the year for which it was initially set, except as provided under section 401(a)(9)(H).

This transition rule could apply in three situations: (1) The employee died with a non-spousal eligible designated beneficiary (so that the applicable distribution period under § 1.401(a)(9)–5, Q&A–5(c)(1), is determined based on the remaining life expectancy of the eligible designated beneficiary for the calendar year following the calendar year of the employee's death); (2) the employee died after the required beginning date without a designated beneficiary (so that the applicable distribution period under § 1.401(a)(9)–5, Q&A–5(c)(3), is determined based on the remaining life expectancy of the employee for the year of the employee's death); and (3) the employee, who is younger than the designated beneficiary, died after the required beginning date (so that the applicable distribution period under § 1.401(a)(9)–5, Q&A–5(a)(1), is determined based on the remaining life expectancy of the employee for the year of the employee's death).

These regulations illustrate the application of this transition rule with an example involving an employee who died at age 80 in 2019 with a designated beneficiary (who was not the employee's spouse) who was age 75 in the year of the employee's death and who continues to be alive until at least 2022. For 2020, the distribution period that applies for the beneficiary is 12.7 years (the period applicable for a 76-year-old under the Single Life Table in formerly applicable § 1.401(a)(9)–9), and for 2021, it is 11.7 years (the original distribution period, reduced by 1 year). For 2022, taking into account the life expectancy tables under these regulations and applying the transition rule, the applicable distribution period would be 12.1 years (the 14.1-year life expectancy for a 76-year-old under the Single Life Table in these regulations, reduced by 2 years).

A similar transition rule applies if an employee's sole beneficiary is the employee's surviving spouse and the spouse died before January 1, 2022. Under the rules of § 1.401(a)(9)–5, Q&A–5(c)(2), the distribution period that applies for the spouse's beneficiary is equal to the single life expectancy for the spouse calculated for the calendar year of the spouse's death, reduced by 1 for each subsequent year. Under the transition rule, the initial life expectancy used to determine the distribution period is reset by using the new Single Life Table for the age of the spouse in the calendar year of the spouse's death. For distribution calendar years beginning on or after January 1, 2022, the distribution period is determined by reducing that initial life expectancy by 1 for each year subsequent to the year for which it was initially set. However, this transition rule only applies to the extent consistent with section 401(a)(9)(H).

These transition rules, under which there is a one-time reset for the relevant life expectancy using the Single Life Table under these regulations, are designed to recognize that the general population has longer life expectancies than the life expectancies set forth in the formerly applicable § 1.401(a)(9)–9. However, because the reset life expectancy is based on the age for which life expectancy was originally determined (rather than the relevant individual's current age), it is consistent with Congressional intent to limit recalculation of life expectancy to the employee and the employee's spouse.

V. Use of Revised Tables to Determine Substantially Equal Periodic Payments

The Treasury Department and the IRS anticipate issuing guidance that would update Rev. Rul. 2002–62. This update would apply the life expectancy, distribution period, and mortality tables set forth in these regulations for purposes of determining substantially equal periodic payments once these regulations become effective.

Special Analyses

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations.

It is hereby certified pursuant to the Regulatory Flexibility Act (5 U.S.C., chapter 6) that these regulations will not have a significant economic impact on a substantial number of small entities. These regulations apply to all employers that sponsor defined contribution plans regardless of size. Although data are not available to estimate the number of small entitles affected, the rule may affect a substantial number. This rule updates life expectancies that are required to be used by statute.

Although the rule may affect a substantial number of small entities, the economic impact of these regulations is not likely to be significant. Small businesses generally comply with the minimum required distribution rules

using either third-party administrators or software, creating economies of scale that mitigate the cost of updating life expectancy tables. That software is updated periodically irrespective of a change in life expectancies used to determine minimum required distributions. The portion of the cost of a periodic update that is attributable to the implementation of the life expectancy and distribution period tables in these regulations will be spread over the client base of a service provider that uses software developed in-house and over the group of purchasers of generally-available plan administration software. Because, in either case, the cost of changing software to implement the updated life expectancies is spread over a large group of businesses that maintain retirement plans, it is estimated that the incremental cost for each affected small businesses as a result of the use of updated life expectancies is not significant.

Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding this regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small entities. No comments were received from the Chief Counsel for the Office of Advocacy of the Small Business Administration.

Drafting Information

The principal authors of these regulations are Arslan Malik and Linda S.F. Marshall, of the Office of the Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes). However, other personnel from the Treasury Department and the IRS participated in the development of the proposed regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAX

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

Authority: 26 U.S.C. 401(m)(9) and 26 U.S.C. 7805.

* * * * *

§ 1.401(a)(9)–5 [Amended]

■ **Par. 2.** Section 1.401(a)(9)–5 is amended by:

■ 1. Removing the language ''A–1 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(b)'' in its place.

■ 2. Removing the language ''A–2 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(c)'' in its place.

■ 3. Removing the language ''A–3 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(d)'' in its place.

§ 1.401(a)(9)–6 [Amended]

■ **Par. 3.** Section 1.401(a)(9)–6 is amended by:

■ 1. Removing the language ''A–1 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(b)'' in its place.

■ 2. Removing the language ''A–2 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(c)'' in its place.

■ 3. Removing the language ''A–3 of in § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(d)'' in its place.

§ 1.401(a)(9)–8 [Amended]

■ **Par. 4.** Section 1.401(a)(9)–8 is amended by removing the language ''A–2 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(c)'' in its place.

■ **Par. 5.** Section 1.401(a)(9)–9 is revised to read as follows:

§ 1.401(a)(9)–9 Life expectancy and distribution period tables.

(a) *In general.* This section specifies the life expectancy and applicable distribution period tables that apply for purposes of determining required minimum distributions under section 401(a)(9). Paragraphs (b), (c), and (d) of this section set forth these tables. Paragraph (e) of this section provides the mortality rates that are used to develop these tables. Paragraph (f) of this section provides applicability date rules.

(b) *Single Life Table.* The following table, referred to as the Single Life Table, sets forth the life expectancy of an individual at each age.

TABLE 1 TO PARAGRAPH (b)

Age	Life expectancy
0	84.6
1	83.7
2	82.8
3	81.8
4	80.8
5	79.8
6	78.8
7	77.9
8	76.9
9	75.9
10	74.9
11	73.9
12	72.9
13	71.9
14	70.9
15	69.9

TABLE 1 TO PARAGRAPH (b)—Continued

Age	Life expectancy
16	69.0
17	68.0
18	67.0
19	66.0
20	65.0
21	64.1
22	63.1
23	62.1
24	61.1
25	60.2
26	59.2
27	58.2
28	57.3
29	56.3
30	55.3
31	54.4
32	53.4
33	52.5
34	51.5
35	50.5
36	49.6
37	48.6
38	47.7
39	46.7
40	45.7
41	44.8
42	43.8
43	42.9
44	41.9
45	41.0
46	40.0
47	39.0
48	38.1
49	37.1
50	36.2
51	35.3
52	34.3
53	33.4
54	32.5
55	31.6
56	30.6
57	29.8
58	28.9
59	28.0
60	27.1
61	26.2
62	25.4
63	24.5
64	23.7
65	22.9
66	22.0
67	21.2
68	20.4
69	19.6
70	18.8
71	18.0
72	17.2
73	16.4
74	15.6
75	14.8
76	14.1
77	13.3
78	12.6
79	11.9
80	11.2
81	10.5
82	9.9
83	9.3
84	8.7
85	8.1
86	7.6

TABLE 1 TO PARAGRAPH (b)—Continued

Age	Life expectancy
87	7.1
88	6.6
89	6.1
90	5.7
91	5.3
92	4.9
93	4.6
94	4.3
95	4.0
96	3.7
97	3.4
98	3.2
99	3.0
100	2.8
101	2.6
102	2.5
103	2.3
104	2.2
105	2.1
106	2.1
107	2.1
108	2.0
109	2.0
110	2.0
111	2.0
112	2.0
113	1.9
114	1.9
115	1.8
116	1.8
117	1.6
118	1.4
119	1.1
120+	1.0

(c) *Uniform Lifetime Table.* The following table, referred to as the Uniform Lifetime Table, sets forth the distribution period that applies for lifetime distributions to an employee in situations in which the employee's surviving spouse is not the sole designated beneficiary. This table is also used if the employee's surviving spouse is the sole designated beneficiary but is not more than 10 years younger than the employee.

TABLE 2 TO PARAGRAPH (c)

Age of employee	Distribution period
72	27.4
73	26.5
74	25.5
75	24.6
76	23.7
77	22.9
78	22.0
79	21.1
80	20.2
81	19.4
82	18.5
83	17.7
84	16.8
85	16.0
86	15.2
87	14.4
88	13.7
89	12.9
90	12.2
91	11.5
92	10.8
93	10.1

TABLE 2 TO PARAGRAPH (c)—Continued

Age of employee	Distribution period
94	9.5
95	8.9
96	8.4
97	7.8
98	7.3
99	6.8
100	6.4
101	6.0
102	5.6
103	5.2
104	4.9
105	4.6
106	4.3
107	4.1
108	3.9
109	3.7
110	3.5
111	3.4
112	3.3
113	3.1
114	3.0
115	2.9
116	2.8
117	2.7
118	2.5
119	2.3
120+	2.0

(d) *Joint and Last Survivor Table.* The following table, referred to as the Joint and Last Survivor Table, is used for determining the joint and last survivor life expectancy of two individuals.

TABLE 3 TO PARAGRAPH (d)

Ages	0	1	2	3	4	5	6	7	8
0	91.9	91.4	91.0	90.5	90.1	89.7	89.4	89.0	88.7
1	91.4	90.9	90.4	90.0	89.5	89.1	88.8	88.4	88.1
2	91.0	90.4	89.9	89.4	89.0	88.5	88.1	87.8	87.4
3	90.5	90.0	89.4	88.9	88.4	88.0	87.6	87.1	86.8
4	90.1	89.5	89.0	88.4	87.9	87.4	87.0	86.6	86.2
5	89.7	89.1	88.6	88.0	87.4	86.9	86.5	86.0	85.6
6	89.4	88.8	88.1	87.6	87.0	86.5	85.9	85.5	85.0
7	89.0	88.4	87.8	87.1	86.6	86.0	85.5	84.9	84.5
8	88.7	88.1	87.4	86.8	86.2	85.6	85.0	84.5	83.9
9	88.4	87.8	87.1	86.4	85.8	85.2	84.6	84.0	83.5
10	88.2	87.5	86.8	86.1	85.4	84.8	84.2	83.6	83.0
11	87.9	87.2	86.5	85.8	85.1	84.4	83.8	83.2	82.6
12	87.7	87.0	86.2	85.5	84.8	84.1	83.4	82.8	82.2
13	87.5	86.7	86.0	85.2	84.5	83.8	83.1	82.4	81.8
14	87.3	86.5	85.7	85.0	84.2	83.5	82.8	82.1	81.4
15	87.1	86.3	85.5	84.7	84.0	83.2	82.5	81.8	81.1
16	86.9	86.1	85.3	84.5	83.7	83.0	82.2	81.5	80.8
17	86.8	86.0	85.1	84.3	83.5	82.7	82.0	81.2	80.5
18	86.6	85.8	85.0	84.1	83.3	82.5	81.7	81.0	80.2
19	86.5	85.7	84.8	84.0	83.1	82.3	81.5	80.7	80.0
20	86.4	85.5	84.7	83.8	83.0	82.2	81.3	80.5	79.8
21	86.2	85.4	84.5	83.7	82.8	82.0	81.2	80.3	79.5
22	86.1	85.3	84.4	83.5	82.7	81.8	81.0	80.2	79.3
23	86.0	85.2	84.3	83.4	82.5	81.7	80.8	80.0	79.2
24	85.9	85.1	84.2	83.3	82.4	81.6	80.7	79.8	79.0
25	85.9	85.0	84.1	83.2	82.3	81.4	80.6	79.7	78.8
26	85.8	84.9	84.0	83.1	82.2	81.3	80.4	79.6	78.7
27	85.7	84.8	83.9	83.0	82.1	81.2	80.3	79.4	78.6
28	85.6	84.7	83.8	82.9	82.0	81.1	80.2	79.3	78.4
29	85.6	84.7	83.8	82.8	81.9	81.0	80.1	79.2	78.3
30	85.5	84.6	83.7	82.8	81.8	80.9	80.0	79.1	78.2

TABLE 3 TO PARAGRAPH (d)—Continued

Ages	0	1	2	3	4	5	6	7	8
31	85.4	84.6	83.6	82.7	81.8	80.9	79.9	79.0	78.1
32	85.4	84.5	83.6	82.6	81.7	80.8	79.9	78.9	78.0
33	85.3	84.5	83.5	82.6	81.6	80.7	79.8	78.9	77.9
34	85.3	84.4	83.5	82.5	81.6	80.7	79.7	78.8	77.9
35	85.3	84.4	83.4	82.5	81.5	80.6	79.7	78.7	77.8
36	85.2	84.3	83.4	82.4	81.5	80.5	79.6	78.7	77.7
37	85.2	84.3	83.3	82.4	81.4	80.5	79.5	78.6	77.7
38	85.2	84.3	83.3	82.3	81.4	80.4	79.5	78.6	77.6
39	85.1	84.2	83.3	82.3	81.4	80.4	79.5	78.5	77.6
40	85.1	84.2	83.2	82.3	81.3	80.4	79.4	78.5	77.5
41	85.1	84.2	83.2	82.2	81.3	80.3	79.4	78.4	77.5
42	85.0	84.1	83.2	82.2	81.3	80.3	79.3	78.4	77.4
43	85.0	84.1	83.1	82.2	81.2	80.3	79.3	78.3	77.4
44	85.0	84.1	83.1	82.2	81.2	80.2	79.3	78.3	77.3
45	85.0	84.1	83.1	82.1	81.2	80.2	79.2	78.3	77.3
46	84.9	84.0	83.1	82.1	81.1	80.2	79.2	78.2	77.3
47	84.9	84.0	83.1	82.1	81.1	80.2	79.2	78.2	77.3
48	84.9	84.0	83.0	82.1	81.1	80.1	79.2	78.2	77.2
49	84.9	84.0	83.0	82.1	81.1	80.1	79.1	78.2	77.2
50	84.9	84.0	83.0	82.0	81.1	80.1	79.1	78.1	77.2
51	84.8	84.0	83.0	82.0	81.0	80.1	79.1	78.1	77.2
52	84.8	83.9	83.0	82.0	81.0	80.1	79.1	78.1	77.1
53	84.8	83.9	83.0	82.0	81.0	80.0	79.1	78.1	77.1
54	84.8	83.9	82.9	82.0	81.0	80.0	79.0	78.1	77.1
55	84.8	83.9	82.9	82.0	81.0	80.0	79.0	78.1	77.1
56	84.8	83.9	82.9	81.9	81.0	80.0	79.0	78.0	77.1
57	84.8	83.9	82.9	81.9	81.0	80.0	79.0	78.0	77.0
58	84.8	83.9	82.9	81.9	80.9	80.0	79.0	78.0	77.0
59	84.7	83.9	82.9	81.9	80.9	80.0	79.0	78.0	77.0
60	84.7	83.8	82.9	81.9	80.9	79.9	79.0	78.0	77.0
61	84.7	83.8	82.9	81.9	80.9	79.9	79.0	78.0	77.0
62	84.7	83.8	82.9	81.9	80.9	79.9	78.9	78.0	77.0
63	84.7	83.8	82.9	81.9	80.9	79.9	78.9	78.0	77.0
64	84.7	83.8	82.8	81.9	80.9	79.9	78.9	77.9	77.0
65	84.7	83.8	82.8	81.9	80.9	79.9	78.9	77.9	77.0
66	84.7	83.8	82.8	81.9	80.9	79.9	78.9	77.9	76.9
67	84.7	83.8	82.8	81.9	80.9	79.9	78.9	77.9	76.9
68	84.7	83.8	82.8	81.8	80.9	79.9	78.9	77.9	76.9
69	84.7	83.8	82.8	81.8	80.9	79.9	78.9	77.9	76.9
70	84.7	83.8	82.8	81.8	80.9	79.9	78.9	77.9	76.9
71	84.7	83.8	82.8	81.8	80.9	79.9	78.9	77.9	76.9
72	84.7	83.8	82.8	81.8	80.9	79.9	78.9	77.9	76.9
73	84.6	83.8	82.8	81.8	80.8	79.9	78.9	77.9	76.9
74	84.6	83.8	82.8	81.8	80.8	79.9	78.9	77.9	76.9
75	84.6	83.8	82.8	81.8	80.8	79.9	78.9	77.9	76.9
76	84.6	83.8	82.8	81.8	80.8	79.9	78.9	77.9	76.9
77	84.6	83.8	82.8	81.8	80.8	79.8	78.9	77.9	76.9
78	84.6	83.8	82.8	81.8	80.8	79.8	78.9	77.9	76.9
79	84.6	83.8	82.8	81.8	80.8	79.8	78.9	77.9	76.9
80	84.6	83.8	82.8	81.8	80.8	79.8	78.9	77.9	76.9
81	84.6	83.8	82.8	81.8	80.8	79.8	78.9	77.9	76.9
82	84.6	83.8	82.8	81.8	80.8	79.8	78.9	77.9	76.9
83	84.6	83.7	82.8	81.8	80.8	79.8	78.9	77.9	76.9
84	84.6	83.7	82.8	81.8	80.8	79.8	78.9	77.9	76.9
85	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
86	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
87	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
88	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
89	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
90	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
91	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
92	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
93	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
94	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
95	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
96	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
97	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
98	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
99	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
100	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
101	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
102	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9

TABLE 3 TO PARAGRAPH (d)—Continued

Ages	0	1	2	3	4	5	6	7	8
103	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
104	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
105	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
106	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
107	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
108	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
109	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
110	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
111	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
112	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
113	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
114	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
115	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
116	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
117	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
118	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
119	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
120+	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9

Ages	9	10	11	12	13	14	15	16	17
0	88.4	88.2	87.9	87.7	87.5	87.3	87.1	86.9	86.8
1	87.8	87.5	87.2	87.0	86.7	86.5	86.3	86.1	86.0
2	87.1	86.8	86.5	86.2	86.0	85.7	85.5	85.3	85.1
3	86.4	86.1	85.8	85.5	85.2	85.0	84.7	84.5	84.3
4	85.8	85.4	85.1	84.8	84.5	84.2	84.0	83.7	83.5
5	85.2	84.8	84.4	84.1	83.8	83.5	83.2	83.0	82.7
6	84.6	84.2	83.8	83.4	83.1	82.8	82.5	82.2	82.0
7	84.0	83.6	83.2	82.8	82.4	82.1	81.8	81.5	81.2
8	83.5	83.0	82.6	82.2	81.8	81.4	81.1	80.8	80.5
9	82.9	82.5	82.0	81.6	81.2	80.8	80.4	80.1	79.8
10	82.5	81.9	81.5	81.0	80.6	80.2	79.8	79.4	79.1
11	82.0	81.5	80.9	80.5	80.0	79.6	79.2	78.8	78.4
12	81.6	81.0	80.5	79.9	79.5	79.0	78.6	78.2	77.8
13	81.2	80.6	80.0	79.5	79.0	78.5	78.0	77.6	77.2
14	80.8	80.2	79.6	79.0	78.5	78.0	77.5	77.0	76.6
15	80.4	79.8	79.2	78.6	78.0	77.5	77.0	76.5	76.0
16	80.1	79.4	78.8	78.2	77.6	77.0	76.5	76.0	75.5
17	79.8	79.1	78.4	77.8	77.2	76.6	76.0	75.5	75.0
18	79.5	78.8	78.1	77.4	76.8	76.2	75.6	75.0	74.5
19	79.2	78.5	77.8	77.1	76.4	75.8	75.2	74.6	74.0
20	79.0	78.2	77.5	76.8	76.1	75.4	74.8	74.2	73.6
21	78.8	78.0	77.2	76.5	75.8	75.1	74.4	73.8	73.2
22	78.5	77.8	77.0	76.2	75.5	74.8	74.1	73.4	72.8
23	78.3	77.5	76.8	76.0	75.2	74.5	73.8	73.1	72.5
24	78.2	77.3	76.5	75.8	75.0	74.2	73.5	72.8	72.1
25	78.0	77.2	76.4	75.6	74.8	74.0	73.3	72.5	71.8
26	77.8	77.0	76.2	75.4	74.6	73.8	73.0	72.3	71.5
27	77.7	76.8	76.0	75.2	74.4	73.6	72.8	72.0	71.3
28	77.6	76.7	75.8	75.0	74.2	73.4	72.6	71.8	71.0
29	77.4	76.6	75.7	74.9	74.0	73.2	72.4	71.6	70.8
30	77.3	76.4	75.6	74.7	73.9	73.0	72.2	71.4	70.6
31	77.2	76.3	75.5	74.6	73.7	72.9	72.0	71.2	70.4
32	77.1	76.2	75.3	74.5	73.6	72.7	71.9	71.0	70.2
33	77.0	76.1	75.2	74.3	73.5	72.6	71.7	70.9	70.0
34	77.0	76.0	75.1	74.2	73.3	72.5	71.6	70.7	69.9
35	76.9	76.0	75.0	74.1	73.2	72.4	71.5	70.6	69.7
36	76.8	75.9	75.0	74.0	73.1	72.2	71.4	70.5	69.6
37	76.7	75.8	74.9	74.0	73.1	72.1	71.3	70.4	69.5
38	76.7	75.7	74.8	73.9	73.0	72.1	71.2	70.3	69.4
39	76.6	75.7	74.7	73.8	72.9	72.0	71.1	70.2	69.3
40	76.6	75.6	74.7	73.7	72.8	71.9	71.0	70.1	69.2
41	76.5	75.6	74.6	73.7	72.8	71.8	70.9	70.0	69.1
42	76.5	75.5	74.6	73.6	72.7	71.8	70.8	69.9	69.0
43	76.4	75.5	74.5	73.6	72.6	71.7	70.8	69.8	68.9
44	76.4	75.4	74.5	73.5	72.6	71.6	70.7	69.8	68.8
45	76.4	75.4	74.4	73.5	72.5	71.6	70.6	69.7	68.8
46	76.3	75.4	74.4	73.4	72.5	71.5	70.6	69.7	68.7
47	76.3	75.3	74.4	73.4	72.4	71.5	70.5	69.6	68.7
48	76.3	75.3	74.3	73.4	72.4	71.5	70.5	69.6	68.6
49	76.2	75.3	74.3	73.3	72.4	71.4	70.5	69.5	68.6

TABLE 3 TO PARAGRAPH (d)

Ages	9	10	11	12	13	14	15	16	17
50	76.2	75.2	74.3	73.3	72.3	71.4	70.4	69.5	68.5
51	76.2	75.2	74.2	73.3	72.3	71.3	70.4	69.4	68.5
52	76.2	75.2	74.2	73.2	72.3	71.3	70.4	69.4	68.4
53	76.1	75.2	74.2	73.2	72.3	71.3	70.3	69.4	68.4
54	76.1	75.1	74.2	73.2	72.2	71.3	70.3	69.3	68.4
55	76.1	75.1	74.2	73.2	72.2	71.2	70.3	69.3	68.3
56	76.1	75.1	74.1	73.2	72.2	71.2	70.2	69.3	68.3
57	76.1	75.1	74.1	73.1	72.2	71.2	70.2	69.3	68.3
58	76.1	75.1	74.1	73.1	72.1	71.2	70.2	69.2	68.3
59	76.0	75.1	74.1	73.1	72.1	71.2	70.2	69.2	68.2
60	76.0	75.0	74.1	73.1	72.1	71.1	70.2	69.2	68.2
61	76.0	75.0	74.1	73.1	72.1	71.1	70.1	69.2	68.2
62	76.0	75.0	74.0	73.1	72.1	71.1	70.1	69.2	68.2
63	76.0	75.0	74.0	73.0	72.1	71.1	70.1	69.1	68.2
64	76.0	75.0	74.0	73.0	72.1	71.1	70.1	69.1	68.2
65	76.0	75.0	74.0	73.0	72.0	71.1	70.1	69.1	68.1
66	76.0	75.0	74.0	73.0	72.0	71.1	70.1	69.1	68.1
67	76.0	75.0	74.0	73.0	72.0	71.0	70.1	69.1	68.1
68	75.9	75.0	74.0	73.0	72.0	71.0	70.1	69.1	68.1
69	75.9	75.0	74.0	73.0	72.0	71.0	70.0	69.1	68.1
70	75.9	74.9	74.0	73.0	72.0	71.0	70.0	69.1	68.1
71	75.9	74.9	74.0	73.0	72.0	71.0	70.0	69.0	68.1
72	75.9	74.9	73.9	73.0	72.0	71.0	70.0	69.0	68.1
73	75.9	74.9	73.9	73.0	72.0	71.0	70.0	69.0	68.1
74	75.9	74.9	73.9	73.0	72.0	71.0	70.0	69.0	68.0
75	75.9	74.9	73.9	72.9	72.0	71.0	70.0	69.0	68.0
76	75.9	74.9	73.9	72.9	72.0	71.0	70.0	69.0	68.0
77	75.9	74.9	73.9	72.9	72.0	71.0	70.0	69.0	68.0
78	75.9	74.9	73.9	72.9	71.9	71.0	70.0	69.0	68.0
79	75.9	74.9	73.9	72.9	71.9	71.0	70.0	69.0	68.0
80	75.9	74.9	73.9	72.9	71.9	71.0	70.0	69.0	68.0
81	75.9	74.9	73.9	72.9	71.9	71.0	70.0	69.0	68.0
82	75.9	74.9	73.9	72.9	71.9	70.9	70.0	69.0	68.0
83	75.9	74.9	73.9	72.9	71.9	70.9	70.0	69.0	68.0
84	75.9	74.9	73.9	72.9	71.9	70.9	70.0	69.0	68.0
85	75.9	74.9	73.9	72.9	71.9	70.9	70.0	69.0	68.0
86	75.9	74.9	73.9	72.9	71.9	70.9	70.0	69.0	68.0
87	75.9	74.9	73.9	72.9	71.9	70.9	70.0	69.0	68.0
88	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
89	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
90	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
91	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
92	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
93	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
94	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
95	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
96	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
97	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
98	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
99	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
100	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
101	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
102	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
103	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
104	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
105	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
106	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
107	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
108	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
109	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
110	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
111	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
112	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
113	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
114	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
115	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
116	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
117	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
118	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
119	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
120+	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0

TABLE 3 TO PARAGRAPH (d)

Ages	18	19	20	21	22	23	24	25	26
0	86.6	86.5	86.4	86.2	86.1	86.0	85.9	85.9	85.8
1	85.8	85.7	85.5	85.4	85.3	85.2	85.1	85.0	84.9
2	85.0	84.8	84.7	84.5	84.4	84.3	84.2	84.1	84.0
3	84.1	84.0	83.8	83.7	83.5	83.4	83.3	83.2	83.1
4	83.3	83.1	83.0	82.8	82.7	82.5	82.4	82.3	82.2
5	82.5	82.3	82.2	82.0	81.8	81.7	81.6	81.4	81.3
6	81.7	81.5	81.3	81.2	81.0	80.8	80.7	80.6	80.4
7	81.0	80.7	80.5	80.3	80.2	80.0	79.8	79.7	79.6
8	80.2	80.0	79.8	79.5	79.3	79.2	79.0	78.8	78.7
9	79.5	79.2	79.0	78.8	78.5	78.3	78.2	78.0	77.8
10	78.8	78.5	78.2	78.0	77.8	77.5	77.3	77.2	77.0
11	78.1	77.8	77.5	77.2	77.0	76.8	76.5	76.4	76.2
12	77.4	77.1	76.8	76.5	76.2	76.0	75.8	75.6	75.4
13	76.8	76.4	76.1	75.8	75.5	75.2	75.0	74.8	74.6
14	76.2	75.8	75.4	75.1	74.8	74.5	74.2	74.0	73.8
15	75.6	75.2	74.8	74.4	74.1	73.8	73.5	73.3	73.0
16	75.0	74.6	74.2	73.8	73.4	73.1	72.8	72.5	72.3
17	74.5	74.0	73.6	73.2	72.8	72.5	72.1	71.8	71.5
18	74.0	73.5	73.0	72.6	72.2	71.8	71.5	71.1	70.8
19	73.5	73.0	72.5	72.0	71.6	71.2	70.8	70.5	70.1
20	73.0	72.5	72.0	71.5	71.0	70.6	70.2	69.8	69.5
21	72.6	72.0	71.5	71.0	70.5	70.0	69.6	69.2	68.8
22	72.2	71.6	71.0	70.5	70.0	69.5	69.0	68.6	68.2
23	71.8	71.2	70.6	70.0	69.5	69.0	68.5	68.0	67.6
24	71.5	70.8	70.2	69.6	69.0	68.5	68.0	67.5	67.1
25	71.1	70.5	69.8	69.2	68.6	68.0	67.5	67.0	66.5
26	70.8	70.1	69.5	68.8	68.2	67.6	67.1	66.5	66.0
27	70.5	69.8	69.1	68.5	67.8	67.2	66.6	66.1	65.5
28	70.3	69.5	68.8	68.1	67.5	66.8	66.2	65.6	65.1
29	70.0	69.3	68.5	67.8	67.1	66.5	65.8	65.2	64.6
30	69.8	69.0	68.3	67.5	66.8	66.2	65.5	64.9	64.2
31	69.6	68.8	68.0	67.3	66.6	65.8	65.2	64.5	63.9
32	69.4	68.6	67.8	67.0	66.3	65.6	64.9	64.2	63.5
33	69.2	68.4	67.6	66.8	66.0	65.3	64.6	63.9	63.2
34	69.0	68.2	67.4	66.6	65.8	65.1	64.3	63.6	62.9
35	68.9	68.0	67.2	66.4	65.6	64.8	64.1	63.3	62.6
36	68.7	67.9	67.1	66.2	65.4	64.6	63.8	63.1	62.3
37	68.6	67.7	66.9	66.1	65.2	64.4	63.6	62.8	62.1
38	68.5	67.6	66.8	65.9	65.1	64.2	63.4	62.6	61.9
39	68.4	67.5	66.6	65.8	64.9	64.1	63.3	62.4	61.6
40	68.3	67.4	66.5	65.6	64.8	63.9	63.1	62.3	61.5
41	68.2	67.3	66.4	65.5	64.6	63.8	62.9	62.1	61.3
42	68.1	67.2	66.3	65.4	64.5	63.6	62.8	61.9	61.1
43	68.0	67.1	66.2	65.3	64.4	63.5	62.7	61.8	61.0
44	67.9	67.0	66.1	65.2	64.3	63.4	62.5	61.7	60.8
45	67.9	66.9	66.0	65.1	64.2	63.3	62.4	61.5	60.7
46	67.8	66.9	65.9	65.0	64.1	63.2	62.3	61.4	60.6
47	67.7	66.8	65.9	65.0	64.0	63.1	62.2	61.3	60.5
48	67.7	66.7	65.8	64.9	64.0	63.0	62.1	61.2	60.3
49	67.6	66.7	65.7	64.8	63.9	63.0	62.1	61.2	60.3
50	67.6	66.6	65.7	64.8	63.8	62.9	62.0	61.1	60.2
51	67.5	66.6	65.6	64.7	63.8	62.8	61.9	61.0	60.1
52	67.5	66.5	65.6	64.7	63.7	62.8	61.9	60.9	60.0
53	67.4	66.5	65.5	64.6	63.7	62.7	61.8	60.9	59.9
54	67.4	66.5	65.5	64.6	63.6	62.7	61.7	60.8	59.9
55	67.4	66.4	65.5	64.5	63.6	62.6	61.7	60.8	59.8
56	67.4	66.4	65.4	64.5	63.5	62.6	61.6	60.7	59.8
57	67.3	66.4	65.4	64.5	63.5	62.5	61.6	60.7	59.7
58	67.3	66.3	65.4	64.4	63.5	62.5	61.6	60.6	59.7
59	67.3	66.3	65.4	64.4	63.4	62.5	61.5	60.6	59.6
60	67.3	66.3	65.3	64.4	63.4	62.4	61.5	60.5	59.6
61	67.2	66.3	65.3	64.3	63.4	62.4	61.5	60.5	59.6
62	67.2	66.2	65.3	64.3	63.4	62.4	61.4	60.5	59.5
63	67.2	66.2	65.3	64.3	63.3	62.4	61.4	60.5	59.5
64	67.2	66.2	65.2	64.3	63.3	62.3	61.4	60.4	59.5
65	67.2	66.2	65.2	64.3	63.3	62.3	61.4	60.4	59.5
66	67.2	66.2	65.2	64.2	63.3	62.3	61.3	60.4	59.4
67	67.1	66.2	65.2	64.2	63.3	62.3	61.3	60.4	59.4
68	67.1	66.2	65.2	64.2	63.2	62.3	61.3	60.3	59.4
69	67.1	66.1	65.2	64.2	63.2	62.3	61.3	60.3	59.4
70	67.1	66.1	65.2	64.2	63.2	62.2	61.3	60.3	59.4
71	67.1	66.1	65.1	64.2	63.2	62.2	61.3	60.3	59.3

TABLE 3 TO PARAGRAPH (d)—Continued

Ages	18	19	20	21	22	23	24	25	26
72	67.1	66.1	65.1	64.2	63.2	62.2	61.3	60.3	59.3
73	67.1	66.1	65.1	64.2	63.2	62.2	61.2	60.3	59.3
74	67.1	66.1	65.1	64.1	63.2	62.2	61.2	60.3	59.3
75	67.1	66.1	65.1	64.1	63.2	62.2	61.2	60.3	59.3
76	67.1	66.1	65.1	64.1	63.2	62.2	61.2	60.2	59.3
77	67.0	66.1	65.1	64.1	63.1	62.2	61.2	60.2	59.3
78	67.0	66.1	65.1	64.1	63.1	62.2	61.2	60.2	59.3
79	67.0	66.1	65.1	64.1	63.1	62.2	61.2	60.2	59.3
80	67.0	66.1	65.1	64.1	63.1	62.1	61.2	60.2	59.2
81	67.0	66.0	65.1	64.1	63.1	62.1	61.2	60.2	59.2
82	67.0	66.0	65.1	64.1	63.1	62.1	61.2	60.2	59.2
83	67.0	66.0	65.1	64.1	63.1	62.1	61.2	60.2	59.2
84	67.0	66.0	65.1	64.1	63.1	62.1	61.2	60.2	59.2
85	67.0	66.0	65.1	64.1	63.1	62.1	61.2	60.2	59.2
86	67.0	66.0	65.1	64.1	63.1	62.1	61.1	60.2	59.2
87	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
88	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
89	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
90	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
91	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
92	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
93	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
94	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
95	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
96	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
97	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
98	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
99	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
100	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
101	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
102	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
103	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
104	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
105	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
106	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
107	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
108	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
109	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
110	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
111	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
112	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
113	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
114	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
115	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
116	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
117	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
118	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
119	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
120+	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2

Ages	27	28	29	30	31	32	33	34	35
0	85.7	85.6	85.6	85.5	85.4	85.4	85.3	85.3	85.3
1	84.8	84.7	84.7	84.6	84.6	84.5	84.5	84.4	84.4
2	83.9	83.8	83.8	83.7	83.6	83.6	83.5	83.5	83.4
3	83.0	82.9	82.8	82.8	82.7	82.6	82.6	82.5	82.5
4	82.1	82.0	81.9	81.8	81.8	81.7	81.6	81.6	81.5
5	81.2	81.1	81.0	80.9	80.9	80.8	80.7	80.7	80.6
6	80.3	80.2	80.1	80.0	79.9	79.9	79.8	79.7	79.7
7	79.4	79.3	79.2	79.1	79.0	78.9	78.9	78.8	78.7
8	78.6	78.4	78.3	78.2	78.1	78.0	77.9	77.9	77.8
9	77.7	77.6	77.4	77.3	77.2	77.1	77.0	77.0	76.9
10	76.8	76.7	76.6	76.4	76.3	76.2	76.1	76.0	76.0
11	76.0	75.8	75.7	75.6	75.5	75.3	75.2	75.1	75.0
12	75.2	75.0	74.9	74.7	74.6	74.5	74.3	74.2	74.1
13	74.4	74.2	74.0	73.9	73.7	73.6	73.5	73.3	73.2
14	73.6	73.4	73.2	73.0	72.9	72.7	72.6	72.5	72.4
15	72.8	72.6	72.4	72.2	72.0	71.9	71.7	71.6	71.5
16	72.0	71.8	71.6	71.4	71.2	71.0	70.9	70.7	70.6
17	71.3	71.0	70.8	70.6	70.4	70.2	70.0	69.9	69.7
18	70.5	70.3	70.0	69.8	69.6	69.4	69.2	69.0	68.9
19	69.8	69.5	69.3	69.0	68.8	68.6	68.4	68.2	

TABLE 3 TO PARAGRAPH (d)

Ages	27	28	29	30	31	32	33	34	35
20	69.1	68.8	68.5	68.3	68.0	67.8	67.6	67.4	67.2
21	68.5	68.1	67.8	67.5	67.3	67.0	66.8	66.6	66.4
22	67.8	67.5	67.1	66.8	66.6	66.3	66.0	65.8	65.6
23	67.2	66.8	66.5	66.2	65.8	65.6	65.3	65.1	64.8
24	66.6	66.2	65.8	65.5	65.2	64.9	64.6	64.3	64.1
25	66.1	65.6	65.2	64.9	64.5	64.2	63.9	63.6	63.3
26	65.5	65.1	64.6	64.2	63.9	63.5	63.2	62.9	62.6
27	65.0	64.5	64.1	63.7	63.2	62.9	62.5	62.2	61.9
28	64.5	64.0	63.5	63.1	62.7	62.3	61.9	61.5	61.2
29	64.1	63.5	63.0	62.6	62.1	61.7	61.3	60.9	60.5
30	63.7	63.1	62.6	62.0	61.6	61.1	60.7	60.3	59.9
31	63.2	62.7	62.1	61.6	61.1	60.6	60.1	59.7	59.3
32	62.9	62.3	61.7	61.1	60.6	60.1	59.6	59.1	58.7
33	62.5	61.9	61.3	60.7	60.1	59.6	59.1	58.6	58.1
34	62.2	61.5	60.9	60.3	59.7	59.1	58.6	58.1	57.6
35	61.9	61.2	60.5	59.9	59.3	58.7	58.1	57.6	57.1
36	61.6	60.9	60.2	59.5	58.9	58.3	57.7	57.2	56.6
37	61.3	60.6	59.9	59.2	58.6	57.9	57.3	56.7	56.2
38	61.1	60.3	59.6	58.9	58.2	57.6	56.9	56.3	55.7
39	60.9	60.1	59.4	58.6	57.9	57.2	56.6	55.9	55.3
40	60.7	59.9	59.1	58.4	57.6	56.9	56.3	55.6	55.0
41	60.5	59.7	58.9	58.1	57.4	56.7	56.0	55.3	54.6
42	60.3	59.5	58.7	57.9	57.1	56.4	55.7	55.0	54.3
43	60.1	59.3	58.5	57.7	56.9	56.2	55.4	54.7	54.0
44	60.0	59.1	58.3	57.5	56.7	55.9	55.2	54.4	53.7
45	59.8	59.0	58.1	57.3	56.5	55.7	54.9	54.2	53.4
46	59.7	58.8	58.0	57.2	56.3	55.5	54.7	54.0	53.2
47	59.6	58.7	57.9	57.0	56.2	55.4	54.5	53.7	53.0
48	59.5	58.6	57.7	56.9	56.0	55.2	54.4	53.6	52.8
49	59.4	58.5	57.6	56.7	55.9	55.0	54.2	53.4	52.6
50	59.3	58.4	57.5	56.6	55.8	54.9	54.1	53.2	52.4
51	59.2	58.3	57.4	56.5	55.6	54.8	53.9	53.1	52.2
52	59.1	58.2	57.3	56.4	55.5	54.7	53.8	52.9	52.1
53	59.0	58.1	57.2	56.3	55.4	54.6	53.7	52.8	52.0
54	59.0	58.0	57.1	56.2	55.3	54.5	53.6	52.7	51.8
55	58.9	58.0	57.1	56.2	55.3	54.4	53.5	52.6	51.7
56	58.8	57.9	57.0	56.1	55.2	54.3	53.4	52.5	51.6
57	58.8	57.9	56.9	56.0	55.1	54.2	53.3	52.4	51.5
58	58.7	57.8	56.9	56.0	55.0	54.1	53.2	52.3	51.4
59	58.7	57.8	56.8	55.9	55.0	54.1	53.2	52.2	51.3
60	58.7	57.7	56.8	55.9	54.9	54.0	53.1	52.2	51.3
61	58.6	57.7	56.7	55.8	54.9	54.0	53.0	52.1	51.2
62	58.6	57.6	56.7	55.8	54.8	53.9	53.0	52.1	51.1
63	58.6	57.6	56.7	55.7	54.8	53.9	52.9	52.0	51.1
64	58.5	57.6	56.6	55.7	54.8	53.8	52.9	52.0	51.0
65	58.5	57.5	56.6	55.7	54.7	53.8	52.8	51.9	51.0
66	58.5	57.5	56.6	55.6	54.7	53.7	52.8	51.9	50.9
67	58.5	57.5	56.5	55.6	54.7	53.7	52.8	51.8	50.9
68	58.4	57.5	56.5	55.6	54.6	53.7	52.7	51.8	50.9
69	58.4	57.5	56.5	55.6	54.6	53.7	52.7	51.8	50.8
70	58.4	57.4	56.5	55.5	54.6	53.6	52.7	51.7	50.8
71	58.4	57.4	56.5	55.5	54.6	53.6	52.7	51.7	50.8
72	58.4	57.4	56.5	55.5	54.5	53.6	52.6	51.7	50.8
73	58.4	57.4	56.4	55.5	54.5	53.6	52.6	51.7	50.7
74	58.3	57.4	56.4	55.5	54.5	53.6	52.6	51.7	50.7
75	58.3	57.4	56.4	55.5	54.5	53.5	52.6	51.6	50.7
76	58.3	57.4	56.4	55.4	54.5	53.5	52.6	51.6	50.7
77	58.3	57.3	56.4	55.4	54.5	53.5	52.6	51.6	50.7
78	58.3	57.3	56.4	55.4	54.5	53.5	52.6	51.6	50.6
79	58.3	57.3	56.4	55.4	54.5	53.5	52.5	51.6	50.6
80	58.3	57.3	56.4	55.4	54.4	53.5	52.5	51.6	50.6
81	58.3	57.3	56.4	55.4	54.4	53.5	52.5	51.6	50.6
82	58.3	57.3	56.3	55.4	54.4	53.5	52.5	51.6	50.6
83	58.3	57.3	56.3	55.4	54.4	53.5	52.5	51.6	50.6
84	58.3	57.3	56.3	55.4	54.4	53.5	52.5	51.5	50.6
85	58.3	57.3	56.3	55.4	54.4	53.5	52.5	51.5	50.6
86	58.2	57.3	56.3	55.4	54.4	53.5	52.5	51.5	50.6
87	58.2	57.3	56.3	55.4	54.4	53.4	52.5	51.5	50.6
88	58.2	57.3	56.3	55.4	54.4	53.4	52.5	51.5	50.6
89	58.2	57.3	56.3	55.4	54.4	53.4	52.5	51.5	50.6
90	58.2	57.3	56.3	55.4	54.4	53.4	52.5	51.5	50.6
91	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6

TABLE 3 TO PARAGRAPH (d)—Continued

Ages	27	28	29	30	31	32	33	34	35
92	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
93	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
94	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
95	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
96	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
97	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
98	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
99	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
100	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
101	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
102	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
103	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
104	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
105	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
106	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
107	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
108	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
109	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
110	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
111	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
112	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
113	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
114	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
115	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
116	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
117	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
118	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
119	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5
120+	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.5

Ages	36	37	38	39	40	41	42	43	44
0	85.2	85.2	85.2	85.1	85.1	85.1	85.0	85.0	85.0
1	84.3	84.3	84.3	84.2	84.2	84.2	84.1	84.1	84.1
2	83.4	83.3	83.3	83.3	83.2	83.2	83.2	83.1	83.1
3	82.4	82.4	82.3	82.3	82.3	82.2	82.2	82.2	82.2
4	81.5	81.4	81.4	81.4	81.3	81.3	81.3	81.2	81.2
5	80.5	80.5	80.4	80.4	80.4	80.3	80.3	80.3	80.2
6	79.6	79.5	79.5	79.5	79.4	79.4	79.3	79.3	79.3
7	78.7	78.6	78.6	78.5	78.5	78.4	78.4	78.3	78.3
8	77.7	77.7	77.6	77.6	77.5	77.5	77.4	77.4	77.3
9	76.8	76.7	76.7	76.6	76.6	76.5	76.5	76.4	76.4
10	75.9	75.8	75.7	75.7	75.6	75.6	75.5	75.5	75.4
11	75.0	74.9	74.8	74.7	74.7	74.6	74.6	74.5	74.5
12	74.0	74.0	73.9	73.8	73.7	73.7	73.6	73.6	73.5
13	73.1	73.1	73.0	72.9	72.8	72.8	72.7	72.6	72.6
14	72.2	72.1	72.1	72.0	71.9	71.8	71.8	71.7	71.6
15	71.4	71.3	71.2	71.1	71.0	70.9	70.8	70.8	70.7
16	70.5	70.4	70.3	70.2	70.1	70.0	69.9	69.8	69.8
17	69.6	69.5	69.4	69.3	69.2	69.1	69.0	68.9	68.8
18	68.7	68.6	68.5	68.4	68.3	68.2	68.1	68.0	67.9
19	67.9	67.7	67.6	67.5	67.4	67.3	67.2	67.1	67.0
20	67.1	66.9	66.8	66.6	66.5	66.4	66.3	66.2	66.1
21	66.2	66.1	65.9	65.8	65.6	65.5	65.4	65.3	65.2
22	65.4	65.2	65.1	64.9	64.8	64.6	64.5	64.4	64.3
23	64.6	64.4	64.2	64.1	63.9	63.8	63.6	63.5	63.4
24	63.8	63.6	63.4	63.3	63.1	62.9	62.8	62.7	62.5
25	63.1	62.8	62.6	62.4	62.3	62.1	61.9	61.8	61.7
26	62.3	62.1	61.9	61.6	61.5	61.3	61.1	61.0	60.8
27	61.6	61.3	61.1	60.9	60.7	60.5	60.3	60.1	60.0
28	60.9	60.6	60.3	60.1	59.9	59.7	59.5	59.3	59.1
29	60.2	59.9	59.6	59.4	59.1	58.9	58.7	58.5	58.3
30	59.5	59.2	58.9	58.6	58.4	58.1	57.9	57.7	57.5
31	58.9	58.6	58.2	57.9	57.6	57.4	57.1	56.9	56.7
32	58.3	57.9	57.6	57.2	56.9	56.7	56.4	56.2	55.9
33	57.7	57.3	56.9	56.6	56.3	56.0	55.7	55.4	55.2
34	57.2	56.7	56.3	55.9	55.6	55.3	55.0	54.7	54.4
35	56.6	56.2	55.7	55.3	55.0	54.6	54.3	54.0	53.7
36	56.1	55.6	55.2	54.7	54.3	54.0	53.6	53.3	53.0
37	55.6	55.1	54.6	54.2	53.8	53.4	53.0	52.6	52.3
38	55.2	54.6	54.1	53.6	53.2	52.8	52.4	52.0	51.6
39	54.7	54.2	53.6	53.1	52.7	52.2	51.8	51.4	51.0

TABLE 3 TO PARAGRAPH (d)

Ages	36	37	38	39	40	41	42	43	44
40	54.3	53.8	53.2	52.7	52.2	51.7	51.2	50.8	50.4
41	54.0	53.4	52.8	52.2	51.7	51.2	50.7	50.2	49.8
42	53.6	53.0	52.4	51.8	51.2	50.7	50.2	49.7	49.2
43	53.3	52.6	52.0	51.4	50.8	50.2	49.7	49.2	48.7
44	53.0	52.3	51.6	51.0	50.4	49.8	49.2	48.7	48.2
45	52.7	52.0	51.3	50.7	50.0	49.4	48.8	48.3	47.7
46	52.4	51.7	51.0	50.3	49.7	49.0	48.4	47.8	47.3
47	52.2	51.5	50.7	50.0	49.3	48.7	48.0	47.4	46.8
48	52.0	51.2	50.5	49.7	49.0	48.4	47.7	47.1	46.4
49	51.8	51.0	50.2	49.5	48.8	48.1	47.4	46.7	46.1
50	51.6	50.8	50.0	49.2	48.5	47.8	47.1	46.4	45.7
51	51.4	50.6	49.8	49.0	48.3	47.5	46.8	46.1	45.4
52	51.3	50.4	49.6	48.8	48.0	47.3	46.5	45.8	45.1
53	51.1	50.3	49.5	48.6	47.8	47.1	46.3	45.6	44.8
54	51.0	50.1	49.3	48.5	47.7	46.9	46.1	45.3	44.6
55	50.9	50.0	49.1	48.3	47.5	46.7	45.9	45.1	44.3
56	50.7	49.9	49.0	48.2	47.3	46.5	45.7	44.9	44.1
57	50.6	49.8	48.9	48.0	47.2	46.3	45.5	44.7	43.9
58	50.5	49.7	48.8	47.9	47.1	46.2	45.4	44.5	43.7
59	50.5	49.6	48.7	47.8	46.9	46.1	45.2	44.4	43.6
60	50.4	49.5	48.6	47.7	46.8	46.0	45.1	44.3	43.4
61	50.3	49.4	48.5	47.6	46.7	45.8	45.0	44.1	43.3
62	50.2	49.3	48.4	47.5	46.6	45.7	44.9	44.0	43.1
63	50.2	49.3	48.3	47.4	46.5	45.7	44.8	43.9	43.0
64	50.1	49.2	48.3	47.4	46.5	45.6	44.7	43.8	42.9
65	50.1	49.1	48.2	47.3	46.4	45.5	44.6	43.7	42.8
66	50.0	49.1	48.2	47.2	46.3	45.4	44.5	43.6	42.7
67	50.0	49.0	48.1	47.2	46.3	45.4	44.4	43.5	42.6
68	49.9	49.0	48.1	47.1	46.2	45.3	44.4	43.5	42.6
69	49.9	49.0	48.0	47.1	46.2	45.2	44.3	43.4	42.5
70	49.9	48.9	48.0	47.0	46.1	45.2	44.3	43.3	42.4
71	49.8	48.9	47.9	47.0	46.1	45.1	44.2	43.3	42.4
72	49.8	48.9	47.9	47.0	46.0	45.1	44.2	43.2	42.3
73	49.8	48.8	47.9	46.9	46.0	45.1	44.1	43.2	42.3
74	49.8	48.8	47.9	46.9	46.0	45.0	44.1	43.2	42.2
75	49.7	48.8	47.8	46.9	45.9	45.0	44.1	43.1	42.2
76	49.7	48.8	47.8	46.9	45.9	45.0	44.0	43.1	42.2
77	49.7	48.8	47.8	46.9	45.9	45.0	44.0	43.1	42.1
78	49.7	48.7	47.8	46.8	45.9	44.9	44.0	43.0	42.1
79	49.7	48.7	47.8	46.8	45.9	44.9	44.0	43.0	42.1
80	49.7	48.7	47.8	46.8	45.9	44.9	43.9	43.0	42.1
81	49.7	48.7	47.7	46.8	45.8	44.9	43.9	43.0	42.0
82	49.7	48.7	47.7	46.8	45.8	44.9	43.9	43.0	42.0
83	49.6	48.7	47.7	46.8	45.8	44.9	43.9	43.0	42.0
84	49.6	48.7	47.7	46.8	45.8	44.9	43.9	42.9	42.0
85	49.6	48.7	47.7	46.8	45.8	44.8	43.9	42.9	42.0
86	49.6	48.7	47.7	46.7	45.8	44.8	43.9	42.9	42.0
87	49.6	48.7	47.7	46.7	45.8	44.8	43.9	42.9	42.0
88	49.6	48.7	47.7	46.7	45.8	44.8	43.9	42.9	42.0
89	49.6	48.7	47.7	46.7	45.8	44.8	43.9	42.9	41.9
90	49.6	48.6	47.7	46.7	45.8	44.8	43.9	42.9	41.9
91	49.6	48.6	47.7	46.7	45.8	44.8	43.9	42.9	41.9
92	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
93	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
94	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
95	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
96	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
97	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
98	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
99	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
100	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
101	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
102	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
103	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
104	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
105	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
106	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
107	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
108	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
109	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
110	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
111	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9

TABLE 3 TO PARAGRAPH (d)—Continued

Ages	36	37	38	39	40	41	42	43	44
112	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
113	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
114	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
115	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
116	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
117	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
118	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
119	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
120+	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9

Ages	45	46	47	48	49	50	51	52	53
0	85.0	84.9	84.9	84.9	84.9	84.9	84.8	84.8	84.8
1	84.1	84.0	84.0	84.0	84.0	84.0	84.0	83.9	83.9
2	83.1	83.1	83.1	83.0	83.0	83.0	83.0	83.0	83.0
3	82.1	82.1	82.1	82.1	82.1	82.0	82.0	82.0	82.0
4	81.2	81.1	81.1	81.1	81.1	81.1	81.0	81.0	81.0
5	80.2	80.2	80.2	80.1	80.1	80.1	80.1	80.1	80.0
6	79.2	79.2	79.2	79.2	79.1	79.1	79.1	79.1	79.1
7	78.3	78.2	78.2	78.2	78.2	78.1	78.1	78.1	78.1
8	77.3	77.3	77.3	77.2	77.2	77.2	77.2	77.1	77.1
9	76.4	76.3	76.3	76.3	76.2	76.2	76.2	76.2	76.1
10	75.4	75.4	75.3	75.3	75.3	75.2	75.2	75.2	75.2
11	74.4	74.4	74.4	74.3	74.3	74.3	74.2	74.2	74.2
12	73.5	73.4	73.4	73.4	73.3	73.3	73.3	73.2	73.2
13	72.5	72.5	72.4	72.4	72.4	72.3	72.3	72.3	72.3
14	71.6	71.5	71.5	71.5	71.4	71.4	71.3	71.3	71.3
15	70.6	70.6	70.5	70.5	70.5	70.4	70.4	70.4	70.3
16	69.7	69.7	69.6	69.6	69.5	69.5	69.4	69.4	69.4
17	68.8	68.7	68.7	68.6	68.6	68.5	68.5	68.4	68.4
18	67.9	67.8	67.7	67.7	67.6	67.6	67.5	67.5	67.4
19	66.9	66.9	66.8	66.7	66.7	66.6	66.6	66.5	66.5
20	66.0	65.9	65.9	65.8	65.7	65.7	65.6	65.6	65.5
21	65.1	65.0	65.0	64.9	64.8	64.8	64.7	64.7	64.6
22	64.2	64.1	64.0	64.0	63.9	63.8	63.8	63.7	63.7
23	63.3	63.2	63.1	63.0	63.0	62.9	62.8	62.8	62.7
24	62.4	62.3	62.2	62.1	62.1	62.0	61.9	61.9	61.8
25	61.5	61.4	61.3	61.2	61.2	61.1	61.0	60.9	60.9
26	60.7	60.6	60.5	60.3	60.3	60.2	60.1	60.0	59.9
27	59.8	59.7	59.6	59.5	59.4	59.3	59.2	59.1	59.0
28	59.0	58.8	58.7	58.6	58.5	58.4	58.3	58.2	58.1
29	58.1	58.0	57.9	57.7	57.6	57.5	57.4	57.3	57.2
30	57.3	57.2	57.0	56.9	56.7	56.6	56.5	56.4	56.3
31	56.5	56.3	56.2	56.0	55.9	55.8	55.6	55.5	55.4
32	55.7	55.5	55.4	55.2	55.0	54.9	54.8	54.7	54.6
33	54.9	54.7	54.5	54.4	54.2	54.1	53.9	53.8	53.7
34	54.2	54.0	53.7	53.6	53.4	53.2	53.1	52.9	52.8
35	53.4	53.2	53.0	52.8	52.6	52.4	52.2	52.1	52.0
36	52.7	52.4	52.2	52.0	51.8	51.6	51.4	51.3	51.1
37	52.0	51.7	51.5	51.2	51.0	50.8	50.6	50.4	50.3
38	51.3	51.0	50.7	50.5	50.2	50.0	49.8	49.6	49.5
39	50.7	50.3	50.0	49.7	49.5	49.2	49.0	48.8	48.6
40	50.0	49.7	49.3	49.0	48.8	48.5	48.3	48.0	47.8
41	49.4	49.0	48.7	48.4	48.1	47.8	47.5	47.3	47.1
42	48.8	48.4	48.0	47.7	47.4	47.1	46.8	46.5	46.3
43	48.3	47.8	47.4	47.1	46.7	46.4	46.1	45.8	45.6
44	47.7	47.3	46.8	46.4	46.1	45.7	45.4	45.1	44.8
45	47.2	46.7	46.3	45.9	45.5	45.1	44.7	44.4	44.1
46	46.7	46.2	45.7	45.3	44.9	44.5	44.1	43.8	43.4
47	46.3	45.7	45.2	44.8	44.3	43.9	43.5	43.1	42.8
48	45.9	45.3	44.8	44.3	43.8	43.3	42.9	42.5	42.1
49	45.5	44.9	44.3	43.8	43.3	42.8	42.3	41.9	41.5
50	45.1	44.5	43.9	43.3	42.8	42.3	41.8	41.4	40.9
51	44.7	44.1	43.5	42.9	42.3	41.8	41.3	40.8	40.4
52	44.4	43.8	43.1	42.5	41.9	41.4	40.8	40.3	39.9
53	44.1	43.4	42.8	42.1	41.5	40.9	40.4	39.9	39.4
54	43.8	43.1	42.5	41.8	41.2	40.6	40.0	39.4	38.9
55	43.6	42.9	42.2	41.5	40.8	40.2	39.6	39.0	38.4
56	43.4	42.6	41.9	41.2	40.5	39.8	39.2	38.6	38.0
57	43.1	42.4	41.6	40.9	40.2	39.5	38.9	38.2	37.6
58	42.9	42.2	41.4	40.7	39.9	39.2	38.6	37.9	37.3
59	42.8	42.0	41.2	40.4	39.7	39.0	38.3	37.6	36.9

TABLE 3 TO PARAGRAPH (d)

Ages	45	46	47	48	49	50	51	52	53
60	42.6	41.8	41.0	40.2	39.5	38.7	38.0	37.3	36.6
61	42.4	41.6	40.8	40.0	39.2	38.5	37.7	37.0	36.3
62	42.3	41.5	40.6	39.8	39.0	38.3	37.5	36.8	36.1
63	42.2	41.3	40.5	39.7	38.9	38.1	37.3	36.6	35.8
64	42.1	41.2	40.4	39.5	38.7	37.9	37.1	36.3	35.6
65	41.9	41.1	40.2	39.4	38.6	37.7	36.9	36.2	35.4
66	41.8	41.0	40.1	39.3	38.4	37.6	36.8	36.0	35.2
67	41.8	40.9	40.0	39.1	38.3	37.5	36.6	35.8	35.0
68	41.7	40.8	39.9	39.0	38.2	37.3	36.5	35.7	34.9
69	41.6	40.7	39.8	38.9	38.1	37.2	36.4	35.5	34.7
70	41.5	40.6	39.7	38.8	38.0	37.1	36.2	35.4	34.6
71	41.5	40.6	39.7	38.8	37.9	37.0	36.1	35.3	34.5
72	41.4	40.5	39.6	38.7	37.8	36.9	36.0	35.2	34.3
73	41.4	40.4	39.5	38.6	37.7	36.8	36.0	35.1	34.2
74	41.3	40.4	39.5	38.6	37.7	36.8	35.9	35.0	34.1
75	41.3	40.3	39.4	38.5	37.6	36.7	35.8	34.9	34.1
76	41.2	40.3	39.4	38.5	37.5	36.6	35.7	34.9	34.0
77	41.2	40.3	39.3	38.4	37.5	36.6	35.7	34.8	33.9
78	41.2	40.2	39.3	38.4	37.5	36.5	35.6	34.7	33.9
79	41.1	40.2	39.3	38.3	37.4	36.5	35.6	34.7	33.8
80	41.1	40.2	39.2	38.3	37.4	36.5	35.5	34.6	33.7
81	41.1	40.1	39.2	38.3	37.3	36.4	35.5	34.6	33.7
82	41.1	40.1	39.2	38.3	37.3	36.4	35.5	34.6	33.7
83	41.1	40.1	39.2	38.2	37.3	36.4	35.4	34.5	33.6
84	41.0	40.1	39.2	38.2	37.3	36.3	35.4	34.5	33.6
85	41.0	40.1	39.1	38.2	37.3	36.3	35.4	34.5	33.6
86	41.0	40.1	39.1	38.2	37.2	36.3	35.4	34.5	33.5
87	41.0	40.1	39.1	38.2	37.2	36.3	35.4	34.4	33.5
88	41.0	40.0	39.1	38.2	37.2	36.3	35.3	34.4	33.5
89	41.0	40.0	39.1	38.1	37.2	36.3	35.3	34.4	33.5
90	41.0	40.0	39.1	38.1	37.2	36.3	35.3	34.4	33.5
91	41.0	40.0	39.1	38.1	37.2	36.2	35.3	34.4	33.5
92	41.0	40.0	39.1	38.1	37.2	36.2	35.3	34.4	33.5
93	41.0	40.0	39.1	38.1	37.2	36.2	35.3	34.4	33.4
94	41.0	40.0	39.1	38.1	37.2	36.2	35.3	34.4	33.4
95	41.0	40.0	39.1	38.1	37.2	36.2	35.3	34.4	33.4
96	41.0	40.0	39.1	38.1	37.2	36.2	35.3	34.3	33.4
97	41.0	40.0	39.1	38.1	37.2	36.2	35.3	34.3	33.4
98	41.0	40.0	39.1	38.1	37.2	36.2	35.3	34.3	33.4
99	41.0	40.0	39.1	38.1	37.2	36.2	35.3	34.3	33.4
100	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
101	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
102	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
103	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
104	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
105	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
106	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
107	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
108	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
109	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
110	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
111	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
112	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
113	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
114	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
115	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
116	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
117	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
118	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
119	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
120+	41.0	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4

Ages	54	55	56	57	58	59	60	61	62
0	84.8	84.8	84.8	84.8	84.8	84.7	84.7	84.7	84.7
1	83.9	83.9	83.9	83.9	83.9	83.9	83.8	83.8	83.8
2	82.9	82.9	82.9	82.9	82.9	82.9	82.9	82.9	82.9
3	82.0	82.0	81.9	81.9	81.9	81.9	81.9	81.9	81.9
4	81.0	81.0	81.0	81.0	80.9	80.9	80.9	80.9	80.9
5	80.0	80.0	80.0	80.0	80.0	80.0	79.9	79.9	79.9
6	79.0	79.0	79.0	79.0	79.0	79.0	79.0	79.0	78.9
7	78.1	78.1	78.0	78.0	78.0	78.0	78.0	78.0	78.0

TABLE 3 TO PARAGRAPH (d)

Ages	54	55	56	57	58	59	60	61	62
8	77.1	77.1	77.1	77.0	77.0	77.0	77.0	77.0	77.0
9	76.1	76.1	76.1	76.1	76.1	76.0	76.0	76.0	76.0
10	75.1	75.1	75.1	75.1	75.1	75.1	75.0	75.0	75.0
11	74.2	74.2	74.1	74.1	74.1	74.1	74.1	74.1	74.0
12	73.2	73.2	73.2	73.1	73.1	73.1	73.1	73.1	73.1
13	72.2	72.2	72.2	72.2	72.1	72.1	72.1	72.1	72.1
14	71.3	71.2	71.2	71.2	71.2	71.2	71.1	71.1	71.1
15	70.3	70.3	70.2	70.2	70.2	70.2	70.2	70.1	70.1
16	69.3	69.3	69.3	69.3	69.2	69.2	69.2	69.2	69.2
17	68.4	68.3	68.3	68.3	68.3	68.2	68.2	68.2	68.2
18	67.4	67.4	67.4	67.3	67.3	67.3	67.3	67.2	67.2
19	66.5	66.4	66.4	66.4	66.3	66.3	66.3	66.3	66.2
20	65.5	65.5	65.4	65.4	65.4	65.4	65.3	65.3	65.3
21	64.6	64.5	64.5	64.5	64.4	64.4	64.4	64.3	64.3
22	63.6	63.6	63.5	63.5	63.5	63.4	63.4	63.4	63.4
23	62.7	62.6	62.6	62.5	62.5	62.5	62.4	62.4	62.4
24	61.7	61.7	61.6	61.6	61.6	61.5	61.5	61.5	61.4
25	60.8	60.8	60.7	60.7	60.6	60.6	60.5	60.5	60.5
26	59.9	59.8	59.8	59.7	59.7	59.6	59.6	59.6	59.5
27	59.0	58.9	58.8	58.8	58.7	58.7	58.7	58.6	58.6
28	58.0	58.0	57.9	57.9	57.8	57.8	57.7	57.7	57.6
29	57.1	57.1	57.0	56.9	56.9	56.8	56.8	56.7	56.7
30	56.2	56.2	56.1	56.0	56.0	55.9	55.9	55.8	55.8
31	55.3	55.3	55.2	55.1	55.0	55.0	54.9	54.9	54.8
32	54.5	54.4	54.3	54.2	54.1	54.1	54.0	54.0	53.9
33	53.6	53.5	53.4	53.3	53.2	53.2	53.1	53.0	53.0
34	52.7	52.6	52.5	52.4	52.3	52.2	52.2	52.1	52.1
35	51.8	51.7	51.6	51.5	51.4	51.3	51.3	51.2	51.1
36	51.0	50.9	50.7	50.6	50.5	50.5	50.4	50.3	50.2
37	50.1	50.0	49.9	49.8	49.7	49.6	49.5	49.4	49.3
38	49.3	49.1	49.0	48.9	48.8	48.7	48.6	48.5	48.4
39	48.5	48.3	48.2	48.0	47.9	47.8	47.7	47.6	47.5
40	47.7	47.5	47.3	47.2	47.1	46.9	46.8	46.7	46.6
41	46.9	46.7	46.5	46.3	46.2	46.1	46.0	45.8	45.7
42	46.1	45.9	45.7	45.5	45.4	45.2	45.1	45.0	44.9
43	45.3	45.1	44.9	44.7	44.5	44.4	44.3	44.1	44.0
44	44.6	44.3	44.1	43.9	43.7	43.6	43.4	43.3	43.1
45	43.8	43.6	43.4	43.1	42.9	42.8	42.6	42.4	42.3
46	43.1	42.9	42.6	42.4	42.2	42.0	41.8	41.6	41.5
47	42.5	42.2	41.9	41.6	41.4	41.2	41.0	40.8	40.6
48	41.8	41.5	41.2	40.9	40.7	40.4	40.2	40.0	39.8
49	41.2	40.8	40.5	40.2	39.9	39.7	39.5	39.2	39.0
50	40.6	40.2	39.8	39.5	39.2	39.0	38.7	38.5	38.3
51	40.0	39.6	39.2	38.9	38.6	38.3	38.0	37.7	37.5
52	39.4	39.0	38.6	38.2	37.9	37.6	37.3	37.0	36.8
53	38.9	38.4	38.0	37.6	37.3	36.9	36.6	36.3	36.1
54	38.4	37.9	37.5	37.1	36.7	36.3	36.0	35.7	35.4
55	37.9	37.4	36.9	36.5	36.1	35.7	35.3	35.0	34.7
56	37.5	36.9	36.5	36.0	35.5	35.1	34.8	34.4	34.1
57	37.1	36.5	36.0	35.5	35.0	34.6	34.2	33.8	33.4
58	36.7	36.1	35.5	35.0	34.5	34.1	33.6	33.2	32.8
59	36.3	35.7	35.1	34.6	34.1	33.6	33.1	32.7	32.3
60	36.0	35.3	34.8	34.2	33.6	33.1	32.6	32.2	31.7
61	35.7	35.0	34.4	33.8	33.2	32.7	32.2	31.7	31.2
62	35.4	34.7	34.1	33.4	32.8	32.3	31.7	31.2	30.8
63	35.1	34.4	33.8	33.1	32.5	31.9	31.3	30.8	30.3
64	34.9	34.2	33.5	32.8	32.2	31.5	31.0	30.4	29.9
65	34.6	33.9	33.2	32.5	31.9	31.2	30.6	30.0	29.5
66	34.4	33.7	33.0	32.3	31.6	30.9	30.3	29.7	29.1
67	34.2	33.5	32.7	32.0	31.3	30.6	30.0	29.4	28.7
68	34.1	33.3	32.5	31.8	31.1	30.4	29.7	29.1	28.4
69	33.9	33.1	32.3	31.6	30.9	30.1	29.4	28.8	28.1
70	33.8	33.0	32.2	31.4	30.7	29.9	29.2	28.5	27.9
71	33.6	32.8	32.0	31.2	30.5	29.7	29.0	28.3	27.6
72	33.5	32.7	31.9	31.1	30.3	29.5	28.8	28.1	27.4
73	33.4	32.6	31.7	30.9	30.1	29.4	28.6	27.9	27.2
74	33.3	32.4	31.6	30.8	30.0	29.2	28.4	27.7	27.0
75	33.2	32.4	31.5	30.7	29.9	29.1	28.3	27.5	26.8
76	33.1	32.3	31.4	30.6	29.8	29.0	28.2	27.4	26.6
77	33.0	32.2	31.3	30.5	29.7	28.8	28.0	27.3	26.5
78	33.0	32.1	31.2	30.4	29.6	28.7	27.9	27.1	26.4
79	32.9	32.0	31.2	30.3	29.5	28.7	27.8	27.0	26.2

TABLE 3 TO PARAGRAPH (d)—Continued

Ages	54	55	56	57	58	59	60	61	62
80	32.9	32.0	31.1	30.3	29.4	28.6	27.8	26.9	26.1
81	32.8	31.9	31.1	30.2	29.3	28.5	27.7	26.9	26.0
82	32.8	31.9	31.0	30.1	29.3	28.4	27.6	26.8	26.0
83	32.7	31.8	31.0	30.1	29.2	28.4	27.5	26.7	25.9
84	32.7	31.8	30.9	30.0	29.2	28.3	27.5	26.7	25.8
85	32.7	31.8	30.9	30.0	29.1	28.3	27.4	26.6	25.8
86	32.6	31.7	30.9	30.0	29.1	28.2	27.4	26.6	25.7
87	32.6	31.7	30.8	29.9	29.1	28.2	27.4	26.5	25.7
88	32.6	31.7	30.8	29.9	29.0	28.2	27.3	26.5	25.6
89	32.6	31.7	30.8	29.9	29.0	28.2	27.3	26.4	25.6
90	32.6	31.7	30.8	29.9	29.0	28.1	27.3	26.4	25.6
91	32.5	31.6	30.7	29.9	29.0	28.1	27.3	26.4	25.6
92	32.5	31.6	30.7	29.8	29.0	28.1	27.2	26.4	25.5
93	32.5	31.6	30.7	29.8	29.0	28.1	27.2	26.4	25.5
94	32.5	31.6	30.7	29.8	28.9	28.1	27.2	26.3	25.5
95	32.5	31.6	30.7	29.8	28.9	28.1	27.2	26.3	25.5
96	32.5	31.6	30.7	29.8	28.9	28.0	27.2	26.3	25.5
97	32.5	31.6	30.7	29.8	28.9	28.0	27.2	26.3	25.5
98	32.5	31.6	30.7	29.8	28.9	28.0	27.2	26.3	25.5
99	32.5	31.6	30.7	29.8	28.9	28.0	27.2	26.3	25.4
100	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
101	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
102	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
103	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
104	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
105	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
106	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
107	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
108	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
109	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
110	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
111	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
112	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
113	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
114	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
115	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
116	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
117	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
118	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
119	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.2	25.4
120+	32.5	31.6	30.6	29.8	28.9	28.0	27.1	26.2	25.4

Ages	63	64	65	66	67	68	69	70	71
0	84.7	84.7	84.7	84.7	84.7	84.7	84.7	84.7	84.7
1	83.8	83.8	83.8	83.8	83.8	83.8	83.8	83.8	83.8
2	82.9	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8
3	81.9	81.9	81.9	81.9	81.9	81.8	81.8	81.8	81.8
4	80.9	80.9	80.9	80.9	80.9	80.9	80.9	80.9	80.9
5	79.9	79.9	79.9	79.9	79.9	79.9	79.9	79.9	79.9
6	78.9	78.9	78.9	78.9	78.9	78.9	78.9	78.9	78.9
7	78.0	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.9
8	77.0	77.0	77.0	76.9	76.9	76.9	76.9	76.9	76.9
9	76.0	76.0	76.0	76.0	76.0	75.9	75.9	75.9	75.9
10	75.0	75.0	75.0	75.0	75.0	75.0	75.0	74.9	74.9
11	74.0	74.0	74.0	74.0	74.0	74.0	74.0	74.0	74.0
12	73.0	73.0	73.0	73.0	73.0	73.0	73.0	73.0	73.0
13	72.1	72.1	72.0	72.0	72.0	72.0	72.0	72.0	72.0
14	71.1	71.1	71.1	71.1	71.0	71.0	71.0	71.0	71.0
15	70.1	70.1	70.1	70.1	70.1	70.1	70.0	70.0	70.0
16	69.1	69.1	69.1	69.1	69.1	69.1	69.1	69.1	69.0
17	68.2	68.2	68.1	68.1	68.1	68.1	68.1	68.1	68.1
18	67.2	67.2	67.2	67.2	67.1	67.1	67.1	67.1	67.1
19	66.2	66.2	66.2	66.2	66.2	66.2	66.1	66.1	66.1
20	65.3	65.2	65.2	65.2	65.2	65.2	65.2	65.2	65.1
21	64.3	64.3	64.3	64.2	64.2	64.2	64.2	64.2	64.2
22	63.3	63.3	63.3	63.3	63.3	63.2	63.2	63.2	63.2
23	62.4	62.3	62.3	62.3	62.3	62.3	62.3	62.2	62.2
24	61.4	61.4	61.4	61.3	61.3	61.3	61.3	61.3	61.3
25	60.5	60.4	60.4	60.4	60.4	60.3	60.3	60.3	60.3
26	59.5	59.5	59.5	59.4	59.4	59.4	59.4	59.4	59.3
27	58.6	58.5	58.5	58.5	58.5	58.4	58.4	58.4	58.4

TABLE 3 TO PARAGRAPH (d)

Ages	63	64	65	66	67	68	69	70	71
28	57.6	57.6	57.5	57.5	57.5	57.5	57.5	57.4	57.4
29	56.7	56.6	56.6	56.6	56.5	56.5	56.5	56.5	56.5
30	55.7	55.7	55.7	55.6	55.6	55.6	55.6	55.5	55.5
31	54.8	54.8	54.7	54.7	54.7	54.6	54.6	54.6	54.6
32	53.9	53.8	53.8	53.7	53.7	53.7	53.7	53.6	53.6
33	52.9	52.9	52.8	52.8	52.8	52.7	52.7	52.7	52.7
34	52.0	52.0	51.9	51.9	51.8	51.8	51.8	51.7	51.7
35	51.1	51.0	51.0	50.9	50.9	50.9	50.8	50.8	50.8
36	50.2	50.1	50.1	50.0	50.0	49.9	49.9	49.9	49.8
37	49.3	49.2	49.1	49.1	49.0	49.0	49.0	48.9	48.9
38	48.3	48.3	48.2	48.2	48.1	48.1	48.0	48.0	47.9
39	47.4	47.4	47.3	47.2	47.2	47.1	47.1	47.0	47.0
40	46.5	46.5	46.4	46.3	46.3	46.2	46.2	46.1	46.1
41	45.7	45.6	45.5	45.4	45.4	45.3	45.2	45.2	45.1
42	44.8	44.7	44.6	44.5	44.4	44.4	44.3	44.3	44.2
43	43.9	43.8	43.7	43.6	43.5	43.5	43.4	43.3	43.3
44	43.0	42.9	42.8	42.7	42.6	42.6	42.5	42.4	42.4
45	42.2	42.1	41.9	41.8	41.8	41.7	41.6	41.5	41.5
46	41.3	41.2	41.1	41.0	40.9	40.8	40.7	40.6	40.6
47	40.5	40.4	40.2	40.1	40.0	39.9	39.8	39.7	39.7
48	39.7	39.5	39.4	39.3	39.1	39.0	38.9	38.8	38.8
49	38.9	38.7	38.6	38.4	38.3	38.2	38.1	38.0	37.9
50	38.1	37.9	37.7	37.6	37.5	37.3	37.2	37.1	37.0
51	37.3	37.1	36.9	36.8	36.6	36.5	36.4	36.2	36.1
52	36.6	36.3	36.2	36.0	35.8	35.7	35.5	35.4	35.3
53	35.8	35.6	35.4	35.2	35.0	34.9	34.7	34.6	34.5
54	35.1	34.9	34.6	34.4	34.2	34.1	33.9	33.8	33.6
55	34.4	34.2	33.9	33.7	33.5	33.3	33.1	33.0	32.8
56	33.8	33.5	33.2	33.0	32.7	32.5	32.3	32.2	32.0
57	33.1	32.8	32.5	32.3	32.0	31.8	31.6	31.4	31.2
58	32.5	32.2	31.9	31.6	31.3	31.1	30.9	30.7	30.5
59	31.9	31.5	31.2	30.9	30.6	30.4	30.1	29.9	29.7
60	31.3	31.0	30.6	30.3	30.0	29.7	29.4	29.2	29.0
61	30.8	30.4	30.0	29.7	29.4	29.1	28.8	28.5	28.3
62	30.3	29.9	29.5	29.1	28.7	28.4	28.1	27.9	27.6
63	29.8	29.4	28.9	28.5	28.2	27.8	27.5	27.2	26.9
64	29.4	28.9	28.4	28.0	27.6	27.2	26.9	26.6	26.3
65	28.9	28.4	28.0	27.5	27.1	26.7	26.3	26.0	25.7
66	28.5	28.0	27.5	27.0	26.6	26.2	25.8	25.4	25.1
67	28.2	27.6	27.1	26.6	26.1	25.7	25.3	24.9	24.5
68	27.8	27.2	26.7	26.2	25.7	25.2	24.8	24.3	24.0
69	27.5	26.9	26.3	25.8	25.3	24.8	24.3	23.9	23.4
70	27.2	26.6	26.0	25.4	24.9	24.3	23.9	23.4	22.9
71	26.9	26.3	25.7	25.1	24.5	24.0	23.4	22.9	22.5
72	26.7	26.0	25.4	24.8	24.2	23.6	23.1	22.5	22.0
73	26.5	25.8	25.1	24.5	23.9	23.3	22.7	22.2	21.6
74	26.2	25.5	24.9	24.2	23.6	23.0	22.4	21.8	21.3
75	26.1	25.3	24.6	24.0	23.3	22.7	22.1	21.5	20.9
76	25.9	25.2	24.4	23.7	23.1	22.4	21.8	21.2	20.6
77	25.7	25.0	24.3	23.5	22.9	22.2	21.5	20.9	20.3
78	25.6	24.8	24.1	23.4	22.7	22.0	21.3	20.6	20.0
79	25.5	24.7	23.9	23.2	22.5	21.8	21.1	20.4	19.8
80	25.3	24.6	23.8	23.1	22.3	21.6	20.9	20.2	19.6
81	25.2	24.5	23.7	22.9	22.2	21.5	20.7	20.0	19.4
82	25.2	24.4	23.6	22.8	22.1	21.3	20.6	19.9	19.2
83	25.1	24.3	23.5	22.7	22.0	21.2	20.5	19.7	19.0
84	25.0	24.2	23.4	22.6	21.9	21.1	20.4	19.6	18.9
85	25.0	24.1	23.3	22.6	21.8	21.0	20.3	19.5	18.8
86	24.9	24.1	23.3	22.5	21.7	20.9	20.2	19.4	18.7
87	24.9	24.0	23.2	22.4	21.6	20.9	20.1	19.3	18.6
88	24.8	24.0	23.2	22.4	21.6	20.8	20.0	19.2	18.5
89	24.8	24.0	23.1	22.3	21.5	20.7	20.0	19.2	18.4
90	24.7	23.9	23.1	22.3	21.5	20.7	19.9	19.1	18.4
91	24.7	23.9	23.1	22.3	21.5	20.7	19.9	19.1	18.3
92	24.7	23.9	23.0	22.2	21.4	20.6	19.8	19.0	18.3
93	24.7	23.8	23.0	22.2	21.4	20.6	19.8	19.0	18.2
94	24.7	23.8	23.0	22.2	21.4	20.6	19.8	19.0	18.2
95	24.6	23.8	23.0	22.2	21.4	20.6	19.7	18.9	18.2
96	24.6	23.8	23.0	22.2	21.3	20.5	19.7	18.9	18.1
97	24.6	23.8	23.0	22.1	21.3	20.5	19.7	18.9	18.1
98	24.6	23.8	22.9	22.1	21.3	20.5	19.7	18.9	18.1
99	24.6	23.8	22.9	22.1	21.3	20.5	19.7	18.9	18.1

TABLE 3 TO PARAGRAPH (d)—Continued

Ages	63	64	65	66	67	68	69	70	71
100	24.6	23.8	22.9	22.1	21.3	20.5	19.7	18.9	18.1
101	24.6	23.8	22.9	22.1	21.3	20.5	19.7	18.9	18.1
102	24.6	23.7	22.9	22.1	21.3	20.5	19.7	18.8	18.0
103	24.6	23.7	22.9	22.1	21.3	20.5	19.6	18.8	18.0
104	24.6	23.7	22.9	22.1	21.3	20.5	19.6	18.8	18.0
105	24.6	23.7	22.9	22.1	21.3	20.5	19.6	18.8	18.0
106	24.6	23.7	22.9	22.1	21.3	20.5	19.6	18.8	18.0
107	24.6	23.7	22.9	22.1	21.3	20.5	19.6	18.8	18.0
108	24.6	23.7	22.9	22.1	21.3	20.5	19.6	18.8	18.0
109	24.6	23.7	22.9	22.1	21.3	20.4	19.6	18.8	18.0
110	24.6	23.7	22.9	22.1	21.3	20.4	19.6	18.8	18.0
111	24.6	23.7	22.9	22.1	21.3	20.4	19.6	18.8	18.0
112	24.6	23.7	22.9	22.1	21.3	20.4	19.6	18.8	18.0
113	24.6	23.7	22.9	22.1	21.3	20.4	19.6	18.8	18.0
114	24.6	23.7	22.9	22.1	21.3	20.4	19.6	18.8	18.0
115	24.6	23.7	22.9	22.1	21.3	20.4	19.6	18.8	18.0
116	24.6	23.7	22.9	22.1	21.3	20.4	19.6	18.8	18.0
117	24.6	23.7	22.9	22.1	21.2	20.4	19.6	18.8	18.0
118	24.5	23.7	22.9	22.1	21.2	20.4	19.6	18.8	18.0
119	24.5	23.7	22.9	22.1	21.2	20.4	19.6	18.8	18.0
120+	24.5	23.7	22.9	22.0	21.2	20.4	19.6	18.8	18.0

Ages	72	73	74	75	76	77	78	79	80
0	84.7	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6
1	83.8	83.8	83.8	83.8	83.8	83.8	83.8	83.8	83.8
2	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8
3	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8
4	80.9	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8
5	79.9	79.9	79.9	79.9	79.9	79.8	79.8	79.8	79.8
6	78.9	78.9	78.9	78.9	78.9	78.9	78.9	78.9	78.9
7	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.9
8	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9
9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9
10	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.9
11	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9
12	73.0	73.0	73.0	72.9	72.9	72.9	72.9	72.9	72.9
13	72.0	72.0	72.0	72.0	72.0	72.0	71.9	71.9	71.9
14	71.0	71.0	71.0	71.0	71.0	71.0	71.0	71.0	71.0
15	70.0	70.0	70.0	70.0	70.0	70.0	70.0	70.0	70.0
16	69.0	69.0	69.0	69.0	69.0	69.0	69.0	69.0	69.0
17	68.1	68.1	68.0	68.0	68.0	68.0	68.0	68.0	68.0
18	67.1	67.1	67.1	67.1	67.1	67.0	67.0	67.0	67.0
19	66.1	66.1	66.1	66.1	66.1	66.1	66.1	66.1	66.1
20	65.1	65.1	65.1	65.1	65.1	65.1	65.1	65.1	65.1
21	64.2	64.2	64.1	64.1	64.1	64.1	64.1	64.1	64.1
22	63.2	63.2	63.2	63.2	63.2	63.1	63.1	63.1	63.1
23	62.2	62.2	62.2	62.2	62.2	62.2	62.2	62.2	62.1
24	61.3	61.2	61.2	61.2	61.2	61.2	61.2	61.2	61.2
25	60.3	60.3	60.3	60.3	60.2	60.2	60.2	60.2	60.2
26	59.3	59.3	59.3	59.3	59.3	59.3	59.3	59.3	59.2
27	58.4	58.4	58.3	58.3	58.3	58.3	58.3	58.3	58.3
28	57.4	57.4	57.4	57.4	57.4	57.3	57.3	57.3	57.3
29	56.5	56.4	56.4	56.4	56.4	56.4	56.4	56.4	56.4
30	55.5	55.5	55.5	55.5	55.4	55.4	55.4	55.4	55.4
31	54.5	54.5	54.5	54.5	54.5	54.5	54.5	54.5	54.4
32	53.6	53.6	53.6	53.5	53.5	53.5	53.5	53.5	53.5
33	52.6	52.6	52.6	52.6	52.6	52.6	52.6	52.5	52.5
34	51.7	51.7	51.7	51.6	51.6	51.6	51.6	51.6	51.6
35	50.8	50.7	50.7	50.7	50.7	50.7	50.6	50.6	50.6
36	49.8	49.8	49.8	49.7	49.7	49.7	49.7	49.7	49.7
37	48.9	48.8	48.8	48.8	48.8	48.8	48.7	48.7	48.7
38	47.9	47.9	47.9	47.8	47.8	47.8	47.8	47.8	47.8
39	47.0	46.9	46.9	46.9	46.9	46.9	46.8	46.8	46.8
40	46.0	46.0	46.0	45.9	45.9	45.9	45.9	45.9	45.9
41	45.1	45.1	45.0	45.0	45.0	45.0	44.9	44.9	44.9
42	44.2	44.1	44.1	44.1	44.0	44.0	44.0	44.0	43.9
43	43.2	43.2	43.2	43.1	43.1	43.1	43.0	43.0	43.0
44	42.3	42.3	42.2	42.2	42.2	42.1	42.1	42.1	42.1
45	41.4	41.4	41.3	41.3	41.2	41.2	41.2	41.1	41.1
46	40.5	40.4	40.4	40.3	40.3	40.3	40.2	40.2	40.2
47	39.6	39.5	39.5	39.4	39.4	39.3	39.3	39.3	39.2

TABLE 3 TO PARAGRAPH (d)

Ages	72	73	74	75	76	77	78	79	80
48	38.7	38.6	38.6	38.5	38.5	38.4	38.4	38.3	38.3
49	37.8	37.7	37.7	37.6	37.5	37.5	37.5	37.4	37.4
50	36.9	36.8	36.8	36.7	36.6	36.6	36.5	36.5	36.5
51	36.0	36.0	35.9	35.8	35.7	35.7	35.6	35.6	35.5
52	35.2	35.1	35.0	34.9	34.9	34.8	34.7	34.7	34.6
53	34.3	34.2	34.1	34.1	34.0	33.9	33.9	33.8	33.7
54	33.5	33.4	33.3	33.2	33.1	33.0	33.0	32.9	32.9
55	32.7	32.6	32.4	32.4	32.3	32.2	32.1	32.0	32.0
56	31.9	31.7	31.6	31.5	31.4	31.3	31.2	31.2	31.1
57	31.1	30.9	30.8	30.7	30.6	30.5	30.4	30.3	30.3
58	30.3	30.1	30.0	29.9	29.8	29.7	29.6	29.5	29.4
59	29.5	29.4	29.2	29.1	29.0	28.8	28.7	28.7	28.6
60	28.8	28.6	28.4	28.3	28.2	28.0	27.9	27.8	27.8
61	28.1	27.9	27.7	27.5	27.4	27.3	27.1	27.0	26.9
62	27.4	27.2	27.0	26.8	26.6	26.5	26.4	26.2	26.1
63	26.7	26.5	26.2	26.1	25.9	25.7	25.6	25.5	25.3
64	26.0	25.8	25.5	25.3	25.2	25.0	24.8	24.7	24.6
65	25.4	25.1	24.9	24.6	24.4	24.3	24.1	23.9	23.8
66	24.8	24.5	24.2	24.0	23.7	23.5	23.4	23.2	23.1
67	24.2	23.9	23.6	23.3	23.1	22.9	22.7	22.5	22.3
68	23.6	23.3	23.0	22.7	22.4	22.2	22.0	21.8	21.6
69	23.1	22.7	22.4	22.1	21.8	21.5	21.3	21.1	20.9
70	22.5	22.2	21.8	21.5	21.2	20.9	20.6	20.4	20.2
71	22.0	21.6	21.3	20.9	20.6	20.3	20.0	19.8	19.6
72	21.6	21.1	20.7	20.4	20.0	19.7	19.4	19.2	18.9
73	21.1	20.7	20.3	19.9	19.5	19.1	18.8	18.6	18.3
74	20.7	20.3	19.8	19.4	19.0	18.6	18.3	18.0	17.7
75	20.4	19.9	19.4	18.9	18.5	18.1	17.8	17.4	17.1
76	20.0	19.5	19.0	18.5	18.1	17.7	17.3	16.9	16.6
77	19.7	19.1	18.6	18.1	17.7	17.2	16.8	16.4	16.1
78	19.4	18.8	18.3	17.8	17.3	16.8	16.4	16.0	15.6
79	19.2	18.6	18.0	17.4	16.9	16.4	16.0	15.6	15.2
80	18.9	18.3	17.7	17.1	16.6	16.1	15.6	15.2	14.7
81	18.7	18.1	17.4	16.9	16.3	15.8	15.3	14.8	14.4
82	18.5	17.9	17.2	16.6	16.0	15.5	15.0	14.5	14.0
83	18.3	17.7	17.0	16.4	15.8	15.2	14.7	14.2	13.7
84	18.2	17.5	16.8	16.2	15.6	15.0	14.4	13.9	13.4
85	18.1	17.4	16.7	16.0	15.4	14.8	14.2	13.6	13.1
86	17.9	17.2	16.5	15.9	15.2	14.6	14.0	13.4	12.9
87	17.8	17.1	16.4	15.7	15.1	14.4	13.8	13.2	12.7
88	17.7	17.0	16.3	15.6	14.9	14.3	13.7	13.1	12.5
89	17.7	16.9	16.2	15.5	14.8	14.2	13.5	12.9	12.3
90	17.6	16.9	16.1	15.4	14.7	14.1	13.4	12.8	12.2
91	17.5	16.8	16.1	15.3	14.6	14.0	13.3	12.7	12.1
92	17.5	16.7	16.0	15.3	14.6	13.9	13.2	12.6	11.9
93	17.4	16.7	15.9	15.2	14.5	13.8	13.1	12.5	11.9
94	17.4	16.6	15.9	15.2	14.4	13.7	13.1	12.4	11.8
95	17.4	16.6	15.9	15.1	14.4	13.7	13.0	12.3	11.7
96	17.4	16.6	15.8	15.1	14.3	13.6	12.9	12.3	11.6
97	17.3	16.6	15.8	15.0	14.3	13.6	12.9	12.2	11.6
98	17.3	16.5	15.8	15.0	14.3	13.6	12.9	12.2	11.5
99	17.3	16.5	15.7	15.0	14.3	13.5	12.8	12.2	11.5
100	17.3	16.5	15.7	15.0	14.2	13.5	12.8	12.1	11.5
101	17.3	16.5	15.7	15.0	14.2	13.5	12.8	12.1	11.4
102	17.3	16.5	15.7	14.9	14.2	13.5	12.8	12.1	11.4
103	17.3	16.5	15.7	14.9	14.2	13.5	12.8	12.1	11.4
104	17.2	16.5	15.7	14.9	14.2	13.5	12.7	12.0	11.4
105	17.2	16.5	15.7	14.9	14.2	13.4	12.7	12.0	11.4
106	17.2	16.5	15.7	14.9	14.2	13.4	12.7	12.0	11.4
107	17.2	16.5	15.7	14.9	14.2	13.4	12.7	12.0	11.4
108	17.2	16.5	15.7	14.9	14.2	13.4	12.7	12.0	11.4
109	17.2	16.4	15.7	14.9	14.2	13.4	12.7	12.0	11.3
110	17.2	16.4	15.7	14.9	14.2	13.4	12.7	12.0	11.3
111	17.2	16.4	15.7	14.9	14.2	13.4	12.7	12.0	11.3
112	17.2	16.4	15.7	14.9	14.2	13.4	12.7	12.0	11.3
113	17.2	16.4	15.7	14.9	14.2	13.4	12.7	12.0	11.3
114	17.2	16.4	15.7	14.9	14.1	13.4	12.7	12.0	11.3
115	17.2	16.4	15.7	14.9	14.1	13.4	12.7	12.0	11.3
116	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
117	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
118	17.2	16.4	15.6	14.9	14.1	13.4	12.6	11.9	11.3
119	17.2	16.4	15.6	14.8	14.1	13.4	12.6	11.9	11.2

TABLE 3 TO PARAGRAPH (d)

Ages	72	73	74	75	76	77	78	79	80
120+	17.2	16.4	15.6	14.8	14.1	13.3	12.6	11.9	11.2
Ages	81	82	83	84	85	86	87	88	89
0	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6
1	83.8	83.8	83.7	83.7	83.7	83.7	83.7	83.7	83.7
2	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8
3	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8
4	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8
5	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8
6	78.9	78.9	78.9	78.9	78.8	78.8	78.8	78.8	78.8
7	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.9
8	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9
9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9
10	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.9
11	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9
12	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9
13	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9
14	71.0	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9
15	70.0	70.0	70.0	70.0	70.0	70.0	70.0	69.9	69.9
16	69.0	69.0	69.0	69.0	69.0	69.0	69.0	69.0	69.0
17	68.0	68.0	68.0	68.0	68.0	68.0	68.0	68.0	68.0
18	67.0	67.0	67.0	67.0	67.0	67.0	67.0	67.0	67.0
19	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0
20	65.1	65.1	65.1	65.1	65.1	65.1	65.0	65.0	65.0
21	64.1	64.1	64.1	64.1	64.1	64.1	64.1	64.1	64.1
22	63.1	63.1	63.1	63.1	63.1	63.1	63.1	63.1	63.1
23	62.1	62.1	62.1	62.1	62.1	62.1	62.1	62.1	62.1
24	61.2	61.2	61.2	61.2	61.2	61.1	61.1	61.1	61.1
25	60.2	60.2	60.2	60.2	60.2	60.2	60.2	60.2	60.2
26	59.2	59.2	59.2	59.2	59.2	59.2	59.2	59.2	59.2
27	58.3	58.3	58.3	58.3	58.3	58.2	58.2	58.2	58.2
28	57.3	57.3	57.3	57.3	57.3	57.3	57.3	57.3	57.3
29	56.4	56.3	56.3	56.3	56.3	56.3	56.3	56.3	56.3
30	55.4	55.4	55.4	55.4	55.4	55.4	55.4	55.4	55.4
31	54.4	54.4	54.4	54.4	54.4	54.4	54.4	54.4	54.4
32	53.5	53.5	53.5	53.5	53.5	53.5	53.4	53.4	53.4
33	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5
34	51.6	51.6	51.6	51.5	51.5	51.5	51.5	51.5	51.5
35	50.6	50.6	50.6	50.6	50.6	50.6	50.6	50.6	50.6
36	49.7	49.7	49.6	49.6	49.6	49.6	49.6	49.6	49.6
37	48.7	48.7	48.7	48.7	48.7	48.7	48.7	48.7	48.7
38	47.7	47.7	47.7	47.7	47.7	47.7	47.7	47.7	47.7
39	46.8	46.8	46.8	46.8	46.8	46.7	46.7	46.7	46.7
40	45.8	45.8	45.8	45.8	45.8	45.8	45.8	45.8	45.8
41	44.9	44.9	44.9	44.9	44.8	44.8	44.8	44.8	44.8
42	43.9	43.9	43.9	43.9	43.9	43.9	43.9	43.9	43.9
43	43.0	43.0	43.0	42.9	42.9	42.9	42.9	42.9	42.9
44	42.0	42.0	42.0	42.0	42.0	42.0	42.0	42.0	41.9
45	41.1	41.1	41.1	41.0	41.0	41.0	41.0	41.0	41.0
46	40.1	40.1	40.1	40.1	40.1	40.1	40.1	40.0	40.0
47	39.2	39.2	39.2	39.2	39.1	39.1	39.1	39.1	39.1
48	38.3	38.3	38.2	38.2	38.2	38.2	38.2	38.2	38.1
49	37.3	37.3	37.3	37.3	37.3	37.2	37.2	37.2	37.2
50	36.4	36.4	36.4	36.3	36.3	36.3	36.3	36.3	36.3
51	35.5	35.5	35.4	35.4	35.4	35.4	35.4	35.3	35.3
52	34.6	34.6	34.5	34.5	34.5	34.5	34.4	34.4	34.4
53	33.7	33.7	33.6	33.6	33.6	33.5	33.5	33.5	33.5
54	32.8	32.8	32.7	32.7	32.7	32.6	32.6	32.6	32.6
55	31.9	31.9	31.8	31.8	31.8	31.7	31.7	31.7	31.7
56	31.1	31.0	31.0	30.9	30.9	30.9	30.8	30.8	30.8
57	30.2	30.1	30.1	30.0	30.0	30.0	29.9	29.9	29.9
58	29.3	29.3	29.2	29.2	29.1	29.1	29.1	29.0	29.0
59	28.5	28.4	28.4	28.3	28.3	28.2	28.2	28.2	28.2
60	27.7	27.6	27.5	27.5	27.4	27.4	27.4	27.3	27.3
61	26.9	26.8	26.7	26.7	26.6	26.6	26.5	26.5	26.4
62	26.0	26.0	25.9	25.8	25.8	25.7	25.7	25.6	25.6
63	25.2	25.2	25.1	25.0	25.0	24.9	24.9	24.8	24.8
64	24.5	24.4	24.3	24.2	24.1	24.1	24.0	24.0	24.0
65	23.7	23.6	23.5	23.4	23.3	23.3	23.2	23.2	23.1
66	22.9	22.8	22.7	22.6	22.6	22.5	22.4	22.4	22.3
67	22.2	22.1	22.0	21.9	21.8	21.7	21.6	21.6	21.5

TABLE 3 TO PARAGRAPH (d)

Ages	81	82	83	84	85	86	87	88	89
68	21.5	21.3	21.2	21.1	21.0	20.9	20.9	20.8	20.7
69	20.7	20.6	20.5	20.4	20.3	20.2	20.1	20.0	20.0
70	20.0	19.9	19.7	19.6	19.5	19.4	19.3	19.2	19.2
71	19.4	19.2	19.0	18.9	18.8	18.7	18.6	18.5	18.4
72	18.7	18.5	18.3	18.2	18.1	17.9	17.8	17.7	17.7
73	18.1	17.9	17.7	17.5	17.4	17.2	17.1	17.0	16.9
74	17.4	17.2	17.0	16.8	16.7	16.5	16.4	16.3	16.2
75	16.9	16.6	16.4	16.2	16.0	15.9	15.7	15.6	15.5
76	16.3	16.0	15.8	15.6	15.4	15.2	15.1	14.9	14.8
77	15.8	15.5	15.2	15.0	14.8	14.6	14.4	14.3	14.2
78	15.3	15.0	14.7	14.4	14.2	14.0	13.8	13.7	13.5
79	14.8	14.5	14.2	13.9	13.6	13.4	13.2	13.1	12.9
80	14.4	14.0	13.7	13.4	13.1	12.9	12.7	12.5	12.3
81	14.0	13.6	13.2	12.9	12.6	12.4	12.2	12.0	11.8
82	13.6	13.2	12.8	12.5	12.2	11.9	11.7	11.5	11.3
83	13.2	12.8	12.4	12.1	11.8	11.5	11.2	11.0	10.8
84	12.9	12.5	12.1	11.7	11.4	11.1	10.8	10.5	10.3
85	12.6	12.2	11.8	11.4	11.0	10.7	10.4	10.1	9.9
86	12.4	11.9	11.5	11.1	10.7	10.4	10.0	9.8	9.5
87	12.2	11.7	11.2	10.8	10.4	10.0	9.7	9.4	9.1
88	12.0	11.5	11.0	10.5	10.1	9.8	9.4	9.1	8.8
89	11.8	11.3	10.8	10.3	9.9	9.5	9.1	8.8	8.5
90	11.6	11.1	10.6	10.1	9.7	9.3	8.9	8.6	8.3
91	11.5	10.9	10.4	9.9	9.5	9.1	8.7	8.3	8.0
92	11.4	10.8	10.3	9.8	9.3	8.9	8.5	8.1	7.8
93	11.3	10.7	10.1	9.6	9.2	8.7	8.3	7.9	7.6
94	11.2	10.6	10.0	9.5	9.0	8.6	8.2	7.8	7.4
95	11.1	10.5	9.9	9.4	8.9	8.5	8.0	7.6	7.3
96	11.0	10.4	9.9	9.3	8.8	8.4	7.9	7.5	7.1
97	11.0	10.4	9.8	9.2	8.7	8.3	7.8	7.4	7.0
98	10.9	10.3	9.7	9.2	8.7	8.2	7.7	7.3	6.9
99	10.9	10.2	9.7	9.1	8.6	8.1	7.6	7.2	6.8
100	10.8	10.2	9.6	9.1	8.5	8.0	7.6	7.2	6.8
101	10.8	10.2	9.6	9.0	8.5	8.0	7.5	7.1	6.7
102	10.8	10.1	9.6	9.0	8.5	8.0	7.5	7.0	6.6
103	10.7	10.1	9.5	9.0	8.4	7.9	7.4	7.0	6.6
104	10.7	10.1	9.5	8.9	8.4	7.9	7.4	7.0	6.6
105	10.7	10.1	9.5	8.9	8.4	7.9	7.4	6.9	6.5
106	10.7	10.1	9.5	8.9	8.4	7.9	7.4	6.9	6.5
107	10.7	10.1	9.5	8.9	8.4	7.9	7.4	6.9	6.5
108	10.7	10.1	9.5	8.9	8.4	7.8	7.4	6.9	6.5
109	10.7	10.1	9.5	8.9	8.4	7.8	7.4	6.9	6.5
110	10.7	10.1	9.5	8.9	8.3	7.8	7.4	6.9	6.5
111	10.7	10.1	9.5	8.9	8.3	7.8	7.3	6.9	6.5
112	10.7	10.1	9.5	8.9	8.3	7.8	7.3	6.9	6.5
113	10.7	10.0	9.4	8.9	8.3	7.8	7.3	6.9	6.4
114	10.7	10.0	9.4	8.9	8.3	7.8	7.3	6.9	6.4
115	10.7	10.0	9.4	8.8	8.3	7.8	7.3	6.8	6.4
116	10.6	10.0	9.4	8.8	8.3	7.7	7.3	6.8	6.4
117	10.6	10.0	9.4	8.8	8.2	7.7	7.2	6.8	6.3
118	10.6	10.0	9.3	8.8	8.2	7.7	7.2	6.7	6.3
119	10.6	9.9	9.3	8.7	8.2	7.6	7.1	6.6	6.2
120+	10.5	9.9	9.3	8.7	8.1	7.6	7.1	6.6	6.1

Ages	90	91	92	93	94	95	96	97	98
0	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6
1	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7
2	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8
3	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8
4	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8
5	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8
6	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8
7	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.9
8	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9
9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9
10	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.9
11	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9
12	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9
13	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9
14	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9
15	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9

TABLE 3 TO PARAGRAPH (d)

Ages	90	91	92	93	94	95	96	97	98
16	69.0	69.0	69.0	69.0	69.0	69.0	69.0	69.0	69.0
17	68.0	68.0	68.0	68.0	68.0	68.0	68.0	68.0	68.0
18	67.0	67.0	67.0	67.0	67.0	67.0	67.0	67.0	67.0
19	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0
20	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0
21	64.1	64.1	64.1	64.1	64.1	64.1	64.1	64.1	64.1
22	63.1	63.1	63.1	63.1	63.1	63.1	63.1	63.1	63.1
23	62.1	62.1	62.1	62.1	62.1	62.1	62.1	62.1	62.1
24	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1
25	60.2	60.2	60.2	60.2	60.2	60.2	60.2	60.2	60.2
26	59.2	59.2	59.2	59.2	59.2	59.2	59.2	59.2	59.2
27	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2
28	57.3	57.3	57.3	57.3	57.3	57.3	57.3	57.3	57.3
29	56.3	56.3	56.3	56.3	56.3	56.3	56.3	56.3	56.3
30	55.4	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3
31	54.4	54.4	54.4	54.4	54.4	54.4	54.4	54.4	54.4
32	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4
33	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5
34	51.5	51.5	51.5	51.5	51.5	51.5	51.5	51.5	51.5
35	50.6	50.6	50.6	50.6	50.6	50.6	50.6	50.6	50.6
36	49.6	49.6	49.6	49.6	49.6	49.6	49.6	49.6	49.6
37	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6
38	47.7	47.7	47.7	47.7	47.7	47.7	47.7	47.7	47.7
39	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7
40	45.8	45.8	45.8	45.8	45.8	45.8	45.8	45.8	45.8
41	44.8	44.8	44.8	44.8	44.8	44.8	44.8	44.8	44.8
42	43.9	43.9	43.8	43.8	43.8	43.8	43.8	43.8	43.8
43	42.9	42.9	42.9	42.9	42.9	42.9	42.9	42.9	42.9
44	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.9
45	41.0	41.0	41.0	41.0	41.0	41.0	41.0	41.0	41.0
46	40.0	40.0	40.0	40.0	40.0	40.0	40.0	40.0	40.0
47	39.1	39.1	39.1	39.1	39.1	39.1	39.1	39.1	39.1
48	38.1	38.1	38.1	38.1	38.1	38.1	38.1	38.1	38.1
49	37.2	37.2	37.2	37.2	37.2	37.2	37.2	37.2	37.2
50	36.3	36.2	36.2	36.2	36.2	36.2	36.2	36.2	36.2
51	35.3	35.3	35.3	35.3	35.3	35.3	35.3	35.3	35.3
52	34.4	34.4	34.4	34.4	34.4	34.4	34.3	34.3	34.3
53	33.5	33.5	33.5	33.4	33.4	33.4	33.4	33.4	33.4
54	32.6	32.5	32.5	32.5	32.5	32.5	32.5	32.5	32.5
55	31.7	31.6	31.6	31.6	31.6	31.6	31.6	31.6	31.6
56	30.8	30.7	30.7	30.7	30.7	30.7	30.7	30.7	30.7
57	29.9	29.9	29.8	29.8	29.8	29.8	29.8	29.8	29.8
58	29.0	29.0	29.0	29.0	28.9	28.9	28.9	28.9	28.9
59	28.1	28.1	28.1	28.1	28.1	28.1	28.0	28.0	28.0
60	27.3	27.3	27.2	27.2	27.2	27.2	27.2	27.2	27.2
61	26.4	26.4	26.4	26.4	26.3	26.3	26.3	26.3	26.3
62	25.6	25.6	25.5	25.5	25.5	25.5	25.5	25.5	25.5
63	24.7	24.7	24.7	24.7	24.7	24.6	24.6	24.6	24.6
64	23.9	23.9	23.9	23.8	23.8	23.8	23.8	23.8	23.8
65	23.1	23.1	23.0	23.0	23.0	23.0	23.0	23.0	22.9
66	22.3	22.3	22.2	22.2	22.2	22.2	22.2	22.1	22.1
67	21.5	21.5	21.4	21.4	21.4	21.4	21.3	21.3	21.3
68	20.7	20.7	20.6	20.6	20.6	20.6	20.5	20.5	20.5
69	19.9	19.9	19.8	19.8	19.8	19.7	19.7	19.7	19.7
70	19.1	19.1	19.0	19.0	19.0	18.9	18.9	18.9	18.9
71	18.4	18.3	18.3	18.2	18.2	18.2	18.1	18.1	18.1
72	17.6	17.5	17.5	17.4	17.4	17.4	17.4	17.3	17.3
73	16.9	16.8	16.7	16.7	16.6	16.6	16.6	16.6	16.5
74	16.1	16.1	16.0	15.9	15.9	15.9	15.8	15.8	15.8
75	15.4	15.3	15.3	15.2	15.2	15.1	15.1	15.0	15.0
76	14.7	14.6	14.6	14.5	14.4	14.4	14.3	14.3	14.3
77	14.1	14.0	13.9	13.8	13.7	13.7	13.6	13.6	13.6
78	13.4	13.3	13.2	13.1	13.1	13.0	12.9	12.9	12.9
79	12.8	12.7	12.6	12.5	12.4	12.3	12.3	12.2	12.2
80	12.2	12.1	11.9	11.9	11.8	11.7	11.6	11.6	11.5
81	11.6	11.5	11.4	11.3	11.2	11.1	11.0	11.0	10.9
82	11.1	10.9	10.8	10.7	10.6	10.5	10.4	10.4	10.3
83	10.6	10.4	10.3	10.1	10.0	9.9	9.9	9.8	9.7
84	10.1	9.9	9.8	9.6	9.5	9.4	9.3	9.2	9.2
85	9.7	9.5	9.3	9.2	9.0	8.9	8.8	8.7	8.7
86	9.3	9.1	8.9	8.7	8.6	8.5	8.4	8.3	8.2
87	8.9	8.7	8.5	8.3	8.2	8.0	7.9	7.8	7.7

TABLE 3 TO PARAGRAPH (d)—Continued

Ages	90	91	92	93	94	95	96	97	98
88	8.6	8.3	8.1	7.9	7.8	7.6	7.5	7.4	7.3
89	8.3	8.0	7.8	7.6	7.4	7.3	7.1	7.0	6.9
90	8.0	7.7	7.5	7.3	7.1	6.9	6.8	6.7	6.6
91	7.7	7.5	7.2	7.0	6.8	6.6	6.5	6.4	6.2
92	7.5	7.2	7.0	6.7	6.5	6.4	6.2	6.1	5.9
93	7.3	7.0	6.7	6.5	6.3	6.1	5.9	5.8	5.7
94	7.1	6.8	6.5	6.3	6.1	5.9	5.7	5.5	5.4
95	6.9	6.6	6.4	6.1	5.9	5.7	5.5	5.3	5.2
96	6.8	6.5	6.2	5.9	5.7	5.5	5.3	5.1	5.0
97	6.7	6.4	6.1	5.8	5.5	5.3	5.1	4.9	4.8
98	6.6	6.2	5.9	5.7	5.4	5.2	5.0	4.8	4.6
99	6.5	6.1	5.8	5.5	5.3	5.0	4.8	4.6	4.5
100	6.4	6.0	5.7	5.4	5.2	4.9	4.7	4.5	4.3
101	6.3	6.0	5.6	5.3	5.1	4.8	4.6	4.4	4.2
102	6.3	5.9	5.6	5.3	5.0	4.7	4.5	4.3	4.1
103	6.2	5.9	5.5	5.2	4.9	4.7	4.5	4.2	4.1
104	6.2	5.8	5.5	5.2	4.9	4.6	4.4	4.2	4.0
105	6.1	5.8	5.4	5.1	4.9	4.6	4.4	4.1	4.0
106	6.1	5.8	5.4	5.1	4.8	4.6	4.3	4.1	3.9
107	6.1	5.8	5.4	5.1	4.8	4.6	4.3	4.1	3.9
108	6.1	5.7	5.4	5.1	4.8	4.5	4.3	4.1	3.9
109	6.1	5.7	5.4	5.1	4.8	4.5	4.3	4.1	3.9
110	6.1	5.7	5.4	5.1	4.8	4.5	4.3	4.1	3.9
111	6.1	5.7	5.4	5.1	4.8	4.5	4.3	4.1	3.9
112	6.1	5.7	5.4	5.1	4.8	4.5	4.3	4.0	3.8
113	6.1	5.7	5.3	5.0	4.7	4.5	4.2	4.0	3.8
114	6.0	5.7	5.3	5.0	4.7	4.4	4.2	4.0	3.8
115	6.0	5.6	5.3	5.0	4.7	4.4	4.2	4.0	3.8
116	6.0	5.6	5.2	4.9	4.6	4.4	4.1	3.9	3.7
117	5.9	5.5	5.2	4.9	4.6	4.3	4.0	3.8	3.6
118	5.8	5.5	5.1	4.8	4.5	4.2	3.9	3.7	3.5
119	5.8	5.4	5.0	4.7	4.4	4.1	3.8	3.6	3.3
120+	5.7	5.3	4.9	4.6	4.3	4.0	3.7	3.4	3.2

Ages	99	100	101	102	103	104	105	106	107
0	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6
1	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7
2	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8
3	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8
4	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8
5	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8
6	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8
7	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.9
8	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9
9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9
10	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.9
11	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9
12	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9
13	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9
14	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9
15	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9
16	69.0	69.0	69.0	69.0	69.0	69.0	69.0	69.0	69.0
17	68.0	68.0	68.0	68.0	68.0	68.0	68.0	68.0	68.0
18	67.0	67.0	67.0	67.0	67.0	67.0	67.0	67.0	67.0
19	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0
20	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0
21	64.1	64.1	64.1	64.1	64.1	64.1	64.1	64.1	64.1
22	63.1	63.1	63.1	63.1	63.1	63.1	63.1	63.1	63.1
23	62.1	62.1	62.1	62.1	62.1	62.1	62.1	62.1	62.1
24	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1
25	60.2	60.2	60.2	60.2	60.2	60.2	60.2	60.2	60.2
26	59.2	59.2	59.2	59.2	59.2	59.2	59.2	59.2	59.2
27	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2
28	57.3	57.3	57.3	57.3	57.3	57.3	57.3	57.3	57.3
29	56.3	56.3	56.3	56.3	56.3	56.3	56.3	56.3	56.3
30	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3
31	54.4	54.4	54.4	54.4	54.4	54.4	54.4	54.4	54.4
32	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4
33	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5
34	51.5	51.5	51.5	51.5	51.5	51.5	51.5	51.5	51.5
35	50.6	50.6	50.6	50.6	50.5	50.5	50.5	50.5	50.5

TABLE 3 TO PARAGRAPH (d)

Ages	99	100	101	102	103	104	105	106	107
36	49.6	49.6	49.6	49.6	49.6	49.6	49.6	49.6	49.6
37	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6
38	47.7	47.7	47.7	47.7	47.7	47.7	47.7	47.7	47.7
39	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7
40	45.8	45.8	45.8	45.8	45.8	45.8	45.7	45.7	45.7
41	44.8	44.8	44.8	44.8	44.8	44.8	44.8	44.8	44.8
42	43.8	43.8	43.8	43.8	43.8	43.8	43.8	43.8	43.8
43	42.9	42.9	42.9	42.9	42.9	42.9	42.9	42.9	42.9
44	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.9
45	41.0	41.0	41.0	41.0	41.0	41.0	41.0	41.0	41.0
46	40.0	40.0	40.0	40.0	40.0	40.0	40.0	40.0	40.0
47	39.1	39.0	39.0	39.0	39.0	39.0	39.0	39.0	39.0
48	38.1	38.1	38.1	38.1	38.1	38.1	38.1	38.1	38.1
49	37.2	37.1	37.1	37.1	37.1	37.1	37.1	37.1	37.1
50	36.2	36.2	36.2	36.2	36.2	36.2	36.2	36.2	36.2
51	35.3	35.3	35.3	35.3	35.3	35.3	35.3	35.3	35.3
52	34.3	34.3	34.3	34.3	34.3	34.3	34.3	34.3	34.3
53	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4
54	32.5	32.5	32.5	32.5	32.5	32.5	32.5	32.5	32.5
55	31.6	31.6	31.6	31.6	31.6	31.6	31.6	31.6	31.6
56	30.7	30.7	30.7	30.7	30.7	30.7	30.7	30.7	30.7
57	29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8
58	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9
59	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0
60	27.2	27.1	27.1	27.1	27.1	27.1	27.1	27.1	27.1
61	26.3	26.3	26.3	26.3	26.3	26.3	26.3	26.3	26.3
62	25.4	25.4	25.4	25.4	25.4	25.4	25.4	25.4	25.4
63	24.6	24.6	24.6	24.6	24.6	24.6	24.6	24.6	24.6
64	23.8	23.8	23.8	23.7	23.7	23.7	23.7	23.7	23.7
65	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9
66	22.1	22.1	22.1	22.1	22.1	22.1	22.1	22.1	22.1
67	21.3	21.3	21.3	21.3	21.3	21.3	21.3	21.3	21.3
68	20.5	20.5	20.5	20.5	20.5	20.5	20.5	20.5	20.5
69	19.7	19.7	19.7	19.7	19.6	19.6	19.6	19.6	19.6
70	18.9	18.9	18.9	18.8	18.8	18.8	18.8	18.8	18.8
71	18.1	18.1	18.1	18.0	18.0	18.0	18.0	18.0	18.0
72	17.3	17.3	17.3	17.3	17.3	17.2	17.2	17.2	17.2
73	16.5	16.5	16.5	16.5	16.5	16.5	16.5	16.5	16.5
74	15.7	15.7	15.7	15.7	15.7	15.7	15.7	15.7	15.7
75	15.0	15.0	15.0	14.9	14.9	14.9	14.9	14.9	14.9
76	14.3	14.2	14.2	14.2	14.2	14.2	14.2	14.2	14.2
77	13.5	13.5	13.5	13.5	13.5	13.5	13.4	13.4	13.4
78	12.8	12.8	12.8	12.8	12.8	12.7	12.7	12.7	12.7
79	12.2	12.1	12.1	12.1	12.1	12.0	12.0	12.0	12.0
80	11.5	11.5	11.4	11.4	11.4	11.4	11.4	11.4	11.4
81	10.9	10.8	10.8	10.8	10.7	10.7	10.7	10.7	10.7
82	10.2	10.2	10.2	10.1	10.1	10.1	10.1	10.1	10.1
83	9.7	9.6	9.6	9.6	9.5	9.5	9.5	9.5	9.5
84	9.1	9.1	9.0	9.0	9.0	8.9	8.9	8.9	8.9
85	8.6	8.5	8.5	8.5	8.4	8.4	8.4	8.4	8.4
86	8.1	8.0	8.0	8.0	7.9	7.9	7.9	7.9	7.9
87	7.6	7.6	7.5	7.5	7.4	7.4	7.4	7.4	7.4
88	7.2	7.2	7.1	7.0	7.0	7.0	6.9	6.9	6.9
89	6.8	6.8	6.7	6.6	6.6	6.6	6.5	6.5	6.5
90	6.5	6.4	6.3	6.3	6.2	6.2	6.1	6.1	6.1
91	6.1	6.0	6.0	5.9	5.9	5.8	5.8	5.8	5.8
92	5.8	5.7	5.6	5.6	5.5	5.5	5.4	5.4	5.4
93	5.5	5.4	5.3	5.3	5.2	5.2	5.1	5.1	5.1
94	5.3	5.2	5.1	5.0	4.9	4.9	4.9	4.8	4.8
95	5.0	4.9	4.8	4.7	4.7	4.6	4.6	4.6	4.6
96	4.8	4.7	4.6	4.5	4.5	4.4	4.4	4.3	4.3
97	4.6	4.5	4.4	4.3	4.2	4.2	4.1	4.1	4.1
98	4.5	4.3	4.2	4.1	4.1	4.0	4.0	3.9	3.9
99	4.3	4.2	4.1	4.0	3.9	3.8	3.8	3.8	3.7
100	4.2	4.1	3.9	3.8	3.7	3.7	3.6	3.6	3.6
101	4.1	3.9	3.8	3.7	3.6	3.5	3.5	3.5	3.4
102	4.0	3.8	3.7	3.6	3.5	3.4	3.4	3.3	3.3
103	3.9	3.7	3.6	3.5	3.4	3.3	3.3	3.2	3.2
104	3.8	3.7	3.5	3.4	3.3	3.3	3.2	3.2	3.2
105	3.8	3.6	3.5	3.4	3.3	3.2	3.1	3.1	3.1
106	3.8	3.6	3.5	3.3	3.2	3.2	3.1	3.1	3.1
107	3.7	3.6	3.4	3.3	3.2	3.2	3.1	3.1	3.0

TABLE 3 TO PARAGRAPH (d)—Continued

Ages	99	100	101	102	103	104	105	106	107
108	3.7	3.6	3.4	3.3	3.2	3.1	3.1	3.0	3.0
109	3.7	3.6	3.4	3.3	3.2	3.1	3.1	3.0	3.0
110	3.7	3.5	3.4	3.3	3.2	3.1	3.1	3.0	3.0
111	3.7	3.5	3.4	3.3	3.2	3.1	3.0	3.0	3.0
112	3.7	3.5	3.4	3.3	3.2	3.1	3.0	3.0	3.0
113	3.6	3.5	3.4	3.2	3.1	3.1	3.0	3.0	2.9
114	3.6	3.5	3.3	3.2	3.1	3.0	3.0	2.9	2.9
115	3.6	3.4	3.3	3.2	3.1	3.0	2.9	2.9	2.9
116	3.5	3.3	3.2	3.1	3.0	2.9	2.8	2.8	2.8
117	3.4	3.3	3.1	3.0	2.9	2.8	2.7	2.7	2.7
118	3.3	3.1	3.0	2.8	2.7	2.6	2.6	2.5	2.5
119	3.1	2.9	2.8	2.6	2.5	2.4	2.4	2.3	2.3
120+	3.0	2.8	2.6	2.5	2.3	2.2	2.1	2.1	2.1

TABLE 3 TO PARAGRAPH (d)

Ages	108	109	110	111	112	113	114	115	116
0	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6
1	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7
2	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8
3	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8
4	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8
5	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8
6	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8
7	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.9
8	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9
9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9
10	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.9
11	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9
12	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9
13	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9
14	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9
15	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9
16	69.0	69.0	69.0	69.0	69.0	69.0	69.0	69.0	69.0
17	68.0	68.0	68.0	68.0	68.0	68.0	68.0	68.0	68.0
18	67.0	67.0	67.0	67.0	67.0	67.0	67.0	67.0	67.0
19	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0
20	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0
21	64.1	64.1	64.1	64.1	64.1	64.1	64.1	64.1	64.1
22	63.1	63.1	63.1	63.1	63.1	63.1	63.1	63.1	63.1
23	62.1	62.1	62.1	62.1	62.1	62.1	62.1	62.1	62.1
24	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1
25	60.2	60.2	60.2	60.2	60.2	60.2	60.2	60.2	60.2
26	59.2	59.2	59.2	59.2	59.2	59.2	59.2	59.2	59.2
27	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2
28	57.3	57.3	57.3	57.3	57.3	57.3	57.3	57.3	57.3
29	56.3	56.3	56.3	56.3	56.3	56.3	56.3	56.3	56.3
30	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3
31	54.4	54.4	54.4	54.4	54.4	54.4	54.4	54.4	54.4
32	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4
33	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5	52.5
34	51.5	51.5	51.5	51.5	51.5	51.5	51.5	51.5	51.5
35	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5
36	49.6	49.6	49.6	49.6	49.6	49.6	49.6	49.6	49.6
37	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6
38	47.7	47.7	47.7	47.7	47.7	47.7	47.7	47.7	47.7
39	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7
40	45.7	45.7	45.7	45.7	45.7	45.7	45.7	45.7	45.7
41	44.8	44.8	44.8	44.8	44.8	44.8	44.8	44.8	44.8
42	43.8	43.8	43.8	43.8	43.8	43.8	43.8	43.8	43.8
43	42.9	42.9	42.9	42.9	42.9	42.9	42.9	42.9	42.9
44	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.9
45	41.0	41.0	41.0	41.0	41.0	41.0	41.0	41.0	41.0
46	40.0	40.0	40.0	40.0	40.0	40.0	40.0	40.0	40.0
47	39.0	39.0	39.0	39.0	39.0	39.0	39.0	39.0	39.0
48	38.1	38.1	38.1	38.1	38.1	38.1	38.1	38.1	38.1
49	37.1	37.1	37.1	37.1	37.1	37.1	37.1	37.1	37.1
50	36.2	36.2	36.2	36.2	36.2	36.2	36.2	36.2	36.2
51	35.3	35.3	35.3	35.3	35.3	35.3	35.3	35.3	35.3
52	34.3	34.3	34.3	34.3	34.3	34.3	34.3	34.3	34.3

TABLE 3 TO PARAGRAPH (d)—Continued

Ages	108	109	110	111	112	113	114	115	116
53	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4
54	32.5	32.5	32.5	32.5	32.5	32.5	32.5	32.5	32.5
55	31.6	31.6	31.6	31.6	31.6	31.6	31.6	31.6	31.6
56	30.7	30.7	30.7	30.7	30.7	30.7	30.7	30.7	30.7
57	29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8	29.8
58	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9
59	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0
60	27.1	27.1	27.1	27.1	27.1	27.1	27.1	27.1	27.1
61	26.3	26.3	26.3	26.3	26.3	26.3	26.3	26.3	26.3
62	25.4	25.4	25.4	25.4	25.4	25.4	25.4	25.4	25.4
63	24.6	24.6	24.6	24.6	24.6	24.6	24.6	24.6	24.6
64	23.7	23.7	23.7	23.7	23.7	23.7	23.7	23.7	23.7
65	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9
66	22.1	22.1	22.1	22.1	22.1	22.1	22.1	22.1	22.1
67	21.3	21.3	21.3	21.3	21.3	21.3	21.3	21.3	21.3
68	20.5	20.4	20.4	20.4	20.4	20.4	20.4	20.4	20.4
69	19.6	19.6	19.6	19.6	19.6	19.6	19.6	19.6	19.6
70	18.8	18.8	18.8	18.8	18.8	18.8	18.8	18.8	18.8
71	18.0	18.0	18.0	18.0	18.0	18.0	18.0	18.0	18.0
72	17.2	17.2	17.2	17.2	17.2	17.2	17.2	17.2	17.2
73	16.5	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4
74	15.7	15.7	15.7	15.7	15.7	15.7	15.7	15.7	15.6
75	14.9	14.9	14.9	14.9	14.9	14.9	14.9	14.9	14.9
76	14.2	14.2	14.2	14.2	14.2	14.2	14.1	14.1	14.1
77	13.4	13.4	13.4	13.4	13.4	13.4	13.4	13.4	13.4
78	12.7	12.7	12.7	12.7	12.7	12.7	12.7	12.7	12.7
79	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0
80	11.4	11.3	11.3	11.3	11.3	11.3	11.3	11.3	11.3
81	10.7	10.7	10.7	10.7	10.7	10.7	10.7	10.7	10.6
82	10.1	10.1	10.1	10.1	10.1	10.0	10.0	10.0	10.0
83	9.5	9.5	9.5	9.5	9.5	9.4	9.4	9.4	9.4
84	8.9	8.9	8.9	8.9	8.9	8.9	8.9	8.8	8.8
85	8.4	8.4	8.3	8.3	8.3	8.3	8.3	8.3	8.3
86	7.8	7.8	7.8	7.8	7.8	7.8	7.8	7.8	7.7
87	7.4	7.4	7.4	7.3	7.3	7.3	7.3	7.3	7.3
88	6.9	6.9	6.9	6.9	6.9	6.9	6.9	6.8	6.8
89	6.5	6.5	6.5	6.5	6.5	6.4	6.4	6.4	6.4
90	6.1	6.1	6.1	6.1	6.1	6.1	6.0	6.0	6.0
91	5.7	5.7	5.7	5.7	5.7	5.7	5.7	5.6	5.6
92	5.4	5.4	5.4	5.4	5.4	5.3	5.3	5.3	5.2
93	5.1	5.1	5.1	5.1	5.1	5.0	5.0	5.0	4.9
94	4.8	4.8	4.8	4.8	4.8	4.7	4.7	4.7	4.6
95	4.5	4.5	4.5	4.5	4.5	4.5	4.4	4.4	4.4
96	4.3	4.3	4.3	4.3	4.3	4.2	4.2	4.2	4.1
97	4.1	4.1	4.1	4.1	4.0	4.0	4.0	4.0	3.9
98	3.9	3.9	3.9	3.9	3.8	3.8	3.8	3.8	3.7
99	3.7	3.7	3.7	3.7	3.7	3.6	3.6	3.6	3.5
100	3.6	3.6	3.5	3.5	3.5	3.5	3.5	3.4	3.3
101	3.4	3.4	3.4	3.4	3.4	3.4	3.3	3.3	3.2
102	3.3	3.3	3.3	3.3	3.3	3.2	3.2	3.2	3.1
103	3.2	3.2	3.2	3.2	3.2	3.1	3.1	3.1	3.0
104	3.1	3.1	3.1	3.1	3.1	3.1	3.0	3.0	2.9
105	3.1	3.1	3.1	3.0	3.0	3.0	3.0	2.9	2.8
106	3.0	3.0	3.0	3.0	3.0	3.0	2.9	2.9	2.8
107	3.0	3.0	3.0	3.0	3.0	2.9	2.9	2.9	2.8
108	3.0	3.0	3.0	3.0	2.9	2.9	2.9	2.8	2.8
109	3.0	3.0	3.0	3.0	2.9	2.9	2.9	2.8	2.8
110	3.0	3.0	3.0	2.9	2.9	2.9	2.9	2.8	2.7
111	3.0	3.0	2.9	2.9	2.9	2.9	2.8	2.8	2.7
112	2.9	2.9	2.9	2.9	2.9	2.9	2.8	2.8	2.7
113	2.9	2.9	2.9	2.9	2.9	2.8	2.8	2.8	2.7
114	2.9	2.9	2.9	2.8	2.8	2.8	2.8	2.7	2.6
115	2.8	2.8	2.8	2.8	2.8	2.8	2.7	2.7	2.6
116	2.8	2.8	2.7	2.7	2.7	2.7	2.6	2.6	2.5
117	2.7	2.6	2.6	2.6	2.6	2.6	2.5	2.5	2.4
118	2.5	2.5	2.5	2.4	2.4	2.4	2.4	2.3	2.2
119	2.3	2.3	2.2	2.2	2.2	2.2	2.1	2.1	2.0
120+	2.0	2.0	2.0	2.0	2.0	1.9	1.9	1.8	1.8

TABLE 3 TO PARAGRAPH (d)

Ages	117	118	119	120+					
0	84.6	84.6	84.6	84.6					
1	83.7	83.7	83.7	83.7					
2	82.8	82.8	82.8	82.8					
3	81.8	81.8	81.8	81.8					
4	80.8	80.8	80.8	80.8					
5	79.8	79.8	79.8	79.8					
6	78.8	78.8	78.8	78.8					
7	77.9	77.9	77.9	77.9					
8	76.9	76.9	76.9	76.9					
9	75.9	75.9	75.9	75.9					
10	74.9	74.9	74.9	74.9					
11	73.9	73.9	73.9	73.9					
12	72.9	72.9	72.9	72.9					
13	71.9	71.9	71.9	71.9					
14	70.9	70.9	70.9	70.9					
15	69.9	69.9	69.9	69.9					
16	69.0	69.0	69.0	69.0					
17	68.0	68.0	68.0	68.0					
18	67.0	67.0	67.0	67.0					
19	66.0	66.0	66.0	66.0					
20	65.0	65.0	65.0	65.0					
21	64.1	64.1	64.1	64.1					
22	63.1	63.1	63.1	63.1					
23	62.1	62.1	62.1	62.1					
24	61.1	61.1	61.1	61.1					
25	60.2	60.2	60.2	60.2					
26	59.2	59.2	59.2	59.2					
27	58.2	58.2	58.2	58.2					
28	57.3	57.3	57.3	57.3					
29	56.3	56.3	56.3	56.3					
30	55.3	55.3	55.3	55.3					
31	54.4	54.4	54.4	54.4					
32	53.4	53.4	53.4	53.4					
33	52.5	52.5	52.5	52.5					
34	51.5	51.5	51.5	51.5					
35	50.5	50.5	50.5	50.5					
36	49.6	49.6	49.6	49.6					
37	48.6	48.6	48.6	48.6					
38	47.7	47.7	47.7	47.7					
39	46.7	46.7	46.7	46.7					
40	45.7	45.7	45.7	45.7					
41	44.8	44.8	44.8	44.8					
42	43.8	43.8	43.8	43.8					
43	42.9	42.9	42.9	42.9					
44	41.9	41.9	41.9	41.9					
45	41.0	41.0	41.0	41.0					
46	40.0	40.0	40.0	40.0					
47	39.0	39.0	39.0	39.0					
48	38.1	38.1	38.1	38.1					
49	37.1	37.1	37.1	37.1					
50	36.2	36.2	36.2	36.2					
51	35.3	35.3	35.3	35.3					
52	34.3	34.3	34.3	34.3					
53	33.4	33.4	33.4	33.4					
54	32.5	32.5	32.5	32.5					
55	31.6	31.6	31.6	31.6					
56	30.7	30.7	30.7	30.6					
57	29.8	29.8	29.8	29.8					
58	28.9	28.9	28.9	28.9					
59	28.0	28.0	28.0	28.0					
60	27.1	27.1	27.1	27.1					
61	26.3	26.3	26.2	26.2					
62	25.4	25.4	25.4	25.4					
63	24.6	24.5	24.5	24.5					
64	23.7	23.7	23.7	23.7					
65	22.9	22.9	22.9	22.9					
66	22.1	22.1	22.1	22.0					
67	21.2	21.2	21.2	21.2					
68	20.4	20.4	20.4	20.4					
69	19.6	19.6	19.6	19.6					
70	18.8	18.8	18.8	18.8					
71	18.0	18.0	18.0	18.0					

TABLE 3 TO PARAGRAPH (d)—Continued

Ages	117	118	119	120+					
72	17.2	17.2	17.2	17.2					
73	16.4	16.4	16.4	16.4					
74	15.6	15.6	15.6	15.6					
75	14.9	14.9	14.8	14.8					
76	14.1	14.1	14.1	14.1					
77	13.4	13.4	13.4	13.3					
78	12.7	12.6	12.6	12.6					
79	12.0	11.9	11.9	11.9					
80	11.3	11.3	11.2	11.2					
81	10.6	10.6	10.6	10.5					
82	10.0	10.0	9.9	9.9					
83	9.4	9.3	9.3	9.3					
84	8.8	8.8	8.7	8.7					
85	8.2	8.2	8.2	8.1					
86	7.7	7.7	7.6	7.6					
87	7.2	7.2	7.1	7.1					
88	6.8	6.7	6.6	6.6					
89	6.3	6.3	6.2	6.1					
90	5.9	5.8	5.8	5.7					
91	5.5	5.5	5.4	5.3					
92	5.2	5.1	5.0	4.9					
93	4.9	4.8	4.7	4.6					
94	4.6	4.5	4.4	4.3					
95	4.3	4.2	4.1	4.0					
96	4.0	3.9	3.8	3.7					
97	3.8	3.7	3.6	3.4					
98	3.6	3.5	3.3	3.2					
99	3.4	3.3	3.1	3.0					
100	3.3	3.1	2.9	2.8					
101	3.1	3.0	2.8	2.6					
102	3.0	2.8	2.6	2.5					
103	2.9	2.7	2.5	2.3					
104	2.8	2.6	2.4	2.2					
105	2.7	2.6	2.4	2.1					
106	2.7	2.5	2.3	2.1					
107	2.7	2.5	2.3	2.1					
108	2.7	2.5	2.3	2.0					
109	2.6	2.5	2.3	2.0					
110	2.6	2.5	2.2	2.0					
111	2.6	2.4	2.2	2.0					
112	2.6	2.4	2.2	2.0					
113	2.6	2.4	2.2	1.9					
114	2.5	2.4	2.1	1.9					
115	2.5	2.3	2.1	1.8					
116	2.4	2.2	2.0	1.8					
117	2.3	2.1	1.9	1.6					
118	2.1	1.9	1.7	1.4					
119	1.9	1.7	1.3	1.1					
120+	1.6	1.4	1.1	1.0					

(e) *Mortality rates.* The following are the mortality rates used to calculate the tables set forth in paragraphs (b), (c), and (d) of this section.

TABLE 4 TO PARAGRAPH (e)

Age	Probability of death
0	0.001762
1	0.000441
2	0.000292
3	0.000232
4	0.000177
5	0.000161
6	0.000153
7	0.000145
8	0.000132
9	0.000127
10	0.000128
11	0.000135
12	0.000146
13	0.000164
14	0.000192
15	0.000223
16	0.000253
17	0.000276
18	0.000293
19	0.000304
20	0.000313
21	0.000343
22	0.000377
23	0.000421
24	0.000466
25	0.000520
26	0.000581
27	0.000630
28	0.000677
29	0.000720
30	0.000763
31	0.000799
32	0.000824
33	0.000833
34	0.000830
35	0.000823
36	0.000819
37	0.000824

TABLE 4 TO PARAGRAPH (e)—Continued

Age	Probability of death
38	0.000836
39	0.000853
40	0.000879
41	0.000909
42	0.000945
43	0.000980
44	0.001019
45	0.001065
46	0.001132
47	0.001225
48	0.001345
49	0.001485
50	0.001656
51	0.001874
52	0.002121
53	0.002397
54	0.002701
55	0.003032
56	0.003390
57	0.003774
58	0.004181
59	0.004613
60	0.005071
61	0.005554
62	0.006071
63	0.006624
64	0.007225
65	0.007884
66	0.008238
67	0.008659
68	0.009163
69	0.009767
70	0.010491
71	0.011358
72	0.012385
73	0.013598
74	0.015014
75	0.016670
76	0.018587
77	0.020815
78	0.023391
79	0.026387
80	0.029850
81	0.033883
82	0.038544
83	0.043880
84	0.049956
85	0.056799
86	0.064436
87	0.072882
88	0.082137
89	0.092172
90	0.102919
91	0.114344
92	0.126605
93	0.139936
94	0.154844
95	0.171902
96	0.187210
97	0.204659
98	0.222921

TABLE 4 TO PARAGRAPH (e)—Continued

Age	Probability of death
99	0.241884
100	0.261476
101	0.281536
102	0.301847
103	0.322371
104	0.342940
105	0.361261
106	0.372886
107	0.381098
108	0.383358
109	0.385709
110	0.388092
111	0.390353
112	0.392822
113	0.395188
114	0.397567
115	0.400000
116	0.400000
117	0.400000
118	0.400000
119	0.400000
120	0.400000

(f) *Applicability dates*—(1) *In general.* The life expectancy tables and Uniform Lifetime Table set forth in this section apply for distribution calendar years beginning on or after January 1, 2022. For life expectancy tables and the Uniform Lifetime Table applicable for earlier distribution calendar years, see § 1.401(a)(9)–9, as set forth in 26 CFR part 1 revised as of April 1, 2020 (formerly applicable § 1.401(a)(9)–9).

(2) *Application to life expectancies that may not be recalculated*—(i) *Redetermination of initial life expectancy using current tables.* If an employee died before January 1, 2022, and, under the rules of § 1.401(a)(9)–5, the distribution period that applies for a calendar year following the calendar year of the employee's death is equal to a single life expectancy calculated as of the calendar year of the employee's death (or, if applicable, the following calendar year), reduced by 1 for each subsequent year, then that life expectancy is reset as provided in paragraph (f)(2)(ii) of this section. Similarly, if an employee's sole beneficiary is the employee's surviving spouse, and the spouse dies before January 1, 2022, then the spouse's life expectancy for the calendar year of the spouse's death (which is used to determine the applicable distribution period for later years) is reset as provided in paragraph (f)(2)(ii) of this section.

(ii) *Determination of applicable distribution period*—(A) *Distribution period based on new life expectancy.* With respect to a life expectancy described in paragraph (f)(2)(i) of this section, the distribution period that applies for a distribution calendar year beginning on or after January 1, 2022, is determined by using the Single Life Table in paragraph (b) of this section to determine the initial life expectancy for the age of the relevant individual in the relevant calendar year and then reducing the resulting distribution period by 1 for each subsequent year. However, see section 401(a)(9)(H)(ii) and (iii) for rules limiting the availability of a life expectancy distribution period.

(B) *Example of redetermination.* Assume that an employee died at age 80 in 2019 and the employee's designated beneficiary (who was not the employee's spouse) was age 75 in the year of the employee's death. For 2020, the distribution period that would have applied for the beneficiary was 12.7 years (the period applicable for a 76-year-old under the Single Life Table in formerly applicable § 1.401(a)(9)–9), and for 2021, it would have been 11.7 years (the original distribution period, reduced by 1 year). For 2022, if the designated beneficiary is still alive, then the applicable distribution period would be 12.1 years (the 14.1-year life expectancy for a 76-year-old under the Single Life Table in paragraph (b) of this section, reduced by 2 years). However, see section 401(a)(9)(H)(iii) for rules regarding how to apply the required distribution rules to defined contribution plans if the eligible designated beneficiary dies prior to distribution of the employee's entire interest.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: October 19, 2020.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

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Part VII

Environmental Protection Agency

40 CFR Part 257

Hazardous and Solid Waste Management System: Disposal of CCR; A Holistic Approach to Closure Part B: Alternate Demonstration for Unlined Surface Impoundments; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 257

[EPA–HQ–OLEM–2019–0173; FRL–10015–88–OLEM]

RIN 2050–AH11

Hazardous and Solid Waste Management System: Disposal of CCR; A Holistic Approach to Closure Part B: Alternate Demonstration for Unlined Surface Impoundments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On April 17, 2015, the Environmental Protection Agency (EPA or the Agency) promulgated national minimum criteria for existing and new coal combustion residuals (CCR) landfills and existing and new CCR surface impoundments. On August 21, 2018, the U.S. Court of Appeals for the D.C. Circuit issued its opinion in the case of *Utility Solid Waste Activities Group* v. *EPA,* 901 F.3d 414 (per curiam) (*USWAG*). This rule finalizes regulations proposed on March 3, 2020, including procedures to allow facilities to request approval to operate an existing CCR surface impoundment with an alternate liner, among other things. Provisions from the proposed rule that are not addressed in this rule will be addressed in a subsequent action.

DATES: This final rule is effective on December 14, 2020.

ADDRESSES: EPA has established a docket for this action under Docket ID. No. EPA–HQ–OLEM–2019–0173. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* 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 electronically through *http://www.regulations.gov.*

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I. General Information

A. Does this action apply to me?

This rule applies to all CCR generated by electric utilities and independent power producers that fall within the North American Industry Classification System (NAICS) code 221112 and may affect the following entities: electric utility facilities and independent power producers that fall under the NAICS code 221112. This discussion is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This discussion lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not described here could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in § 257.50 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is the Agency taking?

EPA is revising certain provisions of the CCR regulations at 40 CFR part 257 in response to the decision issued by the D.C. Circuit on August 21, 2018, in *Utility Solid Waste Activities Group* v. *EPA* 901 F.3d 414 (D.C. Cir.). Specifically, the Agency is finalizing a revision to the 2015 CCR Rule that provides procedures for facilities to request approval to use an alternate liner for CCR surface impoundments.

EPA is finalizing a two-step process for submittal of the necessary documentation for the alternate liner demonstration. The first step consists of an initial application intended to show whether a unit meets certain minimum requirements before embarking on a comprehensive alternate liner demonstration. These minimum requirements are designed to ensure that it is likely that the facility will ultimately be able to make the more extensive demonstration to support continued operation, and that the CCR surface impoundment can operate safely over the short term while the facility collects the data and conducts the analyses necessary to support the demonstration. The first step requires the facility to demonstrate that it is in full compliance with the applicable requirements in 40 CFR part 257 subpart D; that it possesses site characteristics that make it likely that it could qualify for a demonstration; and that there are no constituents listed in part 257 Appendix III that have been detected at a statistically significant increase (SSI) above background. The second step consists of a final demonstration intended to show whether there is a reasonable probability that releases from the impoundment throughout its active life may result in groundwater concentrations of constituents listed in part 257 Appendix IV at a statistically significant level (SSL) in the future. The purpose of this two-step approach is to ensure that units allowed to embark on a comprehensive and time-consuming demonstration meet the minimum requirements to ensure protectiveness throughout the process.

Provisions from the proposed rule that are not addressed in this rule will be addressed in a subsequent rulemaking action. The remaining provisions from the proposed rule are to allow the use of CCR during closure of a CCR unit, to establish an additional closure option for CCR units being closed by removal of CCR, and to establish requirements for annual closure progress reports.

EPA intends that the provisions of this rule be severable. In the event that any individual provision or part of this rule is invalidated, EPA intends that this would not render the entire rule invalid, and that any individual provisions that can continue to operate will be left in place.

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

These regulations are established under the authority of sections 1008(a), 2002(a), 4004, and 4005(a) and (d) of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA) and the Water Infrastructure Improvements for the Nation (WIIN) Act of 2016, 42 U.S.C. 6907(a), 6912(a), 6944, and 6945(a) and (d).

D. What are the incremental costs and benefits of this action?

This action is expected to result in an estimated annualized net cost savings of approximately $4.0 million per year to $8.0 million per year when discounting at 7% and approximately $2.2 million per year to $4.5 million per year when discounting at 3%. Further information on the economic effects of this action can be found in Unit VII of this preamble.

II. Background

A. The ''2015 CCR Rule''

On April 17, 2015, EPA finalized national minimum criteria for the disposal of CCR as a solid waste under Subtitle D of RCRA. 80 FR 21302. The Agency refers to the April 17, 2015 rule as the ''2015 CCR Rule'' in this preamble. CCR are generated from the combustion of coal by electric utilities and independent power producers for the generation of electricity. CCR include fly ash, bottom ash, boiler slag, and flue gas desulfurization materials and are commonly referred to as coal ash. The CCR regulations are codified in subpart D of part 257 of title 40 of the CFR.

The 2015 CCR Rule regulated existing and new CCR landfills and existing and new CCR surface impoundments, as well as all lateral expansions of these CCR units. The federal national minimum criteria consist of location restrictions (siting limitations), design and operating criteria, groundwater monitoring and corrective action requirements, and closure and post-closure care requirements. In addition, the 2015 CCR Rule put in place recordkeeping, notification, and internet posting provisions that require owners and operators of CCR units to maintain a publicly accessible internet site of rule compliance information. The 2015 CCR Rule does not regulate CCR that are beneficially used. It established a definition of ''beneficial use of CCR'' to distinguish between beneficial use and disposal.

Of particular relevance to this action, the 2015 CCR Rule required that any existing unlined CCR surface impoundment that cause groundwater concentrations to exceed a groundwater protection standard (GWPS) must stop receiving waste (CCR and/or non-CCR wastestreams) within six months of making an exceedance determination. This would also trigger the requirement to initiate either unit retrofit or closure activities.[1] See § 257.101(a)(1) at 80 FR 21490 (April 17, 2015). In the 2015 CCR Rule, the term ''unlined'' CCR surface impoundment included any unit not constructed with one of the following types of liners: (1) A composite liner; (2) an alternative composite liner; or (3) a liner consisting of a minimum of two feet of compacted soil with a hydraulic conductivity of no more than 1×10^{-7} centimeters per second. Lined CCR surface impoundments (as defined in the CCR regulations) that impact groundwater above the specified GWPS are not required to close and could continue to operate while corrective action is performed, and the source of the groundwater contamination is addressed.

The 2015 CCR Rule was challenged by several parties, including a coalition of regulated entities and a coalition of environmental organizations (''Environmental Petitioners''). See *USWAG* v *EPA,* 901 F.3d 414 (DC Cir. 2018). The Environmental Petitioners raised two challenges[2] that are relevant to this final rule. First, they challenged the provision that allowed existing, unlined CCR surface impoundments to continue to operate until they cause groundwater contamination. See § 257.101(a)(1) at 80 FR 21490 (April 17, 2015). They contended that EPA failed to show how continued operation of unlined impoundments met RCRA's baseline requirement that any solid waste disposal site pose ''no reasonable probability of adverse effects on health or the environment.'' See 42 U.S.C. 6944(a). The Environmental Petitioners also challenged the provisions that allowed impoundments lined with two feet of clay (*i.e.,* compacted soil) to continue operating even when they leak, requiring only that they remediate the resulting contamination. The petitioners pointed to record evidence that ''clay-lined'' units are likely to leak and contended that EPA's approach ''authorizes an endless cycle of spills and clean-ups'' in violation of RCRA.

B. The 2018 USWAG Decision

The D.C. Circuit issued its decision on *USWAG* v. *EPA* on August 21, 2018. The Court upheld most of the 2015 CCR Rule but ruled for the Environmental Petitioners on the two claims discussed in Unit II.A of this preamble. The Court held that EPA acted ''arbitrarily and capriciously and contrary to RCRA'' in failing to require the closure of unlined surface impoundments and in classifying so-called ''clay-lined'' impoundments as lined, based on the record supporting the rule. 901 F.3d at 431–432. The Court ordered that ''the Final Rule be vacated and remanded with respect to the provisions that permit unlined impoundments to continue receiving coal ash unless they leak, § 257.101(a), [and] classify 'clay-lined' impoundments as lined, see 40 CFR 257.71(a)(1)(i).'' *Id.* The Court issued the mandate for this decision on October 15, 2018. This decision is referred to as the ''*USWAG* decision'' in this action.

C. The March 2020 Proposed Rule

In the March 3, 2020 rule, EPA proposed revisions to the 2015 CCR Rule, including: Procedures to allow facilities to request approval to use an alternate liner for CCR surface impoundments; two co-proposed options to allow the use of CCR during unit closure; an additional closure option for CCR units being closed by removal of CCR; and requirements for annual closure progress reports. In this final rule, the Agency is taking final action on the proposed procedures for facilities to request approval to use an alternate liner for CCR surface impoundments. Provisions from the proposed rule that are not addressed in this rule will be addressed in a subsequent action.

D. Public Participation on the Proposed Rule

The Agency received over 42,000 comments on the proposed rule, with over 170 unique comments. The majority of commenters focused on the alternate liner demonstration (ALD) provisions, as well as use of CCR in closure. Commenters included individual electric utilities and independent power producers, national trade associations, state agencies, public

[1] Certain units may be eligible for the alternative closure procedures specified in § 257.103 which would change the date by which the unit must stop receiving waste.

[2] Environmental Petitioners also challenged the provisions exempting inactive surface impoundments at inactive power plants from regulation. The Court ruled for the Petitioners on these claims, vacating these provisions and remanding to EPA. However, in contrast to the other provisions addressed in this rule, additional rulemaking is necessary to effectuate the Court's order, as the Court's vacatur alone did not subject these units to regulation. This aspect of the decision will be addressed in a subsequent proposal.

interest and environmental groups, and entities involved with the beneficial use of CCR. All public comments submitted in response to the proposal can be found in the docket for this action. EPA's responses to comments on the proposed rule are addressed either in this preamble or in the response to comment document available in the docket to this final rule.

EPA conducted two virtual public hearings on April 7, 2020, and April 9, 2020 using an internet-based software platform. The platform allowed hearing participants to provide oral testimony using a microphone and speakers connected to their computers or using a phone. It provided the ability for any person to listen to the public hearing via their computer. On April 7, 2020, there were 38 speakers and a total of 142 registered attendees. On April 9, 2020, there were 30 speakers and a total of 82 registered attendees. Testimony at the public hearing focused generally on the proposed amendments of allowing the use of alternate liner demonstrations and use of CCR in closure. Several speakers commented on the alternate liner demonstration or the use of CCR in closure to allow CCR to be disposed in unlined surface impoundments indefinitely and contaminating groundwater, and the overall risks, especially health risks, related to CCR. Many speakers advocated for strengthening of the regulations rather than finalizing ''rollbacks.'' Many commenters were concerned that people were unable to attend the public hearing because of the COVID–19 pandemic, and that EPA did not extend the public comment period. Transcripts for both virtual public hearings are included in the docket for this action.

III. Addition of § 257.71(d) To Allow for Alternate Liner Demonstrations

The 2015 CCR Rule required that all existing unlined CCR surface impoundments that caused groundwater concentrations to exceed associated GWPS must stop receiving waste and either retrofit or close. In the 2015 CCR Rule, the term ''unlined'' CCR surface impoundment included any unit not constructed with one of the following types of liners: (1) Composite liner; (2) alternative composite liner; or (3) liner consisting of a minimum of two feet of compacted soil with a hydraulic conductivity of no more than 1×10^{-7} cm/s.[3] See § 257.71(a). Lined CCR surface impoundments (as defined in the CCR regulations) that impact groundwater above the specified GWPS were not required to close and could continue operations while corrective action was performed and the source of the groundwater contamination was addressed.

On August 21, 2018, the U.S. Court of Appeals for the D.C. Circuit found in the *USWAG* decision that the rulemaking record did not support the conclusion that the 2015 CCR Rule would adequately address the adverse effects posed by clay-lined CCR surface impoundments. Therefore, the court vacated the provisions that treated clay-lined surface impoundments differently than unlined impoundments. *USWAG,* 901 F.3d at 449. The result of the court's decision is that such units are now required to either retrofit or close. In response to this ruling, EPA received reports from industry groups and individual companies claiming that the performance of some surface impoundments that would now be required to retrofit or close is equivalent or even superior to the liners required by the 2015 CCR Rule.[4] These impoundments rely on engineered liner components (*e.g.,* manufactured geomembrane, mechanically compacted soil) that deviate from the requirements of the rule and/or on natural low-conductivity soil beneath the unit. EPA agrees that it is possible for individual impoundments that are not lined with a composite liner or an alternative composite liner (as those terms are defined in the CCR regulations) to still be protective of human health and the environment. This is possible if the effective hydraulic conductivity of the engineered liner and/or naturally occurring soil is so low that, even if leachate migrates from the unit, the volume of leachate that can be released to the underlying aquifer over the active life of the impoundment is so small that these releases will not result in adverse effects at any point in the future. Therefore, EPA proposed procedures in the March 2020 rule at § 257.71(d) to allow facilities to submit to EPA an alternate liner demonstration that would provide a sufficient record to support the continued operation of an unlined surface impoundment that can be shown to pose no reasonable probability of adverse effects to human health or the environment.

The current self-implementing regulations limit the ability of owners and operators to make a site-specific demonstration that the design of a particular CCR surface impoundment is equivalent to the composite liner system in §§ 257.71(c); consequently, a regulatory revision would be necessary. However, the Agency's current record does not support conclusions on whether any individual impoundment has a low enough effective hydraulic conductivity to be protective, were the unit allowed to continue operations. This would require site-specific data, such as liner performance and surrounding hydrogeologic characterization information. The data relied upon in the 2014 Risk Assessment were organized into distributions compiled at various geographic scales (*e.g.,* local, regional, national). The resolution of these data were sufficient for identifying the potential for risk at a national scale. However, the same data cannot be used to draw conclusions about any individual impoundment. While reports submitted to EPA by industry since the finalization of the 2015 CCR Rule have provided valuable information about the characteristics of impoundments anticipated to perform equivalent to the liner system required by the 2015 CCR Rule, these reports generally did not include the type or specificity of data needed to support conclusions about individual impoundments.

Therefore, owners and operators who believe an unlined surface impoundment meets the RCRA § 4004(a) standard and should be allowed to continue operation as designed must provide EPA or a Participating State Director with the site-specific data and analysis necessary to demonstrate this fact. Based on the available groundwater monitoring and location restriction data posted on facilities' publicly accessible CCR internet sites, EPA believes that it is likely that only a small fraction of non-composite lined surface impoundments currently in operation will be able to apply successfully for this demonstration.

A. Factual Basis

The factual record supporting the 2015 CCR Rule included a national-scale assessment of the risks associated with disposal of CCR in surface impoundments constructed with various liner types.[5] As part of the 2014 Risk Assessment, EPA modeled peak groundwater concentrations that might occur in off-site wells up to a mile away for a duration of up to 10,000 years. This modeling effort identified potential risks from both unlined and clay-lined surface impoundments: The risk that

[3] The liner terms ''compacted soil'' and ''clay-lined'' are used interchangeably in this preamble discussion.

[4] These reports are available in the docket to this rulemaking.

[5] U.S. EPA. 2014. ''Human and Ecological Risk Assessment of Coal Combustion Residuals.'' Prepared by the Office of Solid Waste and Emergency Response. Washington, DC. December.

groundwater would be contaminated at levels exceeding GWPS and the risk arising from the exposure of human and environmental receptors to contaminated water. It is now known that a greater fraction of operating units are unlined than previously understood. This may shift the national-scale risks reported for all impoundments closer to the risks for just unlined units because a greater fraction of all impoundments would now be modeled as unlined, but it would not substantially alter the high-end risks already modeled for unlined impoundments. Thus, the change in liner designation would not impact the overall conclusions about risk drawn from the 2014 Risk Assessment. Based on this modeling, EPA estimated that releases from up to 36.2% of unlined impoundments and 9.1% of clay-lined surface impoundments could ultimately contaminate off-site wells.[6] EPA is aware that monitoring data indicates that a higher percentage than this have exceeded GWPS. However, monitoring wells are located at the waste boundary, which invariably have higher concentrations than would be found up to a mile away from the unit, and includes additional contributions from background groundwater. In addition, a number of these impoundments are located near water bodies, which intercept some or all of the release before it can reach private wells on the opposite side. Therefore, EPA does not believe that the field data that has become available since finalization of the risk assessment conflicts with previous modeling results.

As explained in the proposed rule, EPA considers it to be theoretically possible for some unlined and clay-lined units to achieve the same level of performance as the composite liners required by the 2015 CCR Rule. In order for this to be the case, the effective hydraulic conductivity of the engineered liner and/or naturally occurring soil would need to be so low that, even if leachate migrates from the unit, the volume of leachate that can be transmitted to the underlying aquifer over time is small enough that it will not adversely affect groundwater quality. For a unit to achieve this, it would need to perform materially better than the clay-lined units evaluated in the 2014 Risk Assessment. Those clay-lined surface impoundments were modeled with a fixed hydraulic conductivity of 1×10^{-7} cm/s and thickness of 3 feet, similar to the minimum design standard for clay-lined units outlined in the 2015 CCR Rule. For this fixed set of parameters, EPA identified risks slightly above the relevant risk criteria only for lithium, one of the most mobile CCR constituents.[7] Based on these model results, an effective hydraulic conductivity of 1×10^{8} cm/s would be sufficient to reduce identified risks to below levels of concern on a national-scale. However, conditions present at individual facilities, such as the thickness of the low-conductivity soil or the presence of a geomembrane liner, might support somewhat higher soil conductivities on a case-by-case basis. Regardless, a conductivity of 1×10^{-7} cm/s for the lowermost soil component of the liner, whether in isolation or beneath a geomembrane component, remains the absolute floor for any unit to even be considered for an alternate liner demonstration.

EPA established the minimum liner requirements for CCR surface impoundments in the 2015 rule based on the original municipal solid waste landfill regulations at 40 CFR part 258. These requirements were based on the Agency's experience with various liner materials and reflect a uniform design that EPA expects to be reliably protective if manufactured and constructed properly. However, EPA acknowledged in the original 1991 rule (56 FR 51059, October 9, 1991) that alternative designs may be able to achieve the same performance. Thus, EPA also acknowledges that the fact that an individual unit does not meet the liner requirements of the 2015 CCR Rule does not in and of itself indicate that a unit will pose risk. Facilities that commented on the proposed rule reported units that were considered unlined based on the 2015 CCR Rule definition for several reasons. Based on the available information from these comments and the Part 258 regulatory record, EPA identified three primary reasons that an alternately lined unit could still be protective.

One type of impoundment that was classified as unlined, but which might still be demonstrated to be protective, is a unit where the soil was not mechanically compacted to the specified depth. It is well-established in the literature that clay-rich soils can achieve hydraulic conductivities lower than 1×10^{-8} cm/s; however, this often requires some degree of compaction to break down any larger clumps of soil and minimize the volume of void spaces between soil particles that allow water to flow. Reports provided by some facilities purport that the necessary compaction of these soils had been accomplished onsite through natural processes. One example of the natural processes envisioned by commenters is glacial compaction, whereby stress from the weight and flow of the glacier compressed the naturally occurring soil. This process has been found to result in regions of soil with conductivities lower than 1×10^{-8} cm/s.[8] Soils from around the perimeter of such units, which have historically been exposed to similar environmental conditions as the soil beneath the unit and so are expected to have similar characteristics, can be collected to confirm that necessary hydraulic conductivity is present and consistent across the site. Therefore, EPA believes the potential exists for facilities to successfully demonstrate that naturally compacted soil can be protective.

Another type of unlined impoundment that may still be demonstrated to be protective is one where the layer of compacted soil was not thick enough to meet the current part 257 requirement. Based on EPA's experience with these liner materials, two feet of soil is the minimum thickness needed to reliably obtain adequate compaction and meet requirements for hydraulic conductivity. This thickness is considered necessary to minimize the number of cracks or imperfections through the entire liner thickness that could allow leachate migration. Based on EPA's experience, a two-foot minimum thickness is believed to be sufficient to reliably inhibit hydraulic short-circuiting of the entire layer. While it is possible to achieve low conductivities with a reduced thickness, there is a far greater risk of lateral and vertical imperfections that may arise during construction. Therefore, EPA believes that successful demonstration is possible here only if the facility can provide data showing the liner achieves an adequately low hydraulic conductivity in-situ.

The final type of unlined impoundment that may still be demonstrated to be protective is one where the geomembrane liner used was not thick enough to meet the current part 257 requirement. The upper component of a composite-lined unit must consist of a minimum of a 30-mil

[6] U.S. EPA. 2014. ''Regulatory Impact Analysis: EPA's 2015 RCRA Final Rule Regulating Coal Combustion Residual (CCR) Landfills and Surface Impoundments at Coal-Fired Electric Utility Power Plants.'' Prepared by the Office of Solid Waste and Emergency Response. Washington, DC. December.

[7] Lithium had a non-cancer hazard quotient of 2.

[8] United States Department of the Interior. 1998. ''National Water-Quality Assessment of the Lake Erie-Lake St. Clair Basin, Michigan, Indiana, Ohio, Pennsylvania, and New York Environmental and Hydrogeologic Setting.'' Water-Resources; Investigations Report 97–4256. Prepared by the United States Geological Survey. Columbus, OH.

geomembrane liner, or 60-mil if the liner is constructed with high density polyethylene. Based on EPA's experience with these liner materials, these are the minimum thicknesses necessary to ensure adequate liner performance, including being able to withstand the stress of construction and to ensure that adequate seams can be made. Commenters argued that, due to improvements in welding technology and quality control procedures since these standards were first promulgated, concerns regarding welding thinner HDPE geomembranes have greatly diminished. If the facility is able to document the integrity of the liner design, then the performance of these liners will be primarily a function of construction quality. Commenters acknowledged that thinner liners are theoretically more susceptible to defects during installation, but also argued that no such trends have been identified in the literature. The 2014 Risk Assessment found that a well-constructed geomembrane liner can remain protective, even with a higher proportion of imperfections. Therefore, EPA believes the potential exists for facilities to successfully demonstrate that alternate geomembrane liners can be protective, provided that the soil directly beneath the geomembrane has sufficiently low conductivity.

To support the conclusion that the long-term performance of an alternately lined CCR surface impoundment can meet the RCRA § 4004 protectiveness standard, EPA would need several categories of information. EPA proposed two categories of information that must be provided for the demonstration step, which the Agency is finalizing as part of this rulemaking. The first category is a characterization of the site-specific hydrogeology surrounding the surface impoundment. The purpose of these data is to define the variability of the soil around the surface impoundment to determine whether preferential flow pathways exist that effectively negate the low conductivity of the alternate liner. The second category of data is a characterization of the potential for infiltration through any engineered liner and/or naturally occurring soil that control the release and transport of leachate. These data will provide for a reasonable estimate of the rate at which contaminants may be released and transported to groundwater over time. Based on comments received, EPA is also finalizing a third category of information. This additional category is documentation of material properties and unit construction quality. The purpose of these data is to document that the impoundment can be expected to achieve the low conductivity specified in the unit designs. This category is included in the application step to confirm upfront that conditions simulated in a laboratory setting as part of the demonstration step are a reasonable reflection of field conditions.

Thus, EPA concludes that there is potential for some existing unlined and clay-lined CCR surface impoundments to continue operating without presenting unacceptable risk. However, the Agency's current risk assessment does not support conclusions on whether any individual surface impoundment has a low enough effective hydraulic conductivity that operation of the unit will continue to be protective in the future. This would require the site-specific data discussed above, including, for example, data on the ability of the engineered liner and/or naturally occurring soil to limit the release and transport of leachate away from the unit. Therefore, EPA proposed procedures at § 257.71(d) to allow facilities to submit such information to EPA to demonstrate that the engineered liner and/or naturally occurring soil will remain protective, and consequently the continued operation of an individual unlined surface impoundments will present no reasonable probability of adverse effects to human health or the environment.

Specifically, EPA proposed a two-step process. In the first step, a facility would be required to submit an initial application to demonstrate that they meet certain minimum requirements before embarking on a comprehensive alternate liner demonstration. These minimum requirements are designed to ensure that it is likely a facility will ultimately be able to make the more extensive demonstration to support continued operation, and that the CCR surface impoundment can operate safely over the near term while the facility collects the data and conducts the analyses necessary to support the demonstration. In the second step, the facility would be required to submit the data and analyses necessary to support a determination that the CCR surface impoundment can sustain its current performance and operate safely for the remainder of its active life.

Most industry groups and individual facilities voiced support for the option to make this type of demonstration, stating that the definition of a lined CCR surface impoundment in the 2015 CCR Rule is inflexible and would result in the unnecessary closure of some unlined CCR surface impoundments that, as designed, are as protective as lined CCR surface impoundments. Many environmental groups and private citizens were critical of the proposal and commented that it was unsupportable and would lead to greater risks to human health and the environment. Some of the same commenters noted that, while the types of information required may be useful to differentiate non-compliant and underperforming units, there were concerns that the amount of information required would be difficult or impossible to collect and review.

1. Existing Record

Environmental groups stated the existing risk record does not support the conclusion that alternate liners can be protective, citing the potential risks identified for clay-lined units in the 2014 Risk Assessment. Some of these commenters further argued that the reports submitted by facilities to date are inadequate and similarly do not support the continued operation of the units documented therein. These commenters provided critiques of the individual units and concluded that the information provided in the associated reports is not sufficient to demonstrate whether on-site groundwater monitoring wells are adequate in number or construction to accurately reflect upgradient and downgradient conditions at the site. Further, commenters concluded that some facilities have inappropriately handled monitoring data to erroneously show that the CCR surface impoundment has not contaminated groundwater. Commenters also critiqued a report prepared by the Electric Power Research Institute (EPRI), which they claim shows that clay liners cannot be equivalent to composite liners in protecting health and the environment.

As stated in the proposal and above, EPA agrees that neither the 2014 Risk Assessment nor the industry reports support conclusions about any individual unlined surface impoundment. In order to draw conclusions about the protectiveness of any individual CCR surface impoundment, EPA needs site-specific information on the performance of the engineered liner and/or the naturally occurring soil. This is why EPA proposed a process for facilities to submit documentation that would support the continued operation of an unlined surface impoundment. At an absolute minimum, the performance of these CCR units would need to surpass that of the clay liners previously modeled, making them distinct from the far broader universe of clay-lined and unlined CCR surface impoundments considered in the *USWAG* decision.

Although the reports submitted to EPA by individual facilities since finalization of the 2015 CCR Rule provide an indication on which impoundments are most likely to seek an ALD, EPA stated in the proposal that these reports did not include the type or specificity of data necessary to support conclusions about these individual surface impoundments. As a result, EPA did not rely on the conclusions of these reports to support any provisions of this final rule. As discussed in more detail below in Unit III.B, part of the purpose of the initial application step is to determine whether the types of deficiencies raised by commenters are present at a particular site, and if so, to ensure that these facilities do not progress to the longer ALD process.

The report submitted by EPRI considered more broadly whether alternative liners can achieve GWPS near the CCR waste boundary. The modeling approach in many ways mirrored that used by EPA in the 2014 Risk Assessment. Although EPRI initially made some assumptions that would tend to overestimate risk, such as ignoring the effects of constituent sorption onto the soil, these assumptions were later explored in select sensitivity analyses. Ultimately, EPRI found that even thick clay liners with a hydraulic conductivity of 1×10^{-7} cm/s could result in exceedances of GWPS under high-end conditions, while thinner clay liners with a conductivity at and above 1×10^{-8} cm/s did not. These results generally comport with the conclusions drawn from the 2014 Risk Assessment and suggest that there are plausible scenarios in which alternative liners can be protective. Critiques of the EPRI report by commenters focused heavily on the fact that the modeled clay liners did not perform equivalently to composite liners, meaning that the alternative liner could result in releases greater than a composite liner. However, after consideration of the comments received, the Agency believes this type of ''equivalence'' is not the appropriate standard to apply in an alternate liner demonstration. It would be difficult for an owner or operator to demonstrate that a clay liner of any thickness would prevent migration just as effectively as a composite liner, which includes a flexible membrane liner that, by design, is impermeable. Such a standard would unnecessarily limit the ability of owners and operators to utilize otherwise protective designs. Therefore, EPA believes the appropriate standard for an alternate liner demonstration is that there is no reasonable probability that releases throughout the active life of the CCR surface impoundment will result in adverse effects to human health or the environment. This is the standard relied upon in the 2015 CCR Rule to determine that composite-lined units were protective. This standard is achieved in an ALD by documenting that the peak groundwater concentration that may result from releases over the active life of the impoundment will not exceed GWPS at the waste boundary.

Therefore EPA is making revisions at § 257.71(d) to specify the owner or operator of a CCR surface impoundment constructed without a composite liner or alternative composite liner, as defined in § 257.70(b) or (c), may submit an Alternate Liner Demonstration to the Administrator or the Participating State Director to demonstrate that the design of the current liner system or the naturally occurring media will remain protective of human health and the environment.

2. Potential Risks to Surface Water

Several environmental groups expressed concern that the focus on protection of groundwater would exclude protection of ecological receptors in nearby surface water. In particular, commenters highlighted the potential for some constituents to be toxic for aquatic wildlife at lower levels than for human ingestion of groundwater. These commenters also stated that the *USWAG* decision faulted EPA for not directly addressing potential risks to ecological receptors identified in the 2014 Risk Assessment. Another commenter pointed to the damage cases relied upon in the 2015 CCR Rule that identified additional risks to surface water.

The 2014 Risk Assessment identified the potential for surface water risks from unlined units as a whole, but the existing risk record does not support similar concerns about units that would be able to obtain an ALD. Releases from the base of an impoundment will migrate down to groundwater prior to discharge into downgradient surface water. The risk assessment explicitly modeled this pathway and found that all surface water risks from clay-lined units fall below levels of concern by an order of magnitude or more. If the effective hydraulic conductivity of an alternate liner is sufficient to mitigate the groundwater risks previously identified in the risk assessment, then it will only further reduce downgradient releases to surface water through groundwater discharge. Thus, by demonstrating that an alternately lined impoundment can reliably perform better than the clay-lined units considered in the 2014 Risk Assessment, this confirms that these impoundments will pose no reasonable probability of adverse effects to surface water. Although damage cases considered in the 2015 CCR Rule identified some surface water impacts beyond those reported in the risk assessment, these were frequently associated with scenarios not explicitly modeled in the risk assessment, such as direct discharge of either CCR and/or associated wastewater to surface water or disposal of CCR in high-risk areas (*e.g.,* within the groundwater table). These scenarios have already been addressed under RCRA through requirements for structural integrity and location restrictions, respectively. In addition, EPA is finalizing a requirement as part of this rule that facilities must remain in detection monitoring throughout both the application and demonstration steps. Ensuring that there is no SSI of Appendix III constituents throughout the demonstration will also ensure that Appendix IV constituents will not migrate beyond the waste boundary and pose risk to nearby ecological receptors while the owner or operator prepares the necessary documentation to demonstrate both that the facility complies with all relevant requirements of the 2015 CCR Rule and that the long-term performance of the impoundment will be protective.

3. Continued Operation of CCR Surface Impoundments During Demonstration

Industry groups agreed with EPA's basis for the proposed rule and stated that the D.C. Circuit had not precluded EPA from supplementing the existing risk record to support future decisions about individual unlined CCR surface impoundments. However, several environmental groups argued that the rule was in violation of the *USWAG* decision and contrary to RCRA. These commenters claimed that the D.C. Circuit decision required the closure of all unlined and clay-lined CCR surface impoundments and so any rule that would allow additional time for operation while the CCR surface impoundments complete a demonstration process would violate the decision. Others contended that allowing any additional time for operation would violate RCRA § 4004(a) because it might provide deficient units additional time to contaminate groundwater before addressing the source.

EPA disagrees with the suggestion that this rule is inconsistent with the *USWAG* decision. The D.C. Circuit held that the rulemaking record supporting

the 2015 CCR Rule did not support allowing clay-lined units to continue to operate indefinitely. 901 F.3d at 431–432. The court did not find that the statute per se prohibited such units, but that EPA had failed to provide enough evidence to demonstrate that the statutory standard had been met. *Id.* Consequently, EPA is not precluded from subsequently developing the evidence necessary to support the continued operation of some or all of these units. As discussed in greater detail in subsequent Units of this preamble, the record associated with the specific subset of impoundments that will be eligible under this rule is very different than the record associated with all units regulated under the 2015 CCR rule. For example, in the 2015 CCR rule the majority of units had been operating for years without groundwater monitoring or other regulatory requirements. The record for that rule documented that the majority of these units had likely been contaminating groundwater for years; EPA estimated that the contamination at these units had spread well beyond the waste boundary. And because there was no groundwater monitoring at these facilities, EPA was unable to distinguish between units that did pose a risk and those that did not. By contrast, only units that remain in detection monitoring throughout the application and demonstration process can be approved for an ALD. As discussed later in this preamble, EPA has also addressed the specific faults that the court found in EPA's prior record.

EPA further disagrees with the suggestion that this rule fails to meet the standard in RCRA § 4004(a). EPA purposefully divided the ALD process into two steps to weed out the facilities that fail to meet the RCRA § 4004(a) standard. The initial application ensures that a facility is in compliance with applicable requirements in 40 CFR part 257 subpart D, that the design of the monitoring network is sufficient to identify releases, that the CCR surface impoundment is in detection monitoring, and that the unit has the soil characteristics or engineering quality that would make it possible to meet the ultimate performance standard before a facility is granted any additional time to complete the more comprehensive alternate liner demonstration. The combination of these factors ensures that the only CCR surface impoundments allowed to progress to the demonstration step are those that EPA expects to remain protective during the year-long process to complete the demonstration.

Because the initial application phase will be completed by April 11, 2021 (the deadline for unlined surface impoundments to cease receipt of waste pursuant to § 257.101(a)(1)), this process will grant additional time to operate only to CCR surface impoundments that continue to show that they can operate safely during the time it will take for the process to be completed. As discussed in more detail below, the initial application will be due no later than November 30, 2020, and EPA will make a decision on whether the facility qualifies to submit a demonstration no later than April 11, 2021. Consequently, all facilities that submit an application must still be prepared to cease receipt of waste and to begin closure in the event that the application is ultimately rejected.

Finally, CCR surface impoundments that are able to progress to the demonstration step will have shown that the design of the groundwater monitoring network is sufficient to identify releases from the unit and that there is currently no evidence that releases have occurred or are likely to occur while they are completing the demonstration.

CCR surface impoundments are continuously full of water. The resulting hydraulic head on the liner can be considerably greater than found in landfills, which results in a greater and sustained potential for infiltration into the subsurface. The expectation is that releases from the unit to the subsurface would be limited primarily by the low hydraulic conductivity of the engineered liner and/or naturally occurring soil. Many of the surface impoundments at facilities that commented on the proposed rule have been in operation for over a decade and some for almost 70 years. If GWPS have not been exceeded throughout years of operation, this indicates that some combination of low conductivity soil, the thickness of the soil column above the aquifer, or a geomembrane liner component is effectively limiting or entirely preventing the release and transport of leachate. And for units such as these, with an adequate monitoring network, the fact that they have not triggered assessment monitoring means there is no evidence of any release to groundwater. In addition, these units will continue routine groundwater monitoring while preparing the demonstration to ensure that they continue to perform as anticipated over the year-long demonstration step. CCR units that trigger either assessment monitoring or corrective action at any point during the process would be rendered ineligible to proceed. Thus, any impoundment able to submit a successful ALD would not have had any discernable impact to groundwater quality.

Moreover, it is highly unlikely that a unit with no prior indication of impacts to groundwater will contaminate groundwater above the GWPS within the relatively short timeframe permitted to complete the demonstration. Groundwater transport is a gradual process as the leachate migrates to and mixes with the groundwater. It is not realistic to expect a sudden exceedance of the GWPS after years of no detections from groundwater monitoring. Rather, one would expect to first see the more mobile constituents in Appendix III, such as total dissolved solids, before detecting any of the constituents of concern in Appendix IV. If a unit is leaking but has failed to identify the exceedance due to a deficiency with either the design or implementation of the groundwater monitoring program, that will be identified during the application review. Thus, there is no evidence that these units will present a risk of contaminating groundwater above GWPS or a risk to downgradient human or ecological receptors. Nonetheless, these units will continue routine groundwater monitoring while preparing the demonstration to ensure that the units continue to perform as anticipated.

4. Potential for Future Harm

Some environmental groups contended that it does not matter whether an unlined unit can be shown to have no current groundwater contamination because the existing risk record shows that it can happen in the future. These commenters pointed specifically to the Agency's previous finding that a certain portion of unlined and clay-lined units are anticipated to eventually contaminate groundwater. Commenters further stated that allowing these units to continue operation is contrary to the *USWAG* decision because the risk record does not show whether any future release could be promptly detected and, once detected, promptly remedied before it can result in harm to human health or the environment. Commenters also pointed out that the risk is further compounded by the potential size of the plume from unlined units.

EPA disagrees with the proposition that allowing CCR surface impoundments that meet the requirements for an ALD to continue operation is in violation of the *USWAG* decision. The D.C. Circuit found that it was contrary to RCRA § 4004(a) to allow unlined and clay-lined units to continue

operating because the rulemaking record failed to address a number of the risks associated with these units. For example, the record did not demonstrate that a leak from these units could be reliably contained and addressed before it resulted in harm to human health and the environment. 901 F.3d at 432. The D.C. Circuit specifically pointed to several factors that EPA had failed to address that might prolong the time required to address leaks, including the rate and extent of contaminant release, the well sampling schedule, and the time allowed to implement source control. Id at 42,432. However, the conditions established as part of this rule ensure that these issues will be sufficiently addressed for the subset of CCR surface impoundments able to obtain and operate under an ALD.

First, units with an ALD that enter into assessment monitoring are required to conduct additional analyses to identify the presence and magnitude of any trends of increasing groundwater concentrations in downgradient wells. If these analyses show the potential exists for releases from the impoundment to result in an exceedance of GWPS within the timeframe needed to reliably close the unit, the facility must retrofit or close. This provision is intended to prevent adverse effects to groundwater and, if necessary, to expedite remedial efforts. Use of trend analysis is appropriate to monitor for evidence of increasing groundwater concentrations because the release and transport of inorganic elements through the subsurface is a gradual and steady process. The presence of low conductivity soil beneath a unit would only further limit the speed at which contamination can spread. For example, based on the range of anticipated hydraulic gradients and other relevant soil properties, groundwater moving through soil with a hydraulic conductivity of 1×10^{-7} cm/s would be expected to progress less than a foot a year.[9] In this context, there is little concern that the time between semi-annual monitoring events would substantially delay identification of potential contamination.[10]

Even if corrective action were triggered before closure could be completed, this in no way prevents the concurrent implementation of corrective measures beyond the waste boundary to contain the plume and prevent downgradient exposures. EPA has previously documented how pump and treat can be systematically applied to control plume migration, even when the contaminant source has not yet been addressed.[11] Furthermore, facilities that are able to submit a successful demonstration will be among the most well-characterized units in the country, which would further limit the timeframe needed to contain the plume and the potential for unforeseen setbacks that could result in an inadequate understanding of local hydrogeology.

Ultimately, EPA believes that a judgement on whether a plume can be addressed promptly should be based on the potential for immediate and future harm. This is consistent with the established criteria in § 257.97(d) that require the development of a reasonable schedule to implement remedial actions to be based on a number of factors, such as the immediacy of risk to nearby receptors and the risk of contaminant spread to other environmental media. Altogether, these factors will help ensure that any contamination identified at the waste boundary can be addressed before it results in risk to downgradient receptors, regardless of the original extent of the release.

EPA is also confident that contamination at these sites can be successfully remediated. The inorganic constituents on Appendix IV are not novel. Issues of impracticability at corrective action sites are often associated with the ability to access contaminants in the subsurface. The primary causes have been the hydrophobic behavior of organic compounds, which is not relevant in this context, and the presence of complex site hydrogeology.[12] The CCR location restrictions at § 257.64 prohibit disposal in karst and other unstable areas that might confound remedial efforts. Other highly complex geology, such as fractured bedrock, is notoriously resistant to modeling and unlikely to allow for a successful demonstration. Although corrective action at the remaining sites may be technically complex, it remains feasible. Therefore, there is little concern that corrective action, if required, would not eventually achieve established cleanup goals. For all these reasons, the Agency is not making any amendments to the proposal as a result of these comments.

B. Application

In the March 2020 proposed rule, EPA proposed to establish a two-step process: Requiring an initial application followed by the submission of the alternate liner demonstration. The application step is designed to ensure that a surface impoundment meets minimum requirements before embarking on a comprehensive alternate liner demonstration.

The Agency proposed that in order to apply for an ALD, an owner operator must first submit a letter to EPA declaring their intention to submit a demonstration under the provision. EPA also proposed that along with the letter, a facility must provide documentation showing (1) that a facility is in compliance with all applicable requirements in 40 CFR part 257 subpart D, including all location restrictions, and (2) that there has not been an exceedance of any Appendix IV constituents. EPA further proposed that, as part of this demonstration, a facility must submit documentation to show that the existing network of monitoring wells is sufficient to identify any releases based on direction of flow, well location, screening depth, and other relevant factors. EPA proposed that this could include well construction logs and a sufficient number of diagrams to depict depth to groundwater, the potentiometric surface, and the anticipated directions of groundwater flow across the site. Finally, EPA proposed to require the facility to show there is no indication from groundwater monitoring data that the unit has or will adversely affect groundwater, in part by providing documentation of the most recent statistical tests conducted and the rationale for the methods used in these comparisons. Upon submission of the application, a copy of the written demonstration and all associated documentation must be simultaneously posted to the facility's publicly accessible CCR internet site.

No commenter raised concern about EPA's proposal to require the submission of a letter or the specific requirements applicable to the letter or the two categories of accompanying information required to be submitted. However, some commenters broadly requested that EPA provide greater clarity on the types of information that must be submitted for the application to be considered complete, while other commenters asked for greater clarity on

[9] The maximum hydraulic gradient considered in the 2014 Risk Assessment was 1.0 ft/ft.

[10] Additionally, it is notable that the semi-annual timing between sampling events is designed to ensure a degree of statistical independence in assembled monitoring data. Too-frequent sampling at a given background well can result in highly autocorrelated, non-independent data that can reduce the accuracy of statistical tests.

[11] U.S. EPA. 2008. ''A Systematic Approach for Evaluation of Capture Zones at Pump and Treat Systems.'' EPA 600/R–08/003. Prepared by the Office of Research and Development. Cincinnati, OH. January.

[12] U.S. EPA. 2012. ''Summary of Technical Impracticability Waivers at National Priorities List Sites.'' OSWER Directive 9230.2–24. Prepared by the Office of Solid Waste and Emergency Response. Washington, DC. August.

the specific elements necessary to satisfy the requirements of the rule.

EPA is finalizing much of § 257.71(d)(1) as proposed—retaining the requirement to submit a letter and accompanying information to demonstrate that certain minimum criteria have been met. The final rule also retains the requirements to submit documentation showing that a facility is in compliance with all applicable requirements in 40 CFR part 257 subpart D, including all location restrictions. However, the final rule includes a modified provision requiring facilities to demonstrate that there has not been a statistically significant increase over background levels of any Appendix III constituents throughout the application and demonstration process. EPA has also made several modifications in response to comments requesting greater clarity. Other changes were made to conform the procedures in this rulemaking with the procedures recently adopted in § 257.103. These topics are discussed in further detail in the next Units of this preamble.

1. Application Letter

EPA proposed that the owner or operator must first submit a letter to EPA declaring their intention to submit an alternate liner demonstration. EPA received no comments that raised questions or concerns about the substantive information to be included in the letter. Consequently, the final rule adopts these requirements without substantial revision. The final rule requires the owner or operator of the CCR surface impoundment to submit a letter to EPA or the Participating State Director. This letter will announce the owner or operator's intention to submit an alternate liner demonstration. The application must include the location of the facility and identify the specific CCR surface impoundment for which the demonstration will be made. The application letter must also include the information in § 257.71(d)(1)(i)(A) through (D), as specified in the regulatory text, and further described below.

2. Compliance With the CCR Regulations and Required Documentation

Along with the letter, EPA proposed at § 257.71(d)(1)(i)(A) that the owner or operator must submit information to EPA documenting that the facility is in compliance with the applicable requirements in 40 CFR part 257, subpart D.

EPA continues to believe that requiring facilities to document compliance with the subpart D of part 257 requirements is an important part of the demonstration. Compliance with the rule provides critical support for the determination that these units will not present the types of risks identified in the damage cases considered in the 2015 CCR Rule. For example, some of the damage cases resulted from disposal in high-risk areas (e.g., within the groundwater table). These issues will be addressed through documenting that the surface impoundments meet the requirements of the 2015 CCR Rule (*e.g.,* location restrictions). Similarly, documenting compliance with the groundwater monitoring requirements shows that the design of the groundwater monitoring network is sufficient to identify groundwater contamination in the uppermost aquifer. This, together with the fact that the unit remains in detection monitoring, demonstrates that there is currently no evidence the risks modeled in the 2014 Risk Assessment are present or will result from continued operation of the impoundment in the near term.

Overall, compliance with part 257, subpart D generally provides some guarantee that the risks at the facility are properly managed and adequately mitigated. Consequently, this determination provides critical support for a decision to allow continued operation of the alternately lined surface impoundment. This means that EPA must be able to affirmatively conclude that the facility meets this criterion prior to authorizing any continued operation of the surface impoundment. It also means that EPA cannot grant facilities additional time to cure any noncompliance. However, EPA's determination will be prospective only; accordingly, for purposes of the ALD process, EPA is only interested in the state of a facility's current compliance rather than any instances of historic non-compliance.

In response to commenters who requested that EPA provide greater specificity about what constitutes a complete submission, EPA has amended the regulatory text to identify specific documents that the owner or operator of a CCR unit must provide to demonstrate its current compliance with the requirements of part 257, subpart D. Most of these documents are the same documents that EPA is requiring facilities to provide under the recent amendments to § 257.103. Further, these documents should already exist either because they would have had to be compiled when the unit was first constructed, or they were required to be developed under the existing regulations.

Consistent with the recent amendments to § 257.103 (85 FR 53516, August 28, 2020), EPA has decided that a certification of compliance and the requirement to remain in compliance with the regulations are also necessary in this final rule. The compliance certification is represented at § 257.71(d)(1)(i)(A) to require a certification signed by the owner or operator of the CCR unit saying it is in full compliance with part 257, subpart D, except for the requirement to document that the unit is constructed with either a composite liner or alternative composite liner under § 257.71(a)(1). This approach will prevent non-compliant unlined surface impoundments from operating for an extended period of time into the future. Requiring that only compliant surface impoundments can be approved for an ALD provides additional support for EPA's conclusion that this final rule meets the statutory standard.

3. Groundwater Monitoring Network Documentation

EPA proposed at § 257.71(d)(1)(i)(B) that the facility must show in the initial application that the existing network of monitoring wells is sufficient to identify any releases based on direction of flow, well location, screening depth and other relevant factors, including well construction logs and a sufficient number of diagrams to depict depth to groundwater, the potentiometric surface, and the anticipated direction(s) of groundwater flow across the site (multiple diagrams may be necessary if the direction of flow is affected by seasonal, tidal or other influences). EPA also proposed that these diagrams should include all the water table measurements reported from a standard datum, a map scale, and a legend of any important map symbols. EPA proposed that facilities that have improperly placed groundwater monitoring wells would not be eligible to apply or submit an alternate liner demonstration.

Many commenters requested greater specificity on the types of information required for this part of the application. Some questioned whether facilities will be required to gather additional groundwater and other site-specific data in support of the application, or whether facilities only needed to submit previously collected groundwater monitoring data and analyses conducted for their sites. One commenter asked whether the application required specific information, such as representative geologic cross sections, groundwater contour maps of the facility, or other hydrogeologic data. Another requested inclusion of a

requirement that facilities include the depth of water ponded in the impoundment to ensure that wells intended to reflect background conditions are not impacted by groundwater mounding. Some commenters pointed out that some of the elements required in the application are standard components of the annual groundwater monitoring and corrective action reports already required by § 257.90(e). Examples include groundwater flow maps and statistical test results. These commenters requested that the monitoring reports and other existing documentation be allowed to substitute for some or all of the application through citation, weblink, or other reference. Although some commenters acknowledged that the information requested would facilitate review of the application, others protested the additional burden of repackaging information.

The intent of this provision is to allow for a comprehensive review of the existing well network to determine whether it is sufficient to identify releases from the unit that have occurred or might occur in the future. EPA did not intend to require the collection of any further groundwater data or other site-specific data for the purposes of the application. Facilities have already designed and implemented their site groundwater monitoring programs, and EPA expects the facility would normally have generated the information specified in § 257.71(d)(1)(i)(B)(*1*) of this final rule, either as part of developing or implementing the groundwater monitoring program. However, facilities are encouraged to provide additional detailed interpretation of the data and analyses for consideration during the review.

EPA proposed that the application include documentation of relevant factors considered by the owner or operator when determining the appropriate number and placement of monitoring wells. As highlighted by some commenters, this should include characterization of the local hydrogeology, including the factors detailed in § 257.91(b), and the potential for groundwater mounding beneath the unit to affect characterization of background. However, the appropriate types of data and level of detail will depend largely on the complexity of the site. As a consequence, EPA is not requiring every facility to incorporate discussion of the depth of impounded water as part of the justification for well placement. Any potential for groundwater mounding should have been accounted for when the wells were first installed and so should be reflected in the documentation already required. If mounding is found to be present, then this information must be reflected in any maps of groundwater elevation and flow direction. However, it is considered highly unlikely that a facility with appropriately located wells and releases substantial enough to result in groundwater mounding would remain in detection monitoring and be eligible for an ALD.

Because this record already exists, the facility would only be required to provide all the data and analyses that were relied upon to comply with the relevant standards of the CCR regulations. However, documenting that the existing well network meets the standard in this rule will require a level of detail and discussion beyond what is required in a routine groundwater monitoring report. And, although such reports contain a subset of the required information, it is likely to be divided up among a number of different documents. This will complicate and extend the review process because the key data and figures will not be presented alongside the relevant discussion to provide proper context. Thus, applications that incorporate the required information solely through reference will be considered incomplete.

Because this information is already available, preparation of the application should not require much additional work beyond compiling information in a concise and coherent fashion. EPA discourages facilities from sending hundreds or thousands of pages of laboratory printouts and other raw data; instead, EPA expects the data to be presented in a tabular or other format that has gone through a quality control process to present the data in a concise format. The types of data and analyses considered by facilities beyond what is required to be presented as part of monitoring reports may appropriately vary on a case-by-case basis.

Therefore, EPA is finalizing the provisions at § 257.71(d)(1)(i)(B)(*1*) with amendments to specify the documents that the facility must provide to demonstrate how it has complied with each requirement in § 257.91. The regulatory text can provide an effective checklist for facilities to follow. In order to review a facility's current compliance with the requirements governing groundwater monitoring systems, the Agency will need the following updated list of information: (1) Map(s) of groundwater monitoring well locations (these maps should identify the CCR units as well) that depict the elevation of the potentiometric surface and the direction(s) of groundwater flow across the site; (2) well construction diagrams and drilling logs for all groundwater monitoring wells; (3) maps that characterize the direction of groundwater flow accounting for temporal variations; and (4) any other data and analysis the facility relied upon when determining the number and placement of wells around the unit compiled in a concise and readable format.

4. No Adverse Effects on Groundwater Documentation

EPA proposed at § 257.71(d)(1)(i)(C) that facilities must demonstrate that there is no indication from groundwater monitoring data that the unit has or will adversely affect groundwater (*i.e.,* no statistically significant levels (SSL) of Appendix IV constituents above relevant GWPS), including documentation of the most recent statistical tests conducted and the rationale for the methods used in these comparisons. Facilities that have conducted improper statistical analysis of groundwater monitoring results would not be eligible to apply or submit a demonstration.

The Agency received comments about the proposed language that a facility must demonstrate ''there is no indication from the groundwater monitoring data that the unit has or will adversely affect groundwater . . .'' Commenters expressed concern that this standard was more stringent than required by the subsequent demonstration step and may necessitate collection of an unspecified amount of additional data, such as sampling for Appendix IV constituents at units that had not progressed beyond detection monitoring, which they worried would not be possible to obtain prior to the application deadline.

As discussed previously, EPA did not intend for facilities to conduct additional rounds of sampling for the application beyond that required for ongoing compliance with the CCR regulations. The referenced preamble language was intended to convey that the monitoring data collected to date must show that there is currently no evidence that the unit has contaminated groundwater, as well as no evidence that it might do so in the future. The language in question was based on the assumption that units presently in assessment monitoring could submit an application. However, EPA has reconsidered that position in light of comments received. The final rule instead requires that all units must stay in detection monitoring to remain eligible for an ALD. The fact that a unit remains in detection monitoring

provides better evidence to demonstrate that the standard in the proposed rule has been met (*i.e.,* that the unit is not currently causing adverse effects), and that such effects are not expected to occur in the near term. EPA acknowledges, as demonstrated for composite-lined units in the 2014 Risk Assessment, that releases can occur from even the most well-designed units and that these impoundments can remain protective. However, greater assurance that the impoundment can continue to operate safely throughout the approval process is necessary at this stage, prior to the demonstration that the ultimate performance standard in this rule has been met.

To reflect these changes, EPA is adopting a provision at § 257.71(d)(1)(i)(B)(*2*) to specify that facilities must demonstrate that the unit remains in detection monitoring as a precondition for submitting an application. Consistent with the proposal, as part of demonstrating that the facility remains in detection monitoring, the owner operator must document the most recent statistical tests conducted and the rationale for the methods used in these comparisons.

Many industry and some state commenters requested greater specificity on the types of information required for this part of the application. One commenter requested clarification on the relationship between these requirements and those found in § 257.93 and § 257.94. Another commenter asked whether a qualified professional engineer's certifications that the groundwater monitoring program meets the requirements of the 2015 CCR Rule would provide sufficient documentation.

The intent of this provision is to allow for a comprehensive review of the facility's determination that a unit has not adversely affected groundwater. Certification from a qualified professional engineer alone would not provide the necessary documentation. EPA proposed that facilities include documentation of the most recent statistical test and rationale for the methods selected. Whether the results of the statistical tests are valid depends on all the data and analyses that underpin it. The documentation must demonstrate that the characterization of groundwater quality is sufficient; the management of collected monitoring data has been properly considered and addressed non-detect data, trends, and other relevant factors that may affect data quality; and that the statistical tests applied are appropriate. The specific standards that the application must address are detailed in § 257.93 through § 257.94.

Therefore, EPA is finalizing § 257.71(d)(1)(i)(B)(*2*) with amendments to specify that the facility must document how it has complied with each requirement in §§ 257.93 through 257.94. The regulatory text in these sections can provide an effective checklist for facilities to follow. To support that demonstration, the final rule requires facilities to provide the following: (1) Documentation of the most recent statistical test; and (2) the rationale for the methods used in these comparisons. As part of this rationale, the facility must provide all data and analyses relied upon to comply with each requirement.

5. Location Restrictions

EPA proposed at § 257.71(d)(1)(i)(D) that a unit must be in compliance with all relevant location restrictions at §§ 257.60 through 257.64 in order to be eligible for an ALD.

Many industry commenters requested greater specificity on the types of information required for this part of the application. Specifically, commenters inquired whether facilities were expected to submit the entire package of location restriction demonstrations, or if they can simply certify that the CCR surface impoundment meets all location restrictions. The documents that demonstrate a unit meets a location restriction should already exist because they are required under the existing regulations. Location restrictions were established to ensure that units are constructed in suitable geographic areas. Prohibited locations reflect areas where local conditions have the potential to compromise the integrity of the unit or where, if contamination were to occur, the damages could be particularly severe or difficult to remediate. EPA still believes this is critical to the record supporting continued operation of the unit. Consequently, facilities must submit the entire package of location restriction demonstrations.

Therefore, EPA maintains that documentation that the facility is in compliance with all location restrictions must be submitted to EPA or the Participating State Director as a requirement of the initial application and is finalizing § 257.71(d)(1)(i)(B)(*3*).

6. Structural Stability and Safety Factor Assessment Submission

In order to align with the recent amendments to § 257.103 (85 FR 53516, August 28, 2020)(''Part A final rule''), this final rule specifies that a facility must submit the facility's most recent structural stability assessment required at § 257.73(d) and safety factor assessment required at § 257.73(e) at § 257.71(d)(1)(i)(B)(*4*) and (*5*). EPA's intention to review these items was discussed in the proposed rule as part of the discussion when discussing that a unit must be in full compliance with the 2015 CCR Rule. EPA received no comments raising concern about inclusion of this requirement. The inclusion of this requirement also responds to requests that EPA provide greater specificity on the documents that must be submitted as part of the application.

The Agency recognizes that the requirement to conduct periodic structural stability assessments and safety factor assessments is not applicable to all CCR surface impoundments. As specified in § 257.73(b), only those impoundments with a height of five feet or more and a storage volume of 20 acre-feet or more, or those impoundments with a height of 20 feet or more are subject to these assessment requirements. An owner or operator submitting an ALD application for a unit not meeting these thresholds must include an affirmative statement in the certification signed by the owner or operator under § 257.71(d)(1)(i)(A) indicating that the impoundment is not subject to the structural stability and safety factor assessment requirements under § 257.73(d) and (e). Similarly, EPA is aware that not all impoundment dikes were constructed with soils that are susceptible to liquefaction, and thus are not subject periodic safety factor assessments showing that the calculated liquefaction factor of safety equals or exceeds 1.20. See § 257.73(e)(1)(iv). For impoundments not constructed with soils subject to liquefaction and subject to the safety factor assessment requirements, the owner or operator must include an affirmative statement in the certification required under § 257.71(d)(1)(i)(A) stating that the unit is not subject to the liquefaction factor of safety because it has been determined that the dike(s) was not constructed with soils subject to liquefaction.

7. Documentation of Source Material and Construction Quality

EPA noted in the proposal that geomembrane liners are not as sensitive to the chemical composition of coal ash leachate as soil-based liners and so performance may depend more on the frequency and magnitude of imperfections that arise during installation. In these instances, laboratory infiltration tests on pristine samples are unlikely to provide representative data on field performance. EPA discussed

construction quality reports as a type of documentation that could support characterization of geomembrane liner performance in the field. However, EPA did not require the submission of any particular documents as part of the application.

Multiple commenters indicated that historical data on the construction of impoundments is important to understand whether a unit can perform as intended. Commenters identified several specific factors they believed should be part of the submission, such as the initial saturation, compactive effort, plasticity index, subgrade water content, and clay content of the liner. One commenter also warned that specifications on a manufacturer's product sheet alone may not provide adequate assurance of good performance in the field.

EPA agrees that considerations of construction quality are equally relevant to all types of liners. Indeed, the ability of any liner to achieve performance objectives is predicated on the quality of both the source materials and the construction of the surface impoundment. Therefore, EPA concludes that information on both must be incorporated in the application to provide evidence that the unit has the soil characteristics or engineering quality that would make it possible for the unit to meet the ultimate performance standard is expected to remain protective in the near term while the comprehensive demonstration is completed. The relevant types of information will depend on the design of the surface impoundment. Consequently, EPA is not specifying particular documents or data that must be submitted for every impoundment.

Source quality testing ensures that the materials used to construct the liner conform with project specifications and are able to meet the necessary standards. However, EPA has found negligible correlation between field hydraulic conductivity and many of the common soil characterization parameters identified by the commenter, such as plasticity index and clay content.[13] As a result, EPA previously concluded that it is difficult to determine whether a particular soil is suitable for use as a liner based solely on individual index properties and without relevant confirmatory testing. For engineered soils, this will involve establishing the relationship between water content, density, and hydraulic conductivity in a laboratory setting before construction begins to ensure the liner will be installed under optimum conditions. For naturally-occurring soils, this will involve testing that the pre-existing soil structure achieves a sufficiently and consistently low hydraulic conductivity. For geomembrane liners, this involves confirming that the material can withstand the stresses it will be exposed to and that the seams of the liner can be reliably welded to meet performance requirements. Altogether, this information provides evidence that these materials can meet relevant performance objectives during operation.

Construction quality testing ensures that surface impoundment construction has been performed in accordance with all relevant technical specifications before any waste is accepted. EPA stated in the proposal that collection of in-situ data from an operating surface impoundment will generally be impracticable because of the potential to disrupt the integrity of the liner, and some facilities agreed in their comments. However, laboratory testing cannot account for operational problems during construction that result in substandard conditions, such as desiccation, cracking, poor bonding, and inconsistent compaction of the liner. There are no standardized laboratory tests designed to simulate a liner that has been poorly designed or constructed. Therefore, without contemporaneous documentation that the surface impoundment liner was well constructed, it will be too difficult to confirm that any data subsequently collected for the demonstration reliably represents actual liner conditions. In particular, for soil liners that do not meet the thickness requirement of the rule, field testing is likely the only reliable way to ensure that construction has achieved a sufficiently low and consistent hydraulic conductivity. Considerable guidance exists on factors that must be addressed to ensure the quality of a liner, such as: the proper thickness, compaction, moisture content, and density of compacted soil; the in-situ hydraulic conductivity of compacted soil; protection of soil from desiccation and freezing; placement of the geomembrane liner without excessive waves, with a goal of ensuring intimate contact between the liner and the underlying soil; and protection of geomembranes from puncture by adjacent materials or equipment. Altogether, this information provides evidence that the liner is well constructed and can be reasonably simulated in a laboratory setting.

EPA is finalizing a new requirement at § 257.71(d)(1)(i)(C) that facilities are required to provide documentation of the design specifications for any engineered liner components (*e.g.,* manufactured geomembrane, mechanically compacted soil), as well as all data and analyses the facility relied on when determining that the materials are suitable for use and that the construction of the liner is of good quality and in line with proven and accepted engineering practices.

8. Additional Release Pathways

In the proposal, EPA stated that in some instances direct infiltration to groundwater may not be the sole mechanism by which unpermitted release of leachate from a surface impoundment occurs. It is possible that additional, site-specific release pathways may exist for some impoundments. For example, there may be lateral transport from the surface impoundment directly into the water body driven in part by the hydrostatic head within the surface impoundment. EPA listed proximity to a water body, construction above grade, lack of a geomembrane liner, and the presence of low conductivity soil beneath the unit as factors that could contribute to such releases. EPA stated that, if such conditions are present at a site, then the demonstration would need to address whether such releases may occur and the potential adverse effects on health or the environment associated with these pathways. The same types of data collected to evaluate releases to groundwater should also support evaluation of such pathways.

EPA received no adverse comments on this topic. One commenter affirmed that such pathways are possible and are a concern. No commenters identified other relevant subsurface release pathways beyond the one contemplated in the proposal.

Upon further consideration, EPA now believes that this type of release is already adequately addressed by the requirements of § 257.96(a). Because this issue involves compliance with an aspect of the 2015 CCR Rule, EPA believes it is most appropriately addressed as part of the application step. As clarified in the Phase One Rule, this provision requires a facility to commence corrective action ''immediately upon detection of a release from a CCR unit'' for any non-groundwater releases. 83 FR 11584 (March 15, 2018). Thus, the existence of subsurface releases directly to surface water would trigger immediate corrective action. Further, unlike groundwater, there is no standardized

[13] U.S. EPA. 2002. ''Assessment and Recommendations for Improving the Performance of Waste Containment Systems.'' EPA/600/R–02/099. Prepared by the Office of Research and Development. December.

method to monitor the progression or effects of this type of release to confirm that the unit remains protective. Therefore, if the design of a surface impoundment cannot be shown to reliably prevent such releases, it would be ineligible for an ALD.

Therefore, EPA is finalizing a requirement at § 257.71(d)(1)(i)(D) that facilities with surface impoundments located on properties adjacent to a water body must demonstrate that there is no reasonable probability that a complete and direct transport pathway (*i.e.,* not mediated by groundwater) could exist between the impoundment and any nearby water body. If the potential for such releases is identified, then the unit would not be eligible to submit a demonstration. If ongoing releases are identified, the owner or operator of the CCR unit must address these releases in accordance with § 257.96(a).

C. Alternate Liner Demonstration

EPA proposed that the ALD must present evidence to demonstrate, with a reasonable degree of certainty, that based on the construction of the unit and surrounding site conditions, operation of the surface impoundment will not result in groundwater concentrations above relevant GWPS at the waste boundary.

EPA proposed at § 257.71(d)(1)(ii) that the liner demonstrations must be certified by a professional engineer. Some commenters requested that the qualifications necessary to certify the ALD be broadened beyond professional engineers to include geologists and hydrogeologists. The commenter noted that licensed professional geologists or hydrogeologists are trained and experienced in investigation and analysis of groundwater and subsurface contaminant flow and chemistry. EPA previously considered this exact request and rationale as part of the 2015 CCR Rule. The Agency concluded there that, while some environmental professionals (*e.g.,* hydrologists, geologists) may be qualified to make certain certifications, EPA was not convinced that either hydrologists or geologists licensed by a state are held to the same standards as a professional engineer. 80 FR 21337 (April 17, 2015). One commenter requested that EPA use the term ''qualified professional engineer'' rather than ''professional engineer,'' as this is the term that was used in the 2015 CCR Rule. EPA agrees with this suggestion and will be finalizing the rule requiring that certification must be provided by a ''qualified professional engineer''.

The qualified professional engineer must certify that the demonstration package presents evidence to demonstrate that there is no reasonable probability that peak groundwater concentrations that may result from releases throughout the active life of the surface impoundment will exceed GWPS at the waste boundary based on the construction of the unit and surrounding site conditions.

EPA proposed two lines of evidence for which site-specific data must be collected and incorporated into the demonstration. These are the characterization of site hydrogeology and the potential for infiltration. EPA identified these lines of evidence because the hydraulic conductivity of the engineered liner and/or naturally occurring soil is expected to be the primary mechanism that will limit release and transport of contaminants from the unit. These data will be used to model the potential for the release of contaminants and their transport through the environment. For each line of evidence, as well as any other data and assumptions incorporated into the determination, EPA proposed that the facility must include documentation on how the data were collected and why these data and assumptions are believed to adequately reflect potential contaminant transport at and around that specific surface impoundment.

1. Line of Evidence #1—Characterization of Site Hydrogeology

The first line of evidence that EPA proposed at § 257.71(d)(1)(ii)(A) requires characterization of the variability of the site-specific soil and hydrogeology that surrounds the CCR surface impoundment. Some surface impoundments are located on soils that are expected to have extremely low hydraulic conductivity. However, there are concerns that heterogeneity within these soils may result in preferential flow pathways that effectively negate the low conductivity of the remaining soil. For example, many electric utilities are located in close proximity to bodies of water. The flow path of these water bodies is likely to have shifted over geologic time, which could result in complex depositional environments with interconnected lenses of sand. Therefore, the purpose of this first line of evidence is twofold: to define the broader connectivity of higher conductivity soils that might act as preferential flow pathways and to characterize the variability of the soil to guide collection of samples for the second line of evidence.

EPA proposed that characterization of site hydrogeology must include all of the following: (1) Measurements of the hydraulic conductivity in the uppermost aquifer from existing monitoring wells and discussion of the methods used to obtain these measurements; (2) Subsurface samples collected to characterize site hydrogeology must be located around the perimeter of the surface impoundment at a spatial resolution sufficient to ensure that any regions of substantially higher conductivity have been identified; (3) Conceptual site models with cross-sectional depictions of site stratigraphy that include the relative location of the surface impoundment (with depth of ponded water noted), monitoring wells (with screening depths noted), and all other subsurface samples used in the development of the models; (4) Narrative description of site geological history; and (5) All data used in the conceptual site model summarized into easily readable graphs or tables. EPA did not receive any comments relevant to § 257.71(d)(1)(ii)(A)(*4*). Therefore, EPA is finalizing this requirement as proposed with updated numbering to reflect changes in the other regulatory text paragraphs. Discussion of comments on other provisions are provided in the following Units.

a. Measurements from Existing Wells

EPA proposed at § 257.71(d)(1)(ii)(A)(*1*) that the demonstration must include measurements of the hydraulic conductivity in the uppermost aquifer measured from existing monitoring wells and discussion of the methods used to obtain these measurements.

One commenter stated that EPA should consider modifying or removing the requirement that uppermost aquifer hydraulic conductivity measurements must be measured from existing monitoring wells. They argued that there may be additional data points and locations that may be more representative than conductivity measurements taken from the existing well locations. The commenter requested that locations for these measurements be determined by the technical team preparing the demonstration and should not be limited to these prescriptive locations.

The waste boundary is the point of compliance for all GWPS. These standards apply to all units subject to the existing regulations, including those submitting an ALD. Thus, the hydrogeologic conditions in the vicinity of the wells used to determine compliance are highly relevant. However, § 257.71(d)(1)(ii)(A)(*1*) only establishes a minimum standard for the demonstration. Facilities can collect and incorporate additional data beyond this minimum in the demonstration, as

warranted to further delineate hydrogeologic conditions. Therefore, EPA made no amendment to the rule language in response to this comment.

b. Sampling at the Perimeter of a Surface Impoundment

EPA proposed to require that subsurface samples must be collected to characterize site hydrogeology and must be located around the perimeter of the surface impoundment at a spatial resolution sufficient to ensure that any regions of substantially higher conductivity have been identified. In the proposal, EPA acknowledged that some data may already be available from previous investigations, such as sampling or logging done during the installation of monitoring wells or other subsurface evaluations. However, the Agency considered it likely that additional data would be necessary to provide adequate coverage of the subsurface.

Environmental groups raised concerns that it would not be feasible for an owner or operator to collect enough site-specific data to allow for a determination that an existing alternate liner is protective. One commenter stated that site characterization at the necessary spatial resolution would require multiple rounds of sampling, might necessitate installation of additional monitoring wells, and would require far longer than allowed by this rule. Another went further and stated that no characterization of a site's hydrogeology and potential for infiltration will be able to prove that a nonconductive layer is continuous under the entire ash pond.

EPA agrees that it is critical to adequately characterize potential transport beneath the unit but disagrees that it is not possible to collect sufficient data to characterize subsurface transport. For the subset of impoundments that rely on natural soils to limit contaminant transport, it is improbable that any high-conductivity soils present on-site are limited entirely to within the footprint of a unit. The long-term movement of both water bodies and glaciers tend to leave deposits all along the migration path. This is supported by observations across a wide range of depositional environments that layers of sand and clay are typically found in a ''shingled'' or ''laterally offset'' fashion, rather than as a ''layer cake'' with one stacked neatly on top of the other.[14] Thus, collection of samples from around the perimeter is expected to provide reliable information about both the variability of conditions underneath the impoundment and the potential for transport away from the impoundment. Even if isolated lenses of sand or other high-conductivity material were located entirely beneath the impoundment, these disconnected deposits would not negate the low conductivity of the surrounding clay because of a lack of connectivity. Finally, the surficial geophysical methods referenced by one of the same commenters can provide information on soils some distance away from the point of measurement. Depending on the specific geometry of a unit and the methods used, the data collected around the perimeter of the unit can also provide substantial coverage of the soils beneath the unit. Based on these facts, EPA concludes that data collected from around the waste boundary can also provide reasonable estimates of the variability beneath the unit for the purposes of an alternate liner demonstration.

Although fieldwork may take some time, it will not begin from scratch. Facilities allowed to progress to the demonstration step will have already confirmed that there is adequate subsurface characterization available to appropriately site the existing groundwater wells. These data will inform subsequent sampling efforts. In the proposal, EPA contemplated the potential for this line of evidence to also identify the need for additional wells to address previously unidentified regions of high conductivity soil. However, the finalized application step requires documentation that the existing network is sufficient to ensure detection of contamination in the uppermost aquifer. Therefore, this line of evidence will not involve the time-consuming process of installing and sampling new monitoring wells. The standardized geophysical survey methods discussed both in the proposal and raised by commenters can be conducted within the required timeframe, even if more than one round of data collection is ultimately required.

Therefore, EPA is finalizing the requirement at § 257.71(d)(1)(ii)(A)(*2*) without change from the proposal. The final rule requires that measurements of the variability of subsurface soil characteristics must be collected from around the perimeter of the impoundment to identify any regions of substantially higher hydraulic conductivity.

c. Sampling Methods

In the proposal, EPA discussed that traditional geologic mapping, that relies primarily on the Unified Soil Classification System, has been found to underestimate the prevalence and interconnectedness of soil deposits that may act as preferential flow pathways. EPA cited to a practical guide on the use of environmental sequence stratigraphy and facies models to aid in characterization of subsurface heterogeneity.[15] EPA noted that there are a number of methods available that can provide useful data at the necessary spatial resolution, such as direct-push logging (*e.g.,* cone penetration test) and borehole geophysical logging. However, EPA did not propose the use any specific methods, nor did the Agency place explicit restrictions on the types of methods available.

Several industry commenters and one environmental group expressed concern that the proposal unnecessarily required invasive sampling methods to collect the necessary data on conditions below the ground surface. Multiple commenters identified specific methods, such as electrical-resistivity tests, as alternate methods that could provide relevant information. One commenter further pointed to the Interstate Technology and Regulatory Council website on advanced site characterization tools.[16]

EPA acknowledges that the language used in the proposal could be taken to imply that invasive sampling is the only type of method allowed for this line of evidence, but EPA did not intend to restrict the methods available for use in this way. EPA agrees that surficial (or non-invasive) sampling can provide useful information, though these methods often require correlation or a combination of qualitative and quantitative interpretation to properly interpret the data. These surface geophysical tools tend to be most powerful when used in combination with other methods.

Therefore, for clarity, EPA is finalizing an amended version of § 257.71(d)(1)(ii)(A)(*3*). The final rule specifies that characterization of subsurface variability must be conducted with recognized and generally accepted methods. Facilities must document how the combination of methods relied upon provides reliable

[14] U.S. EPA. 2017. ''Best Practices for Environmental Site Management: A Practical Guide for Applying Environmental Sequence Stratigraphy to Improve Conceptual Site Models.'' EPA/600/R–17/293. Prepared by the Office of Research and Development. Cincinnati, OH. September.

[15] U.S. EPA. 2017. ''Best Practices for Environmental Site Management: A Practical Guide for Applying Environmental Sequence Stratigraphy to Improve Conceptual Site Models.'' EPA/600/R–17/293. Prepared by the Office of Research and Development. Cincinnati, OH. September.

[16] *https://asct-1.itrcweb.org/.*

information at a spatial resolution necessary to adequately characterize the variability of subsurface conditions that will control contaminant transport.

d. Sample Depth and Spacing

EPA discussed in the preamble of the proposed rule that samples should extend down to the top of the natural water table or at least 20 feet beneath the bottom of the nearest water body (to identify potential for upwelling), whichever is greater, to ensure that any potential preferential flow pathways have been identified. EPA also discussed that the initial soil samples collected around the perimeter of the unit should be spaced at a distance no greater than 200 feet apart in low-conductivity soils. This distance reflects recommendations by the U.S. Department of Transportation (U.S. DOT) for the characterization of unknown subsurface environments.[17] If there is indication from the site history, collected soil samples, or other sources that high-conductivity deposits may be present at widths narrower than 200 feet, then even finer sample spacing may be warranted. EPA stated that the demonstration must substantiate why the number and types of samples collected are sufficient to capture any heterogeneity of the subsurface and why the data used to estimate contaminant fate and transport through the subsurface are representative of the variability identified. If regions of higher conductivity are present around the site, the potential impacts of preferential flow on groundwater concentrations will need to be considered in the demonstration. Furthermore, if regions of preferential flow are identified in otherwise low-conductivity soils that are not adequately captured by the existing monitoring well network, then re-evaluation of the placement of monitoring wells around the waste boundary would be warranted to address these gaps.

Many commenters argued that the depth and spacing of samples discussed in the preamble was overly strict. No commenters raised issue with the rationale for the proposed sample depths. However, one commenter argued that characterization down to the groundwater table is unnecessarily burdensome for sites with deep groundwater. This commenter stated that if the first 100 feet of the soil overlying the aquifer is not sufficient to prevent contamination of groundwater, then the next 100 feet is unlikely to alter that fact. Several commenters raised questions about the rationale for the proposed sample spacing. One commenter pointed out that EPA has previously written that the number of borings necessary to characterize soils is dependent on the geological complexity, size, potential areal extent of a release, and the importance of defining small-scale discontinuities in formation materials.[18] Many others pointed out that the U.S. DOT guidance referenced in the preamble is not directly related to waste disposal and that the guidance also states that the spacing and depth of the borings should be based on an evaluation of available information.[19] Most of these commenters requested further justification for the criteria for sample spacing.

EPA generally agrees with commenters that the exact depth and spacing of samples should be informed by site conditions. The discussion provided in the proposal was intended to define an initial depth and spacing of samples that would ensure identification of subsurface variability at these sites, not to impose this exact sampling regime at every site. Instead, EPA intended for facilities to document why the number and types of samples collected are sufficient to capture the heterogeneity of the subsurface if sampling deviated from these specifications. Such documentation would not provide additional useful information if all sampling was pre-determined. EPA believes these baseline requirements are warranted because there will be no time for facilities to fill data gaps in the characterization of the site if a demonstration is found to be insufficient. These requirements also help clarify the level of documentation expected as part of the demonstration.

As discussed, the 200 feet spacing was based on a U.S. DOT publication that provides a review of recommended practices for installation of pavement from a geotechnical perspective based on guidelines from textbooks, several state agencies, and the Federal Highway Administration. Commenters are correct that a primary focus of the publication is the stiffness and strength of the soil; however, it also accounts for soil permeability and the presence of discontinuities, fractures, and fissures of subsurface formations, which are relevant to the demonstration. The minimum spacing was selected from this publication based on the professional judgement of Agency staff, who have considerable experience on this topic from work at cleanup sites across the country. For all these reasons, EPA continues to believe that selected minimum spacing is relevant and appropriate. Notably, no commenters indicated that an initial 200 feet spacing was too wide apart to effectively characterize soil, nor did any commenters identify another standard believed to be more directly applicable.

In response to these comments, EPA is finalizing § 257.71(d)(1)(ii)(A)(*4*) with amendments to make clear that facilities must document why the specific number, depth, and spacing of samples collected are sufficient to reflect the variability of subsurface soils if 1) samples are advanced to a depth less than the top of the groundwater table or 20 feet beneath the bottom of the nearest water body, whichever is greater, or 2) samples are spaced farther apart than 200 feet around the surface impoundment perimeter.

e. Conceptual Model

EPA proposed at § 257.71(d)(1)(ii)(A)(*3*) that as part of the first line of evidence, facilities must provide conceptual site models with cross-sectional depictions of site stratigraphy that include the relative location of the surface impoundment (with depth of ponded water noted), monitoring wells (with screening depths noted), and all other subsurface samples used in the development of the models.

One commenter stated that the conceptual models should also include ''all relevant hydraulic information, including depth to saturated zones, piezometric surface elevation, withdrawal points, recharge and discharge areas. Based on groundwater and contaminant flow model projections, the cross sections should extend a sufficient distance from the surface impoundment to incorporate the influence of such features on the site-vicinity hydrogeology.''

EPA agrees that the depiction of site hydrology on these diagrams is important. Although some data identified by the commenter are already required as part of other diagrams, inclusion here allows both an alternate view of these data (cross-sectional instead of aerial) and a more complete understanding of the relationship between site geology and subsurface transport. At the same time, requiring

[17] U.S. DOT. 2006. ''Geotechnical Aspects of Pavement: Reference Manual/Participant Workbook.'' FHWA NHI–05–037. Prepared by the Federal Highway Administration. Washington, DC. May.

[18] U.S. EPA. 1989. ''Interim Final RCRA Facility Investigation (RFI) Guidance Volume II Of IV: Soil, Ground Water And Subsurface Gas Releases.'' EPA 530/SW–89–031. OSWER Directive 9502.00–6D. Prepared by the Office of Solid Waste. Washington, DC. May.

[19] U.S. DOT. 2006. ''Geotechnical Aspects of Pavement.'' FHWA NHI–05–037. Prepared by the Federal Highway Administration. Washington, DC. May.

facilities to depict the full variability of groundwater depth and flow in these cross-sections could dramatically increase the total number of diagrams needed without providing much additional clarity. Instead, EPA believes it is more important for this set of diagrams to depict the range of hydrologic conditions encountered at the site.

Therefore, in response to these comments, EPA is finalizing § 257.71(d)(1)(ii)(A)(*5*) with an amendment that each cross-sectional diagram must also include demarcation of, at a minimum, (1) the upper and lower limits of the uppermost aquifer across the site, (2) the upper and lower limits of the depth to groundwater measured from facility wells if the uppermost aquifer is confined, and (3) both the location and geometry of any nearby points of groundwater discharge or recharge (*e.g.,* surface water bodies, wells) with potential to influence groundwater depth and flow measured around the unit.

2. Line of Evidence #2—Potential for Infiltration

The second line of evidence that EPA proposed at § 257.71(d)(1)(ii)(B) would require evaluation of the potential for infiltration through any liners and underlying soils that control the release and transport of leachate by either in-situ sampling, or by conducting an analysis of the soil-based liner and underlying soil of the unit through laboratory testing. EPA discussed in the preamble that the purpose of this line of evidence is to provide a reasonable estimate of the rate at which contaminants may be released and transported to groundwater over time. However, EPA also questioned whether collection of in-situ data would be feasible for facilities.

EPA received comments from multiple facilities agreeing that collection of data from beneath the surface impoundment could be unnecessarily onerous and may disturb the integrity of the surface impoundment. One environmental group stated that field measurements of hydraulic conductivity were preferable because laboratory measurements have the potential to differ from field measurements. This commenter stated that the hydraulic conductivity of geosynthetic clay liners can be impacted by a variety of factors in the field that may not be adequately addressed in the lab, citing to several studies purported to raise concerns both that laboratory tests were unreliable and that the leaching behavior of clays were too poorly understood to reliably measure in the lab.

EPA agrees with commenters who stated that in-situ analysis of liner performance while the unit operates would be impracticable. Installation of a leachate collection device, such as lysimeter, beneath the impoundment to measure releases in real time risks disruption of the liner. In addition, because the current state of the liner cannot be directly observed or measured during operation, it is not possible to determine whether such measurements reflect the long-term interactions between the liner and CCR leachate. Therefore, EPA is removing the provision that allowed for in-situ sampling of hydraulic conductivity.

EPA disagrees that the studies provided by the commenter raise wider concerns about either the general reliability and reproducibility of laboratory methods or the specific ability to accurately measure hydraulic conductivity in a laboratory setting. The Agency's review of the cited articles found that excerpts quoted by the commenter did not fully reflect the context or conclusions of the studies, that the conclusions the commenter had drawn from some studies were incorrect, and that many of the studies cited had limited or unclear applicability to CCR surface impoundments. Specifically:

• The first study quoted by the commenter evaluated the precision among labs for hydraulic conductivity measurements of fine-grained soils using Method C of ASTM D5084–10.[20] From this study the commenter drew the quote, ''many of the laboratories in the study did not follow the test method precisely.'' However, the authors of this study concluded that the variability of results between labs was not sensitive to these deviations from protocol. Further, the authors found that ''hydraulic conductivity can be measured within a factor of 2 for the 10^{-6} cm/s range, a factor of 1.5 for the 10^{-6} cm/s range, and a factor of 4 for the 10^{-9} cm/s range.'' These results do not support wider concerns about laboratory reproducibility raised by the commenter. First, the commenter fails to acknowledge that measurement uncertainty is an inherent part of any data collection effort and they provide no evidence that field measurements would yield appreciably lower variability. Second, the magnitude of variability identified in the study is minor compared to the multiple orders of magnitude over which soil conductivity can vary. Thus, this source of variability will become less important in lower conductivity soils. Finally, the commenter does not acknowledge that uncertainties can be managed within an evaluation to ensure that long-term contaminant release and transport are not underestimated. For example, under the requirements of this rule, facilities are required to measure the hydraulic conductivity of subsurface soils saturated with CCR leachate, which will simulate the highest conductivity possible for that soil.

• A second study referenced by the commenter compared concentrations in CCR leachate with two different EPA methods, the synthetic precipitation leaching procedure (SPLP; Method 1312) and Leaching Environmental Assessment Framework (LEAF, Method 1313).[21] From this study the commenter pointed to the statement that ''SPLP results were highly variable when compared to the LEAF data.'' The commenter indicated that this was evidence that laboratory tests were not reliable. EPA disagrees. The study authors discussed potential causes of observed differences between the two methods, which they attributed primarily to the different extraction acids used by the two methods, a conclusion supported by the findings of previous studies. This is reasonable because the two leaching tests are designed to represent somewhat different environmental scenarios. There is no indication that either method returned erroneous results for the specified conditions. EPA has subjected the LEAF methods to extensive inter-laboratory validation and has great confidence in the results of these methods.[22] The Agency has also emphasized that the data from leaching tests must be considered carefully to ensure that the test conditions provide relevant information about actual environmental conditions. Therefore, the commenter's assertion that these results raise concerns about the reliability of laboratory methods is incorrect.

• The commenter cited a number of studies as evidence that in-situ conditions exist that cannot be reliably

[20] Benson, C.H. and N. Yesiler, 2016. ''Variability of Saturated Hydraulic Conductivity Measurements Made Using a Flexible-Wall Permeametter,'' Geotechhnical Testing Journal. 39(3):476–491.

[21] da Silva, E.B., S. Li, L.M. de Oliveira, J. Gress, X. Dong, A.C. Wilkie, T. Townsend, and S.Q. Ma. 2018. ''Metal Leachability from Coal Combustion Residuals under Different pHs and Liquid/Solid Ratios.'' Journal of Hazardous Materials. 341:66-74.

[22] U.S. EPA. 2012. ''Interlaboratory Validation of the Leaching Environmental Assessment Framework (LEAF) Method 1313 and Method 1316.'' EPA 600/R–12/623. Prepared by tthe Office of Research and Development. September.

measured. However, many of these studies do not directly address clay liners or even waste disposal, focusing instead on issues such as climate change. Others evaluated liners exposed to extreme conditions, such as sustained operating temperatures above 100 °F and high ammonia concentrations. The commenter provides no indication beyond the ancillary citations how these issues are germane. Nevertheless, the commenter concluded that ''in-situ conditions are very complex and we do not yet have enough understanding of how these complexities affect CCR leachability to ensure that we make accurate models in the lab.'' Yet, this assertion does not comport with the available literature that shows reasonable agreement can be achieved between field and lab measurements when units are well constructed.[23]

EPA maintains that laboratory analysis is the preferred means to measure hydraulic conductivity of soil for the purposes of an ALD. Field analysis typically involves use of an infiltrometer or permeameter to measure the rate that water infiltrates into the uppermost layer of soil. These methods are generally not designed to account for the complexities associated with this type of demonstration. First, the soil to be tested may be located some distance below the ground surface, which will be difficult to isolate and reliably test in the field. Second, field tests are generally designed to use water, rather than a high-ionic strength leachate. As a result, these methods are not designed to collect the effluent needed to track system chemistry. Third, the potentially long test run times could make it difficult to control for environmental variables, such as evaporation. Therefore, to ensure reliable implementation of test methods and consistency between the various samples, EPA concludes that all samples for hydraulic conductivity should be measured in a controlled laboratory setting.

Therefore, EPA is finalizing the requirement at § 257.71(d)(1)(ii)(B) with an amendment that removes the option for in situ sampling. The final rule now specifies that facilities must send all samples of the soil-based liner components and/or naturally-occurring soil for analysis under controlled conditions in a certified laboratory. Samples must be analyzed using a recognized and generally accepted methodology. Facilities must document in the demonstration how the selected test method is designed to simulate field conditions (*e.g.,* hydraulic head, effective stress).

In the proposal, EPA stressed that it is critical that laboratory tests are designed to reflect site conditions to ensure the data generated reflect real-world and long-term operating conditions. EPA provided several examples of potentially relevant site conditions. EPA received a number of comments related to several of these and other site conditions. Discussion of the site conditions and the specific comments received is provided in the following Units of this preamble.

a. Number and Location of Samples

EPA did not provide specific discussion in the proposal about the required number, depth, or spacing of samples for analysis of hydraulic conductivity for the second line of evidence. Instead, EPA stated in the first line of evidence that samples must be located around the perimeter of the surface impoundment at a spatial resolution sufficient to ensure that any regions of substantially higher conductivity have been identified. EPA had intended for the variability of the hydrogeology identified in the first line of evidence to inform the number and location of samples analyzed for the second line of evidence.

Based on comments received, EPA believes that commenters generally assumed EPA had proposed that the location of samples for hydraulic conductivity must coincide with samples collected for the first line of evidence. As such, EPA considers all general comments requesting that the frequency of data collection be based on the variability of the site geology to be equally relevant here.

EPA did not envision that samples collected to characterize hydraulic conductivity would exactly match the number or location of those collected for the first line of evidence. For example, as discussed in Unit III.C.1.b of this preamble, this rule also allows for use of non-intrusive methods to support the first line of evidence. Because non-intrusive methods do not advance equipment into the soil, they do not allow for simultaneous collection of subsurface soil samples. The combination of methods used to characterize site hydrogeology may identify regions of subsurface variability some distance away from the point of measurement. Therefore, facilities should instead use the information available on subsurface variability from the first line of evidence to inform the number and location of samples for the second line of evidence.

Therefore, for clarity and consistency with the first line of evidence, EPA is finalizing a requirement at § 257.71(d)(1)(ii)(B)(*1*) that facilities are required to document where samples were collected around the surface impoundment and how the number, depth, and spacing of these samples (1) are supported by the data collected for the first line of evidence and (2) are sufficient to capture the variability of hydraulic conductivity for the soil-based liner components and/or naturally occurring soil.

b. Permeant Liquid

EPA discussed in the proposal that tests used to estimate hydraulic conductivity need to use a permeant liquid that reflects the composition of the infiltrating surface impoundment porewater. The method must account for the chemistry of CCR porewater that can have both extreme pH and high salinity. Extreme pH may dissolve key components of the soil structure, while high salinity may result in interlayer shrinkage of clays, both of which can result in higher hydraulic conductivity. Use of a non-representative liquid (*e.g.,* deionized water) as the permeant liquid or pre-hydrating the clay may actually decrease the conductivity of clay through swelling and result in a lower measured conductivity than would actually occur in the field.

EPA received no adverse comments on this topic. One commenter raised concern that exposure to CCR leachate can adversely affect the integrity of a liner, though this commenter made no reference to the preamble discussion. Instead, the commenter cited to multiple studies purported to show that CCR leachate can adversely affect geosynthetic clay liners and that pre-hydrating samples with deionized water may underestimate long-term conductivity.

As discussed in the proposal and above, EPA agrees that the effects of leachate chemistry on long-term soil conductivity are potentially significant. Therefore, EPA is finalizing a requirement at § 257.71(d)(1)(ii)(B) that the liquid used to pre-hydrate the clay and measure long-term hydraulic conductivity must reflect the pH and major ion composition of the impoundment porewater.

c. Thixotropic Effects

EPA raised concern in the proposal that preparation of samples intended to reflect compacted soil liners for testing may result in the soil becoming temporarily less permeable as a result of

[23] U.S. EPA. 2002. ''Assessment and Recommendations for Improving the Performance of Waste Containment Systems.'' EPA/600/R–02/099. Prepared by the Office of Research and Development. December.

thixotropic behavior. EPA previously raised the potential for the structure of thixotropic materials, such as certain clays, to become temporarily more dispersed when agitated, which might limit flow through interstitial pores and make it more difficult for water to infiltrate.[24] EPA was concerned that the material will gradually become more permeable as it is allowed to rest and return to its original state. Therefore, EPA stated in the proposal that compacted samples should be allowed to rest for sufficient periods prior to testing to reflect the long-term behavior of the soil in the field.

EPA received no comments that expressed support for this requirement. One commenter questioned whether thixotropy is a relevant consideration and if a ''rest period'' is actually needed to provide a realistic measurement of hydraulic conductivity. This commenter pointed to multiple studies that found minimization of void spaces in the soil macrostructure was a key control on hydraulic conductivity. Based on this literature, the commenter concluded that the microscale structure described with terms such as ''dispersed'' or ''flocculated'' is not a major concern.

The literature provided by the commenter indicates that effects from thixotropy are not a major concern in the measurement of hydraulic conductivity. EPA acknowledges that this topic is not raised in more recent literature discussed as part of this rulemaking. Similarly, none of the standardized tests for hydraulic conductivity reviewed by EPA specifies a need for an extended rest period. In addition, studies conducted more recently by EPA and others have obtained good agreement between measurements in the lab and field for many compacted, low-conductivity soils without a rest period. Finally, this requirement has the potential to add a considerable amount of time to an already time-intensive analysis. For all these reasons, EPA concludes that the available evidence does not support finalization of this provision.

d. Natural Soil Structure

EPA discussed in the proposal that preparation for samples intended to reflect the naturally-occurring soils beneath the surface impoundment for testing may result in the soil becoming permanently less permeable by disturbing the natural structure of the soil and eliminating voids and other features that may act as conduits for infiltration in the field. Failure to preserve the structural integrity of such samples could result in a lower measured conductivity than would actually occur in the field because it results in greater compaction or consolidation than exists in the field. EPA pointed out that standardized methods have been developed to obtain undisturbed soil samples.

EPA received no comments relevant to this topic. Therefore, EPA is finalizing a requirement at § 257.71(d)(1)(ii)(B)(*3*) that facilities must ensure that samples intended to represent the hydraulic conductivity of naturally-occurring soils (*i.e.,* not mechanically compacted) are handled in a manner that will ensure the macrostructure of the soil is not physically disturbed during collection, transport, or analysis (*e.g.,* initial saturation). Facilities must provide documentation of the measures taken to ensure the integrity of the samples relied upon.

e. Test Termination Criteria

EPA discussed that the termination point of a test must be established at a point that ensures the long-term behavior of the liner is accurately reflected. Some tests for hydraulic conductivity stop after the inflow and outflow rates equilibrate or after a specified volume of water has passed through the soil. However, these metrics may not be sufficient to identify the reactions that can occur between the soil and liquid (*e.g.,* exchange of adsorbed cations). Some metrics that more directly address the chemistry of the soil-leachate interactions include equilibration of electrical conductivity and pH. Failure to run the test on a timeframe relevant to the chemical reactions of interest may result in a lower measured conductivity than would actually occur in the field.

One facility stated that the proposed hydraulic conductivity testing is difficult, time-consuming, and not commonly conducted. The facility asserted that the information obtained from such tests would not significantly inform a determination of whether the impoundment is protective. Another commenter suggested two methods as most appropriate for use in the demonstration: ASTM D6766 (Standard Test Method for Evaluation of Hydraulic Properties of Geosynthetic Clay Liners Permeated with Potentially Incompatible Liquids) and ASTM D7100 (Standard Test Method for Hydraulic Conductivity Compatibility Testing of Soils with Aqueous Solutions). This commenter noted that both methods include termination criteria based on chemical equilibrium.

EPA acknowledges that it can take considerable time for hydraulic conductivity tests to meet termination criteria, and that criteria based on chemical equilibrium may require more time than those based on other metrics. However, the Agency disagrees that these tests provide no useful information. By allowing the chemistry of the system to reach equilibrium, it ensures that the long-term effects of leachate chemistry on the soil are adequately characterized. High ionic strength liquids have been shown to increase the long-term hydraulic conductivity of some soil materials by orders of magnitude compared to deionized water. The fact that these types of tests have been uncommon does not negate their importance.

EPA agrees that the two methods referenced by the second commenter are more appropriate for use in the demonstration than ASTM D5084, which EPA provided as an example in the preamble. However, the two methods referenced by the commenter identify somewhat different termination criteria based on solution chemistry. While one method identifies only equilibrium for electrical conductivity, the other further identifies pH, concentrations of unspecified solutes, and/or the dielectric constant. Electrical conductivity and pH provide a means to identify changes in the dominant solution chemistry. In addition, both can be tested for rapidly and easily. That is why EPA believes they serve as practical indicators for the hydraulic conductivity tests. While other criteria, such as specific solute concentrations, can provide further information on how the leachate interacts with the soil (*e.g.,* which ions are substituted on the soil surface), EPA has not seen evidence that these additional parameters will identify significant changes in the solution chemistry that electrical conductivity and pH would not.

Therefore, EPA is finalizing a requirement at § 257.71(d)(1)(ii)(B)(*4*) that any test for hydraulic conductivity relied upon must include, in addition to other relevant termination criteria specified by the method, criteria that equilibrium has been achieved within acceptable tolerance limits between the inflow and outflow for both electrical conductivity and pH.

3. Additional Lines of Evidence

EPA solicited comment on whether there are any additional lines of evidence that should be included as part of the demonstration. Various industry groups, individual facilities,

[24] U.S. EPA. 1986. ''Design, Construction, and Evaluation of Clay Liners For Waste Management Facilities.'' EPA/530–SW–86–007–F. Prepared for the Office of Solid Waste and Emergency Response. Washington, DC.

environmental groups, and states all proposed additional factors to be considered. These factors included whether a unit had individual liner components that met the standard of the CCR regulations, previous certification of performance from states or professional engineers, and the impact of closure on releases. These are discussed in more detail in the following Units of this preamble.

a. Presence of Geomembrane Liner

One commenter requested that EPA waive the demonstration requirement for units that have at least a 60-mil geomembrane liner, but do not meet the remaining requirements to be considered a lined unit. This and another commenter indicated that a successful initial application combined with decades of operation without any indication the unit has adversely affected groundwater should be sufficient evidence that the liner is protective.

EPA emphasizes that the intent of a demonstration is to characterize the potential for future groundwater exceedances. It can take years or even decades for leachate released from an impoundment to reach downgradient wells. Thus, the fact that a unit has not yet triggered corrective action does not mean it is not possible at some point in the future. This is why groundwater monitoring is required at all units. Furthermore, as part of the demonstration, facilities are required to test the hydraulic conductivity of the soil component of the composite liner to demonstrate its long-term performance when exposed to leachate. If the soil liner beneath a geomembrane liner is found to be ineffective, then imperfections in the geomembrane liner may lead to unimpeded flow of leachate into the subsurface. Based on this, EPA concludes that information on the subsurface soil component is a necessary line of evidence for all impoundments. Therefore, both an initial application and final demonstration must be submitted as part of an alternate liner demonstration for any impoundment.

b. Previous Certification

Multiple commenters requested that EPA give deference to a previous certification by a professional engineer or prior approval by a state regulatory authority when determining whether to approve a demonstration. Some commenters noted that their states require quality-assurance/quality-control (QA/QC) plans for liner construction and maintenance be included in the permit and that their surface impoundment liner was inspected and certified by a licensed professional engineer with appropriate expertise. One commenter asserted that this helps establish a presumption that a surface impoundment liner is adequately protective. However, none of the commenters elaborated on how the Agency should assign weight to such findings as part of the larger review.

EPA agrees that documentation about the quality of liner construction is necessary to prove that the surface impoundment has been well constructed and so has the potential to be protective. That is why information on construction quality must be provided upfront in the application step. However, the fact that a unit meets an unspecified design standard does not guarantee that particular standard will be protective in the long term. A purpose of the demonstration step is to document that the design of an alternate liner will remain protective in the long-term when exposed to CCR leachate. EPA cannot outright substitute a prior approval by either a qualified professional engineer (PE) or state agency for the comprehensive alternate liner demonstration required by this rule. State requirements can vary in both scope and specificity and EPA does not have a reliable record of what was considered as part of these reviews or how it aligns with the requirements of this rule. To the extent that previous findings by a PE or state authority details how a unit achieves the requirements of this rule, EPA will consider the rationale provided as part of the larger demonstration. However, this rationale does not substitute for providing any of the data or other underlying documentation required by this rule. Therefore, EPA made no changes to the rule in response to these comments.

c. Consideration of Unit Closure

One state recommended that the existence of plans to dewater the surface impoundment and install an impermeable cap be included as an additional line of evidence in the demonstration. The commenter noted such actions could alter the hydrogeologic model and/or reduce groundwater impacts. However, the commenter did not elaborate on how the Agency should weigh such information as part of the larger review.

The intent of the determination is to document the potential environmental impacts associated with continued operation of the unit. Although the installation of an impermeable cap would reduce infiltration, such actions would not be feasible during operation and are already required of all surface impoundments as part of closure. Therefore, it is not clear how this could be incorporated as a line of evidence. Therefore, EPA concludes that is not a relevant line of evidence and made no changes to the regulations in response to this comment.

4. Incorporation of Lines of Evidence Into Demonstration

EPA proposed that the data collected for the two lines of evidence, characterization of site hydrogeology and potential for infiltration, must be incorporated into the final demonstration. Each one provides different, site-specific data necessary to understand the potential for continued operation of the unit to adversely affect groundwater in the future. Consideration of future effects will necessitate some amount of fate and transport modeling. EPA acknowledged that the type of model used will depend on the complexity of the site. Regardless of the modeling approach used, all of the data incorporated into the calculations must be documented and justified.

EPA received some general comments related to the incorporation of the lines of evidence into the demonstration. One commenter stated that groundwater and contaminant flow models should be developed by drawing on the data used for the conceptual site models and run using various scenarios to ensure adequate consideration of a range of operating and site conditions. A second commenter stated that the magnitude of releases from surface impoundments is determined by a myriad of variables and reducing these systems to only one (*i.e.,* hydraulic conductivity) fails to capture this complexity, increasing the chance of mischaracterizing the probability of groundwater contamination.

EPA agrees with the first commenter that it is critical that facilities document how any data relied upon adequately reflect the range of variability in operational and environmental conditions at and around the surface impoundment to ensure that high-end risks are not underestimated. EPA disagrees with the second commenter that the required lines of evidence are not adequate to identify this variability and the potential for adverse effects to groundwater. Although the effective hydraulic conductivity of the engineered liner and/or naturally occurring soil is one of the most important parameters, this does not mean other parameters are not also important or accounted for in the demonstration. EPA previously identified a list of highly sensitive

model parameters in the 2014 Risk Assessment. Data for some of these parameters are already available through the existing groundwater monitoring program (*i.e.,* depth to groundwater, hydraulic gradient). Data for others will be collected for the two lines of evidence required by this rulemaking (*i.e.,* infiltration rate, hydraulic conductivity). EPA did not propose to require the remaining parameters to be collected on a site-specific basis (*i.e.,* leachate concentration, sorption coefficients) because a national-scale record of these parameters already exists for the constituents modeled in the 2014 Risk Assessment. To avoid the need for entirely new, site-specific risk assessments that evaluate impacts to both groundwater and surface water, facilities will need to consider the same high-end leachate concentrations that the clay-lined units were found unable to contain in order to demonstrate that the alternate liner performs materially better. Therefore, EPA is requiring that the owner or operator draw from the existing risk record to characterize leachate chemistry and behavior in the demonstration. Use of these data will help mitigate any uncertainties about the representativeness of the sampled ash or how conditions might change in the future. Altogether, this will ensure confidence that GWPS will not be exceeded.

EPA is finalizing a requirement at § 257.71(d)(1)(ii)(C) that facilities must incorporate the site-specific data collected for the two lines of evidence, characterization of site hydrogeology and potential for infiltration, into a mathematical model used to calculate the potential groundwater concentrations that may result in downgradient wells as a result of the impoundment. EPA is amending the proposed regulatory text to incorporate greater specificity based on the discussion in the preamble to the proposed rule. Accordingly, the final regulation specifies that facilities must also, where available, incorporate the national-scale data on constituent concentrations and behavior provided by the existing risk record. Where an existing record is not available, the owner or operator must justify how the data used are adequate to reflect high-end concentrations and behavior at the site. The regulation also specifies that application of the model must account for the full range of current and potential future conditions at and around the site to ensure that high-end groundwater concentrations have been effectively characterized. All of the data and assumptions incorporated into the model must be documented and justified.

a. Specific Models Used

EPA discussed in the proposal that the model used may vary based on the complexity of a particular site. More complex sites may merit the use of a probabilistic fate and transport model similar to that used in the 2014 Risk Assessment. If a site is less complex (*e.g.,* homogenous, low-conductivity soil), then more deterministic calculations may be sufficient to demonstrate that no adverse effects will occur. Regardless of the approach used, all of the data incorporated into the calculations must be documented and justified.

One commenter expressed concerns that the EPA Composite Model for Leachate Migration with Transformation Products (EPACMTP) is not able to fully represent the complexities of site conditions and so should not be allowed as the basis for decisions about future unit performance. EPACMTP was previously used by the Agency in the 2014 Risk Assessment and later by EPRI in a white paper submitted to EPA to show that some unlined surface impoundments can also be protective. This commenter raised two specific concerns about EPACMTP. First, that the model treats the subsurface environment as homogenous and so is not able to reflect variable hydraulic conductivity in any individual model run. Second, that the model cannot account for constituent mass sinks beyond the unit, such as discharge of groundwater to water bodies.

The Agency agrees that there can be instances where EPACMTP is not the model best suited to represent the complexities of a particular site. EPA discussed one such example in a memorandum included in the docket for the proposed rule.[25] Based on these considerations, EPA did not propose to require use of EPACMTP or any other specific model in a demonstration. However, this does not mean that use of EPACMTP is never appropriate. EPA was cognizant of the limitations of the model when preparing the 2014 Risk Assessment and took steps to ensure that risks were neither underestimated nor overestimated. To address heterogeneity in the subsurface, EPA conducted a probabilistic analysis that varied the hydraulic conductivity based on the range of soil types identified around a facility. To address losses to nearby water bodies, EPA applied a post-processing module to subtract out the intercepted mass. This shows that how a model is applied can be just as important as the model design. Appropriate use of a model will help reduce uncertainties to a degree that allows decisions to be made with the necessary level of confidence.

To ensure that a model is applied appropriately, it is critical to understand all the assumptions built into that model. All models include some degree of simplification compared to the real world so that calculations are both feasible and manageable. More simplistic models may provide less precise results, but that does not mean these results are inadequate. Whether a model is appropriate is more often determined by how it is applied to support decision-making. The goal of modeling in the demonstration step is to provide confidence that peak groundwater concentrations that may result from releases throughout the active life of the impoundment will not exceed GWPS at the waste boundary. In this context, simplifying assumptions that will tend to overestimate the magnitude of contaminant release and transport can actually provide greater confidence in the conclusions of the demonstration.

Therefore, based on the comments received, EPA is finalizing an additional requirement at § 257.71(d)(1)(ii)(C)(*1*) that the models relied upon must be well-established and validated, with background documentation that can be made available for public review. Proprietary models that operate in a black box will not be considered appropriate for use in a demonstration.

b. Use of Groundwater Protection Standards

EPA discussed in the proposal that as part of the demonstration, the owner or operator must demonstrate that the surface impoundment has not and will not result in groundwater concentrations above relevant GWPS at the waste boundary (health-based or background, whichever is higher). EPA stated that this is the standard used to trigger corrective action for lined surface impoundments and it is considered equally appropriate in this context.

Several commenters raised concerns about the use of GWPS as the basis to determine that an impoundment is protective. One commenter alleged that facilities were allowed to set their own GWPS. Another commenter stated that EPA had not provided justification why the standard used to determine that lined surface impoundments must initiate corrective action is equally

[25] U.S. EPA. 2020. ''Review of Analyses in EPRI White Paper: Model Evaluation of Relative Performance of Alternative Liners.'' Prepared by the Office of Land and Emergency Management. February.

appropriate to use in the approval of alternate liners.

EPA believes that use of GWPS is appropriate and protective. GWPS are set as either specific regulatory standards identified in the CCR regulations or background groundwater concentrations, whichever is higher. Facilities are not granted discretion to establish alternate values. These standards are deemed to be protective and used in a number of regulatory programs within the Agency. EPA also considers them to be sufficient to demonstrate if the long-term performance of an alternate lined CCR impoundment can be protective because these standards align with those previously used to determine that composite-lined units are protective.

The 2014 Risk Assessment evaluated the risks associated with releases from CCR surface impoundments. As discussed previously, the only risks identified for clay-lined units in this risk assessment were the result of human ingestion of lithium in groundwater up to a mile away from the waste boundary. Lithium is one of the most mobile CCR constituents. If the engineered liner and/or naturally occurring soil of the alternate liner has an effective hydraulic conductivity sufficient to eliminate the risks associated with high-end lithium concentrations previously considered in the 2014 Risk Assessment, then there is confidence that the alternate liner will also prevent risks to both groundwater or surface water from the remaining constituents. Requiring the impoundment to meet the health-based GWPS for lithium at the waste boundary, where concentrations are highest, will only further limit the potential magnitude of releases from the alternate liner.

Therefore, EPA is adopting a revised provision in the final rule that will better align the ALD requirements with the existing risk record and with the statutory standard in RCRA § 4004(a). EPA is finalizing an additional requirement at § 257.71(d)(1)(ii)(C)(2) that facilities must demonstrate that there is no reasonable probability that the peak groundwater concentrations that may result from releases that occur over the active life of the unit will exceed GWPS at the waste boundary.

c. Consideration of Background Groundwater Concentrations

EPA did not explicitly discuss consideration of existing background groundwater concentrations in the proposal but noted that it is a key factor when establishing GWPS at a particular site. It follows that background is also a factor when determining if these standards have been exceeded. Naturally occurring background concentrations are typically much lower than promulgated GWPS, but have been found to exceed these standards in some places. Even when contributions from the impoundment are small, the addition of these releases to high existing background concentration may still trigger corrective action. Because a characterization of background is available on a site-specific basis and an ALD is required to show that the peak groundwater concentration that may result from releases over the active life of the impoundment will not exceed GWPS, existing background concentrations are a relevant consideration for all constituents. Consideration of existing background concentrations will only further limit the potential magnitude of any releases from the alternate liner.

EPA is finalizing a new provision at § 257.71(d)(1)(ii)(C)(*3*) that documentation of the model outputs must include the peak groundwater concentrations modeled for all Appendix IV constituents attributed to the impoundment both in isolation and in addition to background. This will provide an understanding of both the increase in concentration attributed to releases from the surface impoundment and the overall likelihood for an exceedance of GWPS.

d. Risk From Other Constituents

Some commenters stated that units with ALDs should be forced to close after an SSI over background of any Appendix III constituent. Under this approach, any increase in concentrations distinguishable from background would trigger closure, regardless of the magnitude. Commenters expressed concern that reliance on Appendix IV constituents would not adequately protect against risks from the release of Appendix III constituents, such as boron and sulfate.

EPA disagrees with these commenters. As discussed previously, EPA distinguishes between the situation prior to the time EPA has determined that the unit meets the requirements of the ALD and after EPA has determined that the unit meets the requirements. In the former case EPA must assume that the unit does not have the low hydraulic conductivity necessary to ensure the GWPS will never be exceeded; as a consequence, EPA is requiring the unit to remain in detection monitoring throughout the application process. By contrast, the record is very different with respect to a unit that has been approved for an ALD. In this case the site characteristics can support the additional time needed to determine the appropriate actions to address all the potential risks at that particular site. In addition, the Appendix III list is not intended to identify risk. These constituents and water quality parameters are intended to indicate that the overall groundwater chemistry has shifted, which may be the result of a release from the unit. Some additional constituents that were evaluated in the risk assessment, such as boron and fluoride, were selected because the higher mobility in the subsurface makes them ideal early indicators. EPA did not identify any risks for these constituents from clay-lined units. Therefore, a unit with an ALD that has been found to perform better than the modeled clay-lined units will also pose no concern for these constituents. Sulfate was not modeled in the risk assessment because EPA did not identify any health benchmarks derived in a manner consistent with the OLEM hierarchy for human health toxicity values or relevant ecological benchmarks. Nor did EPA receive any comments on the risk assessment identifying relevant benchmarks that the Agency had omitted. The review of the literature conducted in support of the advisory level identified some potential for laxative effects from elevated sulfate levels, though these effects were not observed for longer-term exposures as individuals appeared to adapt over time. EPA concluded that available data did not permit a full dose-response assessment for sulfate in water and ultimately set an advisory level lower than associated with short-term effects reported by any individual study.[26] The World Health Organization subsequently reached a similar conclusion, stating that ''the existing data do not identify a level of sulfate in drinking-water that is likely to cause adverse human health effects.[27]'' Some organizations have chosen to compare this advisory level to monitoring well data reported by facilities to estimate risk.[28] Even if this were an appropriate use of this advisory level, the report shows that sulfate levels above the advisory level occur concurrently with exceedances of GWPS and do not

[26] U.S. EPA. 2003. ''Drinking Water Advisory: Consumer Acceptability Advice and Health Effects Analysis on Sulfate.'' EPA 822–R–03–007. Office of Water. February.

[27] World Health Organization. 2004. ''Sulfate in Drinking-Water: Background Document for the Development of WHO Guidelines for Drinking-Water Quality.'' WHO/SDE/WSH/03.04/114.

[28] Environmental Integrity Project. 2019. ''Coal's Poisonous Legacy: Groundwater Contaminated by Coal Ash Across the U.S.''

outpace the magnitude of these exceedances. This is expected because several Appendix IV constituents can be associated with sulfate in the ash. There is no indication that the hypothetical risks from sulfate raised by the commenter would not be addressed by the requirements of this rule. Therefore, EPA maintains use of Appendix IV constituents as the basis for the alternate liner demonstration. However, as discussed in Unit IV.D.5.b of this preamble, detection of an SSI of Appendix III constituents will trigger additional measures designed to ensure that levels of Appendix IV constituents are never detected at SSLs. As discussed in Unit IV.D.5.b of this preamble, detection of an SSI of Appendix III parameters will trigger additional measures designed to ensure that an SSL of Appendix IV constituents do not occur.

D. Procedures for Approval and Denial of Alternate Liner Demonstration

As mentioned previously, EPA proposed a two-step process first requiring the submittal of an application, and then, if the application is approved a demonstration. EPA also proposed regulations to govern the procedures for the review of and public comment on those documents. These elements of the proposal are discussed below.

1. Application Process

a. Deadline of Application Submission

EPA proposed at § 257.71(d)(2)(i) that the initial applications were due no later than thirty days after the effective date of the final rule. Industry commenters requested additional time to prepare and submit the application, as well as the ability to provide follow-up information beyond the deadline if EPA finds some aspect of the documentation to be inadequate. Commenters worried generally that a fixed deadline of 30 days would provide little time to prepare an application, and in particular that any time spent waiting for input from EPA would further limit the time remaining to make any necessary updates. Commenters stated that given the significance of this step, EPA must provide facilities with adequate time to assemble this critical preliminary information, which may require the assistance of third-party engineering firms. They further stated that facilities should not be rushed to prepare this information, which, if determined to be insufficient, will disqualify a facility from being able to seek an alternate liner demonstration and subject the unit to closure. EPA received comments requesting the ability to meet with EPA before submitting their application. Additionally, industry commenters were also concerned about the initial application deadline as it related to the proposed deadline of August 31, 2020 to cease receipt of waste, as well as the deadlines for submission of requests to obtain alternative compliance deadlines in 84 FR 65941 (December 2, 2019) (''Part A Proposed Rule'').

EPA agrees with commenters that the proposed thirty-day deadline and the proposed date to cease receipt of waste could have made implementation difficult. In response to the comments, EPA is extending the timeframe available for facilities to submit the initial application. EPA believes that submittal by November 30, 2020, is appropriate for facilities to prepare and submit the application. This is the same date by which facilities will be required to submit requests for extensions pursuant to § 257.103(f), and in the interest of simplifying the regulations it makes sense to coordinate the dates. This will provide sufficient time for facilities to become familiar with requirements of this rule and collect the information needed for the initial application. It is worth noting in this respect that EPA is not requiring the generation of new data or additional sampling to support the initial application. The additional time will also provide the Agency the ability to engage in a limited amount of discussion with a facility before the application submission deadline. Such discussions would need to occur before the deadline for final submission of the application. In regard to the deadline to cease receipt of waste, the Part A final rule established a deadline of April 11, 2021, for those units that are closing pursuant to § 257.101(a)(1) or § 257.101(b)(1)(i). This alleviates the concern that an owner or operator would not have sufficient time to submit an application before the deadline to cease receipt of waste.

EPA also received comments in support of allowing the Participating State Director (*i.e.* the State Director of a State with an approved CCR State Permit Program in accordance with RCRA section 4005(d)) to review and approve alternate liner demonstrations. The commenters said states often have resources and expertise to evaluate applications and the associated technical documents necessary in order to approve alternate liner demonstrations. The Agency agrees that a Participating State Director should have the ability to review and approve an ALD, and therefore finalized provisions in § 257.71(d) to allow that to occur.

Therefore, EPA is finalizing at § 257.71(d)(2)(i) that the owner or operator of the CCR surface impoundment must submit the application to EPA or the Participating State Director by November 30, 2020. This date is consistent with the date in the Part A final rule to submit an alternative closure demonstration.

b. Application Review

EPA proposed at § 257.71(d)(2)(ii) that EPA or the Participating State Director will evaluate the application and may request additional information as necessary to complete its review. If the application was complete it would toll the facility's deadline to cease receipt of waste for that surface impoundment until issuance of a final decision on the surface impoundment's eligibility. However, EPA proposed that incomplete submissions would not toll the deadline. EPA proposed that within sixty days of receiving the application, EPA or the Participating State Director would notify the owner or operator of its determination on the eligibility of their surface impoundment, and finally, that the facility must post the determination to its publicly accessible CCR internet site. EPA stated in the proposed rule that if the Agency or Participating State Director determines the application is lacking necessary information or specificity, the facility may have an opportunity to resubmit with the required information, provided it was submitted before the deadline for all initial applications (*i.e.,* 30 days after the effective date of the final rule). However, no resubmissions could be accepted after this deadline.

Many industry commenters requested clarification as to what information is required to constitute a complete application. Other commenters requested that EPA provide a separate certification process through PE certification, development of a checklist, or other means that could be used to confirm an application is ''complete'' before submittal. Commenters stated that a ''complete'' application consists of all the information necessary to trigger tolling of the facility's deadline to cease receipt of waste into that unit until a final decision on the unit's eligibility is issued. Commenters contrasted this with a ''sufficient'' application, which would allow a facility to proceed to the demonstration step. Because of the relatively short timeline provided to submit an application in the proposal, these commenters worried there would not be an opportunity to resubmit an

application found to be incomplete and the facility would not be allowed to toll the deadline. One commenter said that EPA should provide owners/operators with additional time beyond the original deadlines to make their resubmittals because an insufficient application submittal does not mean the liner itself is insufficient, which is the ultimate point for the alternate liner demonstrations.

EPA is adopting procedures that largely mirror those adopted for requests submitted pursuant to § 257.103(f). Upon receiving the application, EPA will evaluate the application to determine whether it is complete. EPA may request additional, clarifying information to complete its review and/or discuss the application with the facility. Consistent with the proposed rule, submissions that EPA determines to be incomplete will be rejected without further process, at which point any tolling of the facility's deadline will end. (EPA anticipates that the question of tolling for incomplete submissions should not generally arise, as the agency anticipates making these determinations before April 11, 2021). No commenter disagreed that this was appropriate. Incomplete submissions include both the situation in which the submission does not include all of the required material, and the situation in which EPA is unable to determine from the submission whether the facility or the unit meets the criteria for the application. EPA does not agree with the commenter that it would be appropriate to grant additional time to allow a facility to cure an incomplete application; the new deadline of November 30, 2020, provides more than a sufficient amount of time for the facility to submit a complete application. As discussed above, if an application was deemed incomplete, the owner or operator could attempt to cure the deficiencies and resubmit the application provided that it can do so before the November 30, 2020 deadline. If the application is deemed incomplete, the owner or operator may seek an alternative closure deadline pursuant to § 257.103(f)(1) or (f)(2). For more information on this please see Unit III.D.3.

EPA agrees that the timeframes are ambitious but continues to believe that they can be met. As discussed in more detail below, the Agency has limited the issues to be resolved during this process, and, as requested by commenters, has amended the proposed regulation to specify in detail the information needed for a submission to be considered complete. Consequently, EPA anticipates it will be able to make most decisions without further requests for information. Once the owner or operator submits the application to EPA for approval, the owner or operator must place a copy into the facility's operating record and on its publicly accessible CCR internet site. EPA will also post who has submitted an application on EPA's website.

One commenter expressed concern that utilities' alternate liner applications would not be posted publicly prior to a proposed approval, and the beginning of the thirty-day comment period on the alternate liner demonstration would likely be the first time the vast majority of the public would have the opportunity to review many of the highly complex, technical documents that would form the basis of EPA's decision. In response to the comment about not providing an opportunity for public comment on the application and to be consistent with the process established in the Part A final rule, EPA is finalizing a requirement at § 257.71(d)(2)(iii)(C) to provide for public comment on the application by granting a twenty day public comment period. After reviewing the submission, EPA will either post a determination that the submission is incomplete on EPA's website or a proposed decision to grant or to deny the request in the docket on *www.regulations.gov* for public notice and comment. EPA will also post the application on its website. EPA will allow for a 20-day public comment period. EPA will evaluate the comments received and amend its final decision as warranted. EPA will post all decisions on its website, in the relevant docket and notify the facility. EPA will make best efforts to complete the application review within sixty days of receiving the complete application.

Some commenters raised the argument that because part 257 is self-implementing and because certain regulatory provisions might be viewed as ambiguous, there could be differences in opinion on what constitutes compliance. These commenters felt that differences in interpretation should be discussed during EPA's review process and corrected as warranted as part of a facility's completion of its demonstration.

EPA is establishing an expedited process to resolve requests for continued operation under § 257.71(d); in order to meet these time frames EPA has limited the issues to be resolved in this proceeding. One of the primary issues to be resolved will be whether the facility is in compliance with the regulations. Although EPA does not agree that the regulations are ambiguous, EPA may be able to engage in a limited amount of discussion with a facility before the submission deadline. In addition, as explained previously, documentation that a facility remains in compliance with the requirements of part 257 subpart D provides critical support for a decision to allow continued operation of the unlined surface impoundment. This means that EPA must be able to affirmatively conclude that the facility meets this criterion prior to authorizing any continued operation of the unlined surface impoundment. As a consequence, any opportunity to correct the demonstration is limited to the period before the deadline for submission.

Finally, note that any determinations made in evaluating the compliance aspects of submitted applications will be made solely for the purpose of determining whether to grant an initial application. In making these determinations the Agency generally expects to consider and rely on the information in a submission, information contained in submitted comments to a proposed decision, and any other information the Agency has at the time of the determination. These determinations may not be applicable or relevant in any other context. Should the facility's compliance status be considered outside of this context in the future, the Agency may reach a contrary conclusion based, for example, on new information or information that was not considered as part of this process.

EPA is revising the regulatory text (now found at § 257.71(d)(2)(iii)) for the application review to more clearly reflect the circumstances under which a facility's deadline to cease receipt of waste will be tolled. Consistent with the recently promulgated regulations in § 257.103, the regulations provide that the deadline to cease receipt of waste will be tolled by the submission of an application until EPA determines the application is incomplete or the application is denied. As previously discussed, because EPA anticipates making determinations on the initial application before the April 11, 2021 deadline, issues of tolling should not arise for incomplete or denied applications. If EPA approves an application, the deadline to cease receipt of waste will continue to be tolled until EPA determines the demonstration is incomplete or issues the final disposition on the merits of the demonstration. The language in this section will still state that within sixty days of receiving a complete application, EPA or the Participating State Director will notify the owner or operator of its determination on the

eligibility of their surface impoundment. This section will also require that the facility must also post EPA's determination to its publicly accessible CCR internet site. Finally, this section states that the application will be available for public comment on EPA's docket for 20 days. EPA will evaluate comments as part of the review. EPA or the Participating State Director will post the decision on the application on their website and will add it to the docket.

c. Application Denial

EPA proposed at § 257.71(d)(2)(vi) that if EPA or the Participating State Director determines that the unit is not eligible for an ALD, the owner or operator must cease receipt of waste and initiate closure within six months of the denial or by the deadline in § 257.101(a), whichever is later. If a facility needed to obtain alternative capacity, they could do so in accordance with the procedures in § 257.103.

Commenters requested clarification on how the timing of a denial would work with the deadlines applicable to units closing under § 257.101(a) and 257.101(b)(1)(i). EPA is revising its proposal to better account for coordination with the recently promulgated final deadlines and procedures associated with these surface impoundments. As previously discussed, EPA intends to issue a final decision within sixty days of submission of a complete application. Therefore, if the application was received on November 30, 2020, EPA would make best efforts to issue the denial by February 1, 2021 which is two months before the April 11, 2021 deadline by which these units are required to cease receipt of waste. Under the newly promulgated regulations the surface impoundment must either cease receipt of waste no later than April 11, 2021 or the owner or operator may apply for an alternative closure deadline in accordance with § 257.103(f)(1) or (f)(2). Under the procedures associated with § 257.103(f) facilities will have four months to submit an application. EPA is therefore granting facilities that need to submit an application to continue to operate the unit pursuant to § 257.103 four months from the date of denial to submit their application. All other facilities must cease receipt of waste—either by the April 11, 2021 deadline (assuming EPA has issued its decision prior to the deadline) or by the revised deadline which will be included in the denial. This revised deadline will account for the amount of time EPA has taken to issue its decision. EPA has no basis to universally authorize the surface impoundment to continue operating for an additional six months in these circumstances. Those units that can close by the deadline must do so (*e.g.* because they have alternative capacity on site) or the facility must be treated the same as any other facility seeking an extension pursuant to § 257.103(f). Further discussion of the relationship of the timing of an application denial and the alternative closure standards is found in Unit III.D.3 below.

Therefore, EPA is revising § 257.71(d)(2)(vi) to remove the provision requiring the facility to initiate closure ''within six months of the denial.''

d. Multi-Unit Liner Demonstration

The 2015 CCR Rule allowed monitoring networks for CCR units to be designed with consideration of multi-unit systems (*i.e.,* multiple surface impoundments at one site) that share groundwater monitoring systems and other technical features. EPA made no reference to multi-unit systems in the proposed rule. Multiple commenters requested clarification on how ALD requirements would apply to these multi-unit systems. Specifically, commenters inquired whether facilities with multiple units can submit a single application and demonstration that covers all the units, or if documentation for each individual unit must be submitted separately.

Given that decisions about the design and implementation of these groundwater monitoring programs and such sites were made based on consideration of multiple units, EPA considers it to be reasonable that the ALD documentation could also include multiple units to reduce redundancy and ensure that each individual unit is discussed in the full context of the larger system. Further, given that these units are located in close proximity, the data generated for one is likely to be equally applicable to multiple units in the demonstration. For example, grouping data from wells around adjacent units will provide a more comprehensive picture of groundwater depth and flow around the wider facility. Therefore, EPA is amending the rule to make clear that a single application and demonstration may be submitted for multi-unit systems.

2. Demonstration Process

a. Deadline of Demonstration Submission

EPA proposed at § 257.71(d)(2)(i) that the facility would have one year from the date the application was due (*i.e.,* 13 months from the effective date of the final rule) to submit their alternate liner demonstration if EPA approved their application. The proposal also stated that if the owner or operator cannot meet this deadline due to analytical limitations related to the measurement of hydraulic conductivity, the owner or operator must submit a request for an extension no later than 90 days prior to the deadline for submission of the demonstration, that includes a summary of the data collected to date that show the progress towards relevant test termination criteria for all samples responsible for the delay, along with an alternate timeline for completion that has been certified by the laboratory.

One commenter stated that one year would not provide the amount of time needed to perform the robust analyses needed to provide greater certainty that the unit would pose no reasonable probability of adverse effects to human health or the environment. The commenter also stated that some of that one year would be spent waiting for a determination from EPA that the unit is eligible for an ALD. The commenter stated that this gave the facility only 10 months to prepare the ALD if they waited until their application was approved, and that would not be sufficient if they needed to install additional groundwater monitoring wells, validate fate and transport models, develop three-dimensional visualization to support conceptual site models, or establish background water quality to evaluate the potential effects for seasonality in the groundwater quality observations.

EPA does not agree with the commenter. First, a facility should not wait for application approval to start their demonstration work. Second, EPA is not requiring a facility to install additional monitoring wells or further characterize background water quality to support the demonstration. Facilities were required to have installed an appropriate number of monitoring wells and to adequately characterize background water quality to evaluate the potential effects for seasonality years ago under part 257. EPA is not granting additional time as part of this process for facilities to come into compliance with existing requirements. Finally, while three-dimensional visualization may be useful for EPA's review, it is not a requirement. Therefore, the Agency is not revising the amount of time given to develop the demonstration package.

EPA is finalizing § 257.71(d)(2)(i) to require facilities to have one year from the date the application was due to submit their alternate liner demonstration. Therefore,

demonstrations are due no later than November 30, 2021. Once the owner or operator submits the demonstration to EPA for approval, the owner or operator must place a copy into the facility's operating record and on its publicly accessible CCR internet site.

As mentioned above, EPA also proposed to allow extensions on the demonstration submittal deadline in the limited circumstance that it is not feasible for the lab to fully analyze the field samples by the demonstration deadline. EPA proposed that the request must be submitted no later than 90 days prior to the demonstration deadline. The proposal further stated that EPA or a Participating State Director would evaluate the information provided in the request and determine whether the duration of the requested extension is acceptable. EPA did not receive any comments that indicated the type of delay considered in the preamble was unreasonable or entirely avoidable. Some facilities requested additional information on the maximum duration of an extension, what information the facility should provide as part of the request, and whether extensions could be provided for any other reasons.

(i) Extension Due to Analytical Limitations for Chemical Equilibrium

EPA discussed in the proposal that extensions would be allowed on the condition that analytical limitations prevent the necessary data from being collected by the demonstration deadline. EPA specifically pointed to the fact that tests for hydraulic conductivity may take upwards of 300 days to complete for extremely low conductivity soils. It is important that these tests be allowed to run to completion because long-term changes to soil structure, such as flocculation of clay particles, can substantially alter the conductivity of the soil.

One commenter raised concerns that hydraulic conductivity tests for low permeability soils may take longer than the timeframe allotted for the demonstration but made no reference to the deadline extension discussed in the preamble. Another commenter requested clarification on the duration of an extension and what information should be provided as part of the request.

As acknowledged in the proposal, EPA understands that the test methods for hydraulic conductivity may take a considerable amount of time. EPA continues to believe it is critical that these tests are allowed to run to completion to ensure that effects of leachate chemistry on the liner integrity are identified. Therefore, EPA will allow a one-time extension on the deadline for submittal of the demonstration for analytical limitations associated with completing the hydraulic conductivity test. The duration of the extension will be determined solely by the time projected by the lab to achieve termination criteria for chemical equilibrium. These metrics will progress along either a linear or asymptotic curve as the composition of the effluent approaches that of the influent. Thus, it is reasonable, based on these curves and the rate of flow for the lab to estimate how long it will take to approach and maintain conditions for test termination for the necessary duration. EPA expects facilities that receive this extension will use this additional time to prepare all other necessary documentation so that, once the data is available, it will be a relatively straightforward task to run the model and document the results. Once the owner or operator receives the data, they will have 45 days beyond the timeframe certified by the laboratory for the facility to submit the completed demonstration.

In response to comments, EPA is finalizing amendments to clarify that, as part of the extension request, facilities must provide (1) a brief timeline of fieldwork to confirm that samples were collected expeditiously, (2) a chain of custody documenting when samples were sent to the laboratory, (3) written certification from the lab identifying how long it is projected for the necessary termination criteria to be met, and (4) documentation of the progression towards all termination metrics to date.

(ii) Other Analytical Limitations

One commenter requested clarification on what other types of analytical limitations EPA would be considered eligible for extension. However, the commenter did not provide a specific example of another type of analytical limitation that might warrant a similar extension.

It is possible that chemical interactions between the soil and leachate may cause the measured hydraulic conductivity to shift abruptly and substantially due to resulting changes in the soil structure. This shift may be substantial enough that it will take longer for the hydraulic conductivity to stabilize than it will for the chemistry of the system to reach equilibrium. This scenario may occur regardless of whether an extension has been provided to allow system chemistry to reach equilibrium. Yet, unlike chemical equilibrium between the influent and effluent, there is no predefined endpoint for hydraulic conductivity. As a result, there are no reasonable means to predict how much longer it will take for this parameter to fully stabilize. However, it is expected that the bulk of any changes to soil structure and hydraulic conductivity will have occurred by the time that the chemistry of the system has achieved equilibrium. This is because the primary driver of these changes, the exchange of ions between the soil and the leachate, is mostly complete. For this reason, EPA believes that the magnitude of any changes to hydraulic conductivity recorded by the time chemical equilibrium has been established can provide a reasonable upper bound on any future changes. Thus, rather than provide an unspecifiable amount of additional time to allow the hydraulic conductivity to fully stabilize, EPA concludes it is preferable in this case that the owner or operator complete the demonstration within the existing deadline with the available data. Use of appropriate bounds of uncertainty based on the magnitude of changes to hydraulic conductivity measured to date can ensure that long-term contaminant transport is not underestimated.

Therefore, EPA is finalizing amendments to the proposal to clarify that, if the measured hydraulic conductivity has not stabilized to within acceptable tolerance limits by the time the termination criteria for solution chemistry are met, the owner or operator must submit a preliminary demonstration within the existing deadline (with or without the one-time extension for analytical limitations). In this preliminary demonstration, the owner or operator must justify how the bounds of uncertainty applied to the available measurements of hydraulic conductivity ensure that the final value is not underestimated. The preliminary demonstration will be subject to all of the same process, notification and posting requirements of a final demonstration. EPA will review the preliminary demonstration to determine if it is complete and will propose to deny or to tentatively approve the demonstration. Once the final laboratory results are available, the owner or operator must submit a final demonstration that incorporates the finalized hydraulic conductivity data to confirm that the model results in the preliminary demonstration are accurate. Until the time that EPA takes final action on this final demonstration, the surface impoundment must stay in detection monitoring to remain eligible for an ALD. If EPA tentatively approved the preliminary demonstration, EPA will then take action on the newly

submitted final demonstration using the same procedures that apply to the initial determination. The public will have an opportunity to comment only on the new information presented in the complete final demonstration or in EPA's proposed decision on the revised demonstration.

(iii) Extension Request Deadline

EPA proposed that facilities must submit a request for an extension no later than 90 days before the deadline for submission of the demonstration. One commenter requested additional time to submit the request, stating that unforeseen issues might arise late in the demonstration process that necessitate an extension. The commenter did not elaborate on the types of delays that may occur so late in the process. In order to complete the demonstration on time, EPA expects facilities to collect the necessary field data expeditiously and long before the extension request deadline. The facility should be aware of and be able to plan for any complications associated with sample collection. Once data have been collected from the field and analyzed, the remaining modeling and documentation can be completed in the office where the risk of unavoidable delay is minimal. Indeed, much of the necessary documentation can be compiled concurrently with sample collection and analysis. EPA is maintaining the submission deadline for extension requests that the owner or operator of the CCR surface impoundment must submit the extension request no later than September 1, 2021. The owner or operator must also post this extension request on their publicly accessible CCR internet site.

b. Demonstration Review

EPA proposed at § 257.71(d)(2)(iii) that EPA or the Participating State Director will evaluate the demonstration package and may request additional information as necessary to complete its review. Submission of a complete demonstration package will continue to toll the facility's deadline to cease receipt of waste into that unit until issuance of a final decision under § 257.71(d)(2)(v). Incomplete submissions will cease tolling the facility's deadline. EPA also proposed at § 257.71(d)(2)(iv) that EPA or the Participating State Director will propose a decision on the demonstration and post that decision on EPA or Participating State Director's website for a 30-day public comment period. Finally, EPA proposed at § 257.71(d)(2)(v) that after consideration of the comments, EPA or the Participating State Director will make a final decision within four months of receiving the complete alternate liner demonstration and that if no substantive comments were received the decision would become automatically effective 5 days from the close of the comment. The facility must also post EPA's determination on its ALD to its publicly accessible CCR internet site.

Commenters pointed out that there appeared to be an unintended gap in tolling. The proposed regulatory text indicated that the deadline to cease receipt of waste would not be tolled during the period between approval of the initial application and the time the alternate liner demonstration package was submitted. That was not the Agency's intent. EPA intended that the deadline would be tolled during the entire time between an approved application and the final determination on the ALD. Accordingly, the regulatory text has been amended to make this clear.

EPA also received comments that the 30-day public comment period was too short to allow for sufficient opportunity for members of the public to review and comment on such highly complex, technical documents. EPA acknowledges that the public comment period is short but disagrees that it is too short to be meaningful. EPA is requiring facilities to post all submissions on their publicly accessible CCR internet site at the same time they submit them to EPA. The public can start their review at the same time as EPA and begin to gather information and prepare their comments. For similar reasons, EPA also disagrees that a 30-day comment period violates either the Administrative Procedures Act (APA) or RCRA 7004(b). This process is not a rulemaking, but an informal adjudication. Such adjudications do not typically include an opportunity for public comment and therefore the provision of a 30-day comment period meets the mandate in RCRA § 7004(b) to promote public participation. Moreover, the APA imposes neither a requirement to provide an opportunity for public comment nor any minimum time for a comment period for such procedures. Finally, EPA notes that the same commenters requesting longer comment periods have also raised concern that the process grants facilities too much additional time to continue operating. EPA is also interested in not granting undue amounts of additional time for facilities to continue operating and is expediting all aspects of this process, including the comment period. After reviewing the submission, EPA will post a proposed decision to grant or to deny the demonstration in the docket on *www.regulations.gov* for public notice and comment. EPA will also post the demonstration on its website.

One commenter stated that the regulations do not give the reviewing agency a deadline for approving or disapproving a submitted demonstration, so that such a demonstration can remain pending indefinitely. The Agency disagrees with that comment and is finalizing as proposed § 257.71(d)(2)(v) which states that EPA will evaluate the comments received and amend its decision as warranted within four months. EPA will post all final decisions on EPA's website and in the appropriate docket. The facility must post, along with a copy of its demonstration, the Agency's final decision on the facility's publicly accessible CCR internet site.

Finally, EPA is not finalizing the automatic five-day effective date for demonstrations with no substantive comments since this approach would be too difficult to implement.

c. Demonstration Denial

EPA proposed at § 257.71(d)(2)(vi) that if EPA or the Participating State Director determines that the unit's alternate liner does not meet the standard for approval, the owner or operator must cease receipt of waste and initiate closure within six months of the denial. If a facility needs to obtain alternative capacity, they may do so in accordance with the procedures in § 257.103.

Commenters were primarily concerned about the ability to pursue a capacity extension under § 257.103 if their ALD was denied.

If an ALD is denied and the facility lacks capacity, the owner or operator may apply for one of the site-specific alternative deadlines § 257.103(f)(1) or (f)(2) as described below. As discussed in that section the time frames for applying for those alternatives will be governed by § 257.103(f) rather than the six months contemplated by the proposal. By contrast, if the owner or operator chooses to not apply for § 257.103(f)(1) or (f)(2), for example, if they already have alternative capacity to manage their waste on site, then the surface impoundment must cease receipt of waste and initiate closure by the date specified in EPA's decision (which will be the date EPA determines that such actions are technically feasible).

3. Relationship to § 257.103(f)(1) and (f)(2) Alternative Closure Requirements

In the proposal, EPA stated that should a facility pursuing an ALD not have alternative capacity, the owner or operator must continue to actively pursue avenues of obtaining alternative capacity during the time they are pursuing the ALD. Commenters were concerned that this would put the owner or operator in the position of devoting resources to two parallel paths to seek an extension under both § 257.71(d) and under either § 257.103(f)(1) or (f)(2). The Agency understands that the facility will be required to expend resources on two parallel tracks, but continues to believe that owners or operators that are pursuing an ALD who lack alternative capacity in which to manage their wastes must actively work to attain that capacity during the ALD process. As discussed in more detail below, facilities will not be able to obtain more than the maximum time allowed under § 257.103(f); in order to meet these deadlines, facilities will need to be pursuing alternative capacity well before EPA would render a decision on their ALD. To do otherwise would create incentives for facilities to apply for an ALD as a means of obtaining additional time under § 257.103(f)(1) or (f)(2). Any owners or operators that are preparing to submit an ALD and whose facilities lack alternative capacity should therefore also be preparing to submit a demonstration of lack of capacity under either § 257.103(f)(1) or (f)(2) in the event their application is denied.

The current deadline for all facilities who lack capacity and wish to apply for the § 257.103(f)(1) or (f)(2) alternative closure requirements is November 30, 2020. That provides the owner or operator approximately 4 months from the signature date of the Part A final rule to submit the demonstration. Accordingly, if an application is rejected or an ALD is denied the owner or operator will be given four months to apply for either § 257.103(f)(1) or (f)(2). The facility's deadline to cease receipt of waste will be tolled during these four months to allow the owner or operator to develop the § 257.103(f)(1) or (f)(2) demonstration. Thereafter, consistent with the procedures adopted in § 257.103, the deadline to cease receipt of waste will continue to be tolled until the Agency determines whether the submission is incomplete or reaches a final decision. As stated earlier, the Part A final rule requires owners and operators to submit demonstrations under the alternative closure provisions of § 257.103(f)(1) or (f)(2) by November 30, 2020. To accommodate facilities whose application or alternative liner demonstration under § 257.71(d) is denied and who intend to submit a demonstration under the alternative closure provisions, the Agency is revising § 257.103(f)(3)(i)(A) and (C) to allow such demonstrations to be submitted after the deadline of November 30, 2020. Specifically, EPA is revising § 257.103(f)(3)(i)(A) and (C) by adding the clause ''Except as provided by § 257.71(d)(2)(iii)(E) and (viii),'' to each paragraph.

A facility may not be granted more time than the maximum that is provided in § 257.103(f)(1) or (f)(2), even if the owner or operator is applying for the alternate closure requirements after they are denied an ALD. Specifically, a unit that qualifies for alternate closure dates under § 257.103(f)(1) would still be required to cease receipt of waste no later than October 15, 2023. An eligible unlined surface impoundment granted a capacity extension must cease receiving CCR and/or non-CCR wastestreams no later than October 15, 2024. In order to continue to operate until October 15, 2024, the owner or operator must demonstrate that the unit meets the definition of an eligible unlined CCR surface impoundment. Units applying for an ALD that ultimately are granted alternate closure dates under § 257.103(f)(2) would need to cease operation of their coal fired boiler and complete closure of the surface impoundment no later than October 17, 2023 if they are 40 acres or smaller and by October 17, 2028 if they are larger than 40 acres.

4. Recertification

EPA discussed in the proposal that the approved demonstration will be effective for the remaining active life of the unit since the demonstration must show that the engineered liner and/or naturally occurring soil is sufficient to prevent adverse effects from the surface impoundment.

Several facilities and industry groups affirmed that a one-time demonstration is appropriate. Several other commenters argued that units should be required to periodically recertify the results of the ALD. One of these commenters cited to several studies to argue that onsite hydrogeologic conditions can shift suddenly and affect the performance of the liner. These commenters pointed to shifting land use and climate change as phenomena that could impact liner performance. The land uses envisioned by the commenter include increased agriculture or urban development. However, the commenters provided no direct explanation how these changes were expected to impact liner performance.

A study cited by this commenter noted that the climate change would primarily impact surface water, but that there could also be impacts to the quantity and quality of groundwater.[29] The most likely way in which this could impact liner performance would be a decrease in the depth to groundwater. However, the long-term trends considered by these and other studies are often projected out many decades into the future and are variable across the country. Portions of the country are projected to see a decrease in precipitation, while others are projected to see an increase through more intense storms, which may or may not translate to increased groundwater recharge. Similarly, the land uses cited would only further deplete groundwater through increased extraction for agriculture or increased runoff from more impervious surfaces. Regardless, the 2014 Risk Assessment found that variations in the water table height did not substantially shift high-end risks, particularly for the most mobile constituents. Therefore, there is no indication that shifts in the groundwater table would alter the conclusion whether continued operation of a surface impoundment in the near term is protective. In addition, depth to groundwater is a parameter that is routinely measured during all phases of groundwater monitoring and so it will be apparent without recertification if groundwater levels are rising. Changes to the background quality of groundwater that has no direct contact with the unit would have no effect on whether the unit remains protective. As a result, it is not apparent from the comments provided what would be further achieved by requiring facilities to periodically recertify the characterization of local hydrogeology. Therefore, EPA made no amendments to the requirements of the rule in response to this comment.

5. Loss of Authorization

EPA proposed at § 257.71(d)(2)(vii)(A) that authorization of an ALD could be rescinded at any time if the facility fails to maintain the performance standard or any other requirement of this rule. To identify the potential for a future exceedance of GWPS, the Agency proposed that facilities that trigger assessment monitoring would need to

[29] Green, T.R., M. Taniguchi, H. Kooi, J.J. Gurdak, D.M. Allen, K.M. Hiscock, H. Treidel, and A. Aureli. 2011. ''Beneath the Surface of Global Change: Impacts of Climate Change on Groundwater.'' Journal of Hydrology. 405:532–560.

conduct intra-well analyses on each downgradient well to identify any trends of increasing concentrations and this information would be included as part of subsequent groundwater monitoring reports. The proposal further stated that if there is evidence that the unit may exceed GWPS before source control measures were put in place (*e.g.,* dewatering, impermeable cap, clean closure), then the alternative liner authorization would be reconsidered.

EPA also proposed at § 257.71(d)(2)(vii)(B) that the onus would remain on the facility at all times to demonstrate that the unit meets the conditions for authorization of the ALD. The proposal further stated that EPA or the Participating State Director could, without further notice or process, deny or revoke the owner or operator's authorization if these conditions for qualification were no longer being met.

EPA received a number of comments on the proposed loss of authorization provisions. Some industry groups and facilities requested confirmation that an option is available to demonstrate whether increased groundwater concentrations are attributed to a source unrelated to the unit before authorization would be revoked. One facility claimed that it was inappropriate to rely on groundwater monitoring at all to determine compliance. Several environmental groups stated that use of GWPS to determine ongoing compliance is not protective, while several industry groups commented that use of trend analysis was not a reliable way to determine compliance.

a. Use of Groundwater Monitoring To Determine Ongoing Compliance

The proposed rule stated at § 257.71(d)(2)(vii)(A) that if at any time assessment monitoring pursuant to § 257.95 is triggered for the unit, the facility must conduct intra-well analyses on each well as part of subsequent groundwater monitoring reports to identify any trends of increasing concentrations. The proposal further explained that if trend analysis predicts there will be an exceedance of GWPS for any constituent, EPA or the Participating State Director would reconsider the authorization and may revoke it if source control measures could not be put in place while the unit continues to operate.

In response to that provision, one commenter stated it was inappropriate to rely on groundwater monitoring to determine whether a unit continued to meet the standards of the ALD because groundwater monitoring does not provide direct information about whether the conditions of the liner or site soils have changed. Instead, this commenter argued the rule should allow for an examination of changes to the liner itself, or changes in the site soils, hydrology or other site conditions evaluated in the demonstration.

EPA disagrees that groundwater monitoring is an inappropriate method by which to establish whether a unit remains in compliance with this rule. Groundwater monitoring provides direct evidence of the impoundment's impact on groundwater quality. Whether these impacts are a result of a material change to the liner is immaterial to the fact that those impacts have occurred. In addition, the commenter provided no indication of what types of examinations were envisioned, how these examinations would be triggered, how these examinations could be used to prove a unit remains protective, and how this all would proceed faster than groundwater monitoring. To address all of these issues, EPA proposed the use of trend analysis to identify the potential for harm before it would occur so that it can be addressed. Therefore, EPA maintains the requirement to base continued authorization of an ALD on the results of groundwater monitoring.

b. Trend Analysis

EPA proposed at § 257.71(d)(2)(vii)(A) that units with an approved ALD that have entered into assessment monitoring (*i.e.,* SSI of Appendix III) must conduct additional intra-well analysis to identify any increasing trends of Appendix IV constituents in groundwater. A positive trend can show that contaminant levels have gotten worse compared to earlier measurements from the same well. Understanding the nature of the trend, including the rate of increase per unit of time, allows estimation of how rapidly concentration levels are increasing. If the identified trendline is steep enough to result in an exceedance of GWPS within the timeframe required to complete closure of the unit, the facility would have to begin implementation of source control measures at that time.

The final rule adopts a provision that largely tracks the proposal. The final rule requires that if a unit with an approved ALD enters into assessment monitoring, the facility must, in addition to their regular groundwater monitoring, conduct additional intra-well analysis to identify any statistically significant trend of increasing concentrations of appendix IV constituents in groundwater. If the identified trendline is steep enough that it would result in an exceedance of a GWPS at any point during the active life of the unit, the facility must close the unit.[30] This final provision represents a change only for those units that have a geosynthetic liner; the proposal specified that units with only natural soil liners would be required to close at this point, as the agency was aware of no other effective option for source control. The Agency is expanding this requirement to units with geosynthetic liners in response to comments stating that the Agency lacked data to demonstrate that these liners can be effectively repaired.

Trend analysis will require collection of multiple samples to define whether and to what extent concentrations are changing over time. As discussed in the following Unit, EPA is requiring that the necessary samples be collected over the course of the following year; however, there is minimal risk that an impoundment able to obtain an ALD and that has no prior history of releases might trigger corrective action so soon after entering into assessment monitoring. As discussed previously, an SSI of Appendix III constituents is not an indication that adverse effects have occurred or will occur. An SSI only shows that there has been some increase in Appendix III constituents discernable from background, regardless of the magnitude. Multiple constituents on Appendix III were included on this list for their mobility in the environment and so provide the best early indicators that a release has occurred. As a result, at the time that an SSI is first identified, it is possible that there will not have been any associated increase in most Appendix IV constituents. This will be confirmed by the first sample collected within the initial 90-day window in accordance with the existing requirements in § 257.95(b). Any further increase in concentrations of Appendix IV constituents is expected to be gradual based on the documented low conductivity of the engineered liner and/or naturally occuring soil provided in the ALD. The fact that many of these alternately lined units will have operated for decades without ever leaving detection monitoring provides additional evidence that any releases

[30] The comparison of a projected concentration to groundwater standards is not a statistical test of significance because, without measurements of future groundwater concentrations, it is predicated on the assumption that the current trend will persist unchanged. Nevertheless, the fact that the impoundment has entered into assessment monitoring, there is a statistically significant trend of increasing concentration, and the current magnitude of that trend has the potential to result in a future exceedance of GWPS is considered sufficient evidence that a release has occurred and there is a reasonable probability that continued operation of the impoundment could adversely affect groundwater.

identified in the future are indeed slow moving or small in magnitude. It is possible for an impoundment to remain in assessment monitoring for the remainder of its operational life without ever exceeding GWPS. As demonstrated for composite-lined units in the 2014 Risk Assessment, releases can occur from even the most well-designed units and these units can remain protective for the duration of their active life.

EPA received a number of specific comments on the application of trend analysis. These comments and the revisions made to the proposed rule in response are discussed in the following Units of preamble.

(i) Identification of Trends

Commenters claimed that use of trend analysis is inconsistent and inferior to the statistical methods already required and do not meet the performance standards of § 257.93(g). Commenters stated that the proposal provided no guidance on how to identify trends and that the criteria used by EPA to determine that units were noncompliant would be subjective.

Trend analysis serves a distinct purpose from the other statistical methods. Methods detailed in § 257.93(f) for use in assessment monitoring are intended to identify whether groundwater concentrations have exceeded GWPS, while trend analysis, as used in this context, is intended to identify whether GWPS could be exceeded in the future. Trend analysis does not substitute for monitoring data and statistical evaluations already required by the rule. Trend tests are robust statistical methods and have previously been applied by the Agency both to provide evidence of plume migration and the need to expand the monitoring well network. EPA has previously developed guidance and tools to aid in applying trend analysis.[31] [32] Statistical identification of a positive trend involves testing the estimated slope coefficient from the regression trend line. Identification of a pattern of increase within the sampling record provides a reliable method to determine that concentrations have risen more than expected by chance alone. Once the trend is calculated, confidence limits around the trend line should be calculated to account for variability within the dataset. The upper 95th percentile confidence limit on the trend line must be used to ensure potential increases have not been underestimated. Use of the upper percentile is considered appropriate here because the goal is to prevent the impoundment entering into corrective action in the future. Waiting for the corresponding lower confidence limit to exceed GWPS to take action would provide greater certainty that an exceedance will occur by a certain time, but it would also make it far more likely that an exceedance could occur before then.

The final rule also includes a minimum sampling frequency to ensure that the number of samples collected is consistent with the data requirements in § 257.93(e). Four independent samples is generally considered the minimum number necessary to conduct meaningful statistical analysis on a trend. The first of these samples must be collected within 90 days of triggering assessment monitoring in accordance with § 257.95(b). The remaining three must be collected on a quarterly basis within a year of triggering assessment monitoring. After establishing this baseline from the initial sampling events, the subsequent monitoring frequency will be established in accordance with § 257.95(d). The trend analysis must be updated after each sampling event.

There will always be some degree of uncertainty associated with extrapolation of measured data into the future, with uncertainty increasing the further the trend is projected into the future. There is potential that reliance on trends can overestimate the potential of future exceedances. For example, it is possible that linearly increasing concentrations may eventually plateau at some level below GWPS. However, asymptotic conditions occur gradually and during that time concentrations continue to increase, albeit at a slower rate. Therefore, a decline in the slope of the trend does not itself ensure that GWPS will not eventually be exceeded. Additionally, there is no way to guarantee based on existing monitoring data that any plateau in current concentrations will be sustained in perpetuity. The timeframe required for trendline projection is commensurate with the uncertainty associated with closure, which is directly related to the size and complexity of the unit. Although full closure may take the full time projected, the initial steps of ceasing placement of new ash and dewatering the unit will have the greatest relative impact on releases by eliminating the primary mechanisms driving infiltration to the subsurface.

Therefore, EPA is adopting a provision at § 257.71(d)(2)(vii)(A) to ensure that the number of samples available will provide sufficient information to support decisions. Except as provided for in § 257.95(c), the owner or operator must collect a minimum of four independent samples from each well (background and downgradient) within one year of triggering assessment monitoring and analyze each sample for all Appendix IV constituents.[33] After the initial sampling period, monitoring may revert to the previously established frequency.

EPA is also finalizing a requirement at § 257.71(d)(2)(vii)(A)(*1*) to clarify that the owner or operator of the CCR unit must apply an appropriate statistical test to identify trends within the monitoring data. For normal distributions of data, linear regression will be used to identify the presence and magnitude of any trends. For non-normal distributions of data, the Mann-Kendall test will be used to identify the presence of a trend and the Theil-Sen trend line will be used to determine the associated magnitude. The test used shall comply, as appropriate, with the performance standards in § 257.93(g). If a trend is identified, the facility will use the upper 95th percentile confidence limit on the trend line to determine if GWPS could be exceeded in the future. The facility will project this trend line into the future for a duration set to the maximum number of years allowed for closure of the surface impoundment pursuant to § 257.102.

The owner or operator must submit to EPA a report of the results of each sampling event, as well as the initial trend analysis and they must include all data relied upon by the facility to support the analysis. The reports and the final trend analysis must be posted to the facility's publicly accessible CCR internet site and submitted to EPA within 14 days of completion. EPA will publish a proposed decision on the trend analysis on *www.regulations.gov* for a 30-day comment period. After consideration of the comments, EPA will issue its decision. If the trend analysis shows the potential for a future exceedance of a groundwater protection standard the CCR surface impoundment must cease receipt of waste pursuant to the withdrawal notice. Furthermore, if at any time the unit exceeds any GWPS, the authorization will be withdrawn.

[31] U.S. EPA. 2009. ''Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities Unified Guidance.'' EPA 530–R–09–007. Prepared by the Office of Solid Waste and Emergency Response. Washington, DC. March.

[32] U.S. EPA. 2018. ''Groundwater Statistics Tool User's Guide.'' Prepared by the Office of Solid Waste and Emergency Response. Washington, DC. September.

[33] U.S. EPA. 2018. ''Groundwater Statistics Tool User's Guide.'' Prepared by the Office of Solid Waste and Emergency Response. Washington, DC. September.

(ii) Alternative Source Demonstrations Under § 257.94(e)

Under an approved alternative liner demonstration, EPA proposed that if groundwater monitoring detects a statistically significant increase of any Appendix III constituent, the facility would need to complete an alternative source demonstration pursuant to § 257.94(e) or initiate assessment monitoring pursuant to § 257.95. 85 FR 12462 (March 3, 2020). In response to the proposal, commenters noted that the proposed regulatory text did not include a specific provision allowing for alternative source demonstrations to be made under § 257.94(e) prior to proceeding to assessment monitoring. These commenters requested the final rule include such regulatory text. These commenters further requested that the final rule allow facilities the opportunity to complete an alternative source demonstration when an Appendix IV constituent is detected at statistically significant levels above a GWPS pursuant to § 257.95(g) prior to initiating corrective action activities.

The current regulations provide facilities the opportunity under each phase of the groundwater monitoring program to demonstrate that a source other than the CCR unit caused the increase in groundwater concentrations for a constituent or that the increase resulted from an error in sampling, analysis, statistical evaluation, or natural variation in groundwater quality. §§ 257.94(e) and 257.95(g). The final rule does not eliminate the opportunity for an owner or operator to make an alternative source demonstration for an Appendix III constituent pursuant to § 257.94(e), but the Agency has amended it slightly for units with an ALD. Similar to the provision at 257.95(g), the unit with an ALD may pursue an alternate source demonstration simultaneously while conducting the trend analysis. Given that it will take close to a year to complete a trend analysis, EPA considers that waiting an additional 90 days to commence the trend analysis is not warranted in this circumstance. As a consequence, the Agency agrees with commenters that the rule should include a specific provision allowing for alternative source demonstrations to be made under § 257.94(e). This regulatory text is codified in § 257.71(d)(2)(ix)(A)(*1*) in the final rule.

EPA disagrees with commenters that the rule should allow for alternative source demonstrations in the assessment monitoring program under § 257.95(g) when an Appendix IV constituent is detected at a statistically significant level. First, because the purpose of the requirement to close based on the trend analysis is to ensure that no Appendix IV constituent is detected at a statistically significant level, the provision at § 257.95(g) should never be triggered while the unit is operating under an alternative liner demonstration. Nor is it likely that an alternative source of contamination will be present that had not been discovered previously as a consequence of the detection of a statistically significant increase of one or more Appendix III constituents. Finally, while the Agency does agree that the risk of drawing incorrect conclusions about unit performance based on the presence of an error is equally applicable to the trend analysis conducted during assessment monitoring, EPA believes it is more appropriate for the facility to address such errors in the trends analysis sampling results report required under § 257.71(d)(2)(ix)(B). Therefore, the final rule does not allow owners and operators to make use of the alternative source demonstration provisions under § 257.95(g) while operating under the alternative liner demonstration provisions.

If an owner or operator pursuing an alternative liner demonstration makes a successful alternative source demonstration for an Appendix III constituent pursuant to § 257.94(e), the final rule requires the owner or operator to submit the alternative source demonstration to EPA for review and approval. The Agency is requiring review and approval of alternative source demonstrations because a successful demonstration under § 257.94(e) allows a CCR unit to continue with the detection monitoring program instead of progressing to an assessment monitoring program. EPA is finalizing this requirement at § 257.71(d)(2)(ix)(A)(*4*).

The owner or operator must post the alternative source demonstration to the facility's publicly accessible CCR internet site and submit it to EPA for review and approval within 14 days of completing the demonstration. EPA will publish a proposed decision on the alternative source demonstration on *www.regulations.gov* for a 20-day comment period. After consideration of the comments, EPA will issue its decision. If the alternative source demonstration is approved by EPA, the owner operator may return to detection monitoring under § 257.94 and cease conducting the trend analysis. If the alternative source demonstration is denied by EPA, the owner or operator must either complete the trend analysis or cease receipt of waste and initiate closure of the unit, as well as initiating an assessment monitoring program as provided by § 257.94(e). See § 257.71(d)(2)(ix)(A)(*5*).

(iii) Source Control

In the proposed rule EPA explained that if there was evidence that the groundwater concentrations may exceed the groundwater protection standard for any Appendix IV constituent within the operational life of the CCR unit, EPA or the Participating State Director would reevaluate the authorization and may revoke it if source control measures could not be put in place while the unit continues to operate. 85 FR 12462, 12477 (March 3, 2019). EPA further explained that for units without a geomembrane liner the only source control that would be effective was the unit to cease receipt of waste and initiate closure.

Several commenters stated that the proposed rule contemplates repair of clay-lined impoundments as part of source control. These commenters further explained that the available record does not support the conclusion that a clay-lined surface impoundment can be repaired successfully. These commenters also raised the concern that proposal procedures were deficient in that facilities were not required to provide evidence of liner repairability in order to continue to operate. Commenters also stated that the proposed source control provisions would cause harmful delays in closure of unlined impoundments by providing additional time for a facility to continue operating while attempting to put source controls in place after detection of a groundwater protection standard exceedance. EPA received no comments that contradicted the agency's conclusion that closure is the only method of source control that would be effective for units with a natural soil-based liner.

After reviewing the record again, EPA agrees that the agency failed to identify any data to demonstrate that the source of a leak from an impoundment that receives an ALD can be identified and repaired. Therefore, the final rule treats units with a geomembrane the same as impoundments that rely on only a natural soil-based liner and requires them to close upon a determination that a GWPS will be exceeded during the active life of the unit.

IV. Corrections to §§ 257.102 and 257.103

A. Correction to the Alternative Final Cover System Requirements

EPA proposed to revise the alternative final cover system requirements under § 257.102(d)(3)(ii) to correct a typographical error (85 FR 12468, March 3, 2020). In the introductory text to § 257.102(d)(3)(ii), the regulations provide that the ''owner or operator may select an alternative final cover system design, provided the alternative final cover system is designed and constructed to meet the criteria in paragraphs (f)(3)(ii)(A) through (D) . . .'' EPA explained in the proposal that the reference to paragraphs (f)(3)(ii)(A) through (D) is an incorrect cross-reference approval and that the correct cross-reference should be to the criteria in paragraphs (d)(3)(ii)(A) through (C). The Agency received no comments in response to this proposed change. In this action, EPA is finalizing the proposal to revise the introductory text of § 257.102(d)(3)(ii).

B. Revisions to the Alternative Closure Requirements

EPA recently promulgated amendments to the alternative closure requirements under § 257.103 that provide closure options in situations where an owner or operator is closing a CCR unit but has no alternative disposal capacity or is permanently closing the coal-fired boiler in the foreseeable future (85 FR 53516, August 28, 2020)(''Part A final rule''). Since publication of the Part A final rule, the Agency has identified a typographical error in the regulatory text. This error is being corrected in this final rule and are described below.

1. Correction to § 257.103(f)(1)(vi)

Section 257.103(f)(1)(vi) establishes maximum time frames that wastes may be managed in a CCR surface impoundment while operating pursuant to the alternative closure provisions under § 257.103(f)(1). The regulatory text under § 257.103(f)(1)(vi) provides that ''All CCR surface impoundments covered by this *section* must cease receiving waste by the deadlines specified . . .'' (emphasis added). As discussed in the Part A final rule, the maximum time frames provided for in § 257.103(f)(1)(vi) only apply to impoundments operating under § 257.103(f)(1); however, the use of the term ''section'' in this regulatory text could be interpreted incorrectly to apply also to other provisions under § 257.103, such as the alternative closure provisions under § 257.103(f)(2). Therefore, EPA is replacing the word ''section'' in the introductory text of § 257.103(f)(1)(vi) with ''paragraph (f)(1)'' to reflect the intent of the provision.

V. Rationale for 30-Day Effective Date

The effective date of this rule is 30 days after publication in the **Federal Register**. With some exceptions (see 5 U.S.C. 553(a),(d)), the Administrative Procedure Act (APA) provides that publication of a substantive rule shall be made not less than 30 days before its effective date and that this provision applies in the absence of a specific statutory provision establishing an effective date. See 5 U.S.C. 553(d) and 559. EPA has determined there is no specific provision of RCRA addressing the effective date of regulations that would apply here, and thus the APA's 30-day effective date applies.

EPA has previously interpreted section 4004(c) of RCRA to generally establish a six-month effective date for rules issued under subtitle D. See 80 FR 37988, 37990 (July 2, 2015). After further consideration, EPA interprets section 4004(c) to establish an effective date solely for the regulations that were required to be promulgated under subsection (a). Section 4004(c) is silent as to subsequent revisions to those regulations; EPA therefore believes section 4004(c) is ambiguous.

Section 4004(c) states that the prohibition in subsection (b) shall take effect six months after promulgation of regulations under subsection (a). Subsection (a), in turn provides that ''[n]ot later than one year after October 21, 1976 . . . [EPA] shall promulgate regulations containing criteria for determining which facilities shall be classified as sanitary landfills and which shall be classified as open dumps within the meaning of this chapter.'' As noted, section 4004(c) is silent as to revisions to those regulations.

In response to Congress's mandate in section 4004(a), EPA promulgated regulations on September 13, 1979. 44 FR 53438. EPA interprets section 4004(c) to establish an effective date applicable only to that action, and not to future regulations the Agency might issue under this section. In the absence of a specific statutory provision establishing an effective date for this rule, APA section 553(d) applies.

EPA considers that its interpretation is reasonable because there is no indication in RCRA or its legislative history that Congress intended for the agency to have less discretion under RCRA subtitle D than it would have under the APA to establish a suitable effective date for subsequent rules issued under section 4004(c). Consistent with EPA's interpretation of the express language of section 4004, EPA interprets statements in the legislative history, explaining that section 4004(c) provides that the effective date is to be 6 months after the date of promulgation of regulations, as referring to the initial set of regulations required by Congress to be promulgated not later than 1 year after October 21, 1976. These statements do not mandate a 6 month effective date for every regulatory action that EPA takes under this section. This rule contains specific, targeted revisions to the 2015 rule and the legislative history regarding section 4004 speaks only to these initial 1976 mandated regulations.

This reading allows the Agency to establish an effective date appropriate for the nature of the regulation promulgated, which is what EPA believes Congress intended. EPA further considers that the minimum 30-day effective date under the APA is reasonable in this circumstance where none of the provisions being finalized require an extended period of time for regulated entities to comply.

VI. Effect of This Final Rule on States With Approved CCR Programs

This final rule has impacts on states with an approved program. As of this final rule, EPA has granted approvals to the states of Oklahoma and Georgia.

Oklahoma and Georgia were each granted approval for § 257.71, and their regulations continue to operate without change in lieu of the federal program. In essence this means that the revisions promulgated in this rule making will not take effect in either of these states until such time as Oklahoma or Georgia revises the program to adopt them.

EPA has determined that this rule is not more stringent than the current regulations in 40 CFR Subpart D. As a consequence, neither state is required to adopt these provisions in order to maintain program approval. See, RCRA section 4005(d)(1)(D)(i)(II).

The process for approving Oklahoma or Georgia's modifications is the same as for the initial program approval: EPA will propose to approve or deny the program modification and hold a public hearing during the comment period. EPA will then issue the final program determination within 180 days of determining that the state's submission is complete.

VII. The Projected Economic Impacts of This Action

A. Introduction

EPA estimated the costs and benefits of this action in a Regulatory Impact

Analysis (RIA) which is available in the docket for this action. The RIA estimates that the net annualized impact of this proposed regulatory action over a 100-year period of analysis will be annual cost savings of approximately $ 4.0 million to $ 8.0 million when discounting at 7% and approximately $ 2.2 million to $ 4.5 million when discounting at 3%. This action is not considered an economically significant action under Executive Order 12866.

B. Affected Universe

The rule potentially affects coal fired electric utility plants (assigned to the utility sector North American Industry Classification System (NAICS) code 221112) that dispose of their waste onsite in surface impoundments. The universe consists of approximately 523 surface impoundments at 229 facilities.

C. Costs, Cost Savings, and Benefits of the Final Rule

The Alternative Liner Demonstration finalized in this rule results in paperwork costs associated with submitting an application for demonstration and, if approved, the required demonstration. Provision One also results in cost savings associated with delays in closure of units (*i.e.,* time value of money savings). Overall, the RIA estimates that the time value of money cost savings will be greater than the paperwork costs, making this a net cost savings rule of approximately $4.0 million to $8.0 million per year when discounting at 7% and approximately $2.2. million to $4.5 million per year when discounting at 3%.

The rule is not anticipated to result in impacts to benefits. A qualitative discussion of benefits is available in Chapter 3 of the RIA, which can be found in the docket for this rulemaking.

VIII. Executive Orders

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

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because it raises novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is available in the docket and is summarized in Unit VII of this preamble.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2609.02. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

The information to be collected as a part of this rule includes demonstrations that must be made to EPA by owners and operators of units that seek to obtain an alternate liner demonstration under § 257.71(d). These demonstrations will show that the unit in question meets the necessary criteria to receive the extension.

Respondents/affected entities: Coal-fired electric utility plants that will be affected by the rule.

Respondent's obligation to respond: The recordkeeping, notification, and posting are mandatory as part of the minimum national criteria being promulgated under Sections 1008, 4004, and 4005(a) of RCRA.

Estimated number of respondents: 7.

Frequency of response: The frequency of response varies.

Total estimated burden: EPA estimates the total annual burden to respondents to be an increase in burden of approximately 2,179 hours from the currently approved burden. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $900,000 (per year), includes $0 annualized capital costs and $785,000 annualized operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This action is expected to result in net cost savings of approximately $4.0 million to $8.0 million per year when discounting at 7% and $2.2 million to $4.5 million per year when discounting at 3%. These cost savings will accrue to all regulated entities. We have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

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

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications as specified in Executive Order 13175. This action does not impose substantial direct compliance costs or otherwise have a substantial direct effect on one or more Indian tribes, to the best of EPA's knowledge. Neither will it have substantial direct effects on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health risks or safety risks addressed by

this action present a disproportionate risk to children. This action's health and risk assessments are contained in the document titled ''Human and Ecological Risk Assessment of Coal Combustion Residuals,'' which is available in the docket for the final rule as docket item EPA–HQ–RCRA–2009–0640–11993.

As ordered by E.O. 13045 Section 1–101(a), for the ''Final Rule: Hazardous and Solid Waste Management System; Disposal of Coal Combustion Residuals from Electric Utilities'' published April 17, 2015 (80 FR 21302), EPA identified and assessed environmental health risks and safety risks that may disproportionately affect children in the revised risk assessment. The results of the screening assessment found that risks fell below the criteria when wetting and run-on/runoff controls required by the rule are considered. Under the full probabilistic analysis, composite liners required by the rule for new waste management units showed the ability to reduce the 90th percentile child cancer and non-cancer risks for the groundwater to drinking water pathway to well below EPA's criteria. Additionally, the groundwater monitoring and corrective action required by the rule reduced risks from current waste management units. This action does not adversely affect these requirements and EPA believes that this rule will be protective of children's health.

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

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. For the 2015 CCR rule, EPA analyzed the potential impact on electricity prices relative to the ''in excess of one percent'' threshold. Using the Integrated Planning Model (IPM), EPA concluded that the 2015 CCR Rule may increase the weighted average nationwide wholesale price of electricity between 0.18 percent and 0.19 percent in the years 2020 and 2030, respectively. As the final rule represents a cost savings rule relative to the 2015 CCR rule, this analysis concludes that any potential impact on wholesale electricity prices will be lower than the potential impact estimated of the 2015 CCR rule; therefore, this final rule is not expected to meet the criteria of a ''significant adverse effect'' on the electricity markets as defined by Executive Order 13211.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in EPA's Regulatory Impact Analysis (RIA) for the CCR rule which is available in the docket for the 2015 CCR final rule as docket item EPA–HQ–RCRA–2009–0640–12034.

The EPA's risk assessment did not separately evaluate either minority or low-income populations. However, to evaluate the demographic characteristics of communities that may be affected by the CCR rule, the RIA compares the demographic characteristics of populations surrounding coal-fired electric utility plants with broader population data for two geographic areas: (1) One-mile radius from CCR management units (*i.e.,* landfills and impoundments) likely to be affected by groundwater releases from both landfills and impoundments; and (2) watershed catchment areas downstream of surface impoundments that receive surface water run-off and releases from CCR impoundments and are at risk of being contaminated from CCR impoundment discharges (*e.g.,* unintentional overflows, structural failures, and intentional periodic discharges).

For the population as a whole 24.8 percent belong to a minority group and 11.3 percent falls below the Federal Poverty Level. For the population living within one mile of plants with surface impoundments 16.1 percent belong to a minority group and 13.2 percent live below the Federal Poverty Level. These minority and low-income populations are not disproportionately high compared to the general population. The percentage of minority residents of the entire population living within the catchment areas downstream of surface impoundments is disproportionately high relative to the general population *i.e.,* 28.7 percent, versus 24.8 percent for the national population. Also, the percentage of the population within the catchment areas of surface impoundments that is below the Federal Poverty Level is disproportionately high compared with the general population, *i.e.,* 18.6 percent versus 11.3 percent nationally.

Comparing the population percentages of minority and low income residents within one mile of landfills to those percentages in the general population, EPA found that minority and low-income residents make up a smaller percentage of the populations near landfills than they do in the general population, *i.e.,* minorities comprised 16.6 percent of the population near landfills versus 24.8 percent nationwide and low-income residents comprised 8.6 percent of the population near landfills versus 11.3 percent nationwide. In summary, although populations within the catchment areas of plants with surface impoundments appear to have disproportionately high percentages of minority and low-income residents relative to the nationwide average, populations surrounding plants with landfills do not. Because landfills are less likely than impoundments to experience surface water run-off and releases, catchment areas were not considered for landfills.

The CCR rule is risk-reducing with reductions in risk occurring largely within the surface water catchment zones around, and groundwater beneath, coal-fired electric utility plants. Since the CCR rule is risk-reducing and this action does not add to risks, this action will not result in new disproportionate risks to minority or low-income populations.

L. Congressional Review Act (CRA)

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

List of Subjects in 40 CFR Part 257

Environmental protection, Beneficial use, Coal combustion products, Coal combustion residuals, Coal combustion waste, Disposal, Hazardous waste, Landfill, Surface impoundment.

Andrew Wheeler,

Administrator.

For the reasons set out in the preamble, EPA amends 40 CFR part 257 as follows:

PART 257—CRITERIA FOR CLASSIFICATION OF SOLID WASTE DISPOSAL FACILITIES AND PRACTICES

■ 1. The authority citation for part 257 continues to read as follows:

Authority: 42 U.S.C. 6907(a)(3), 6912(a)(1), 6944, 6945(a) and (d); 33 U.S.C. 1345(d) and (e).

■ 2. Amend § 257.71 by adding paragraph (d) to read as follows:

§ 257.71 Liner design criteria for existing CCR surface impoundments.

* * * * *

(d) *Alternate Liner Demonstration.* An owner or operator of a CCR surface impoundment constructed without a composite liner or alternate composite liner, as defined in § 257.70(b) or (c), may submit an Alternate Liner Demonstration to the Administrator or the Participating State Director to demonstrate that based on the construction of the unit and surrounding site conditions, that there is no reasonable probability that continued operation of the surface impoundment will result in adverse effects to human health or the environment. The application and demonstration must be submitted to the Administrator or the Participating State Director no later than the relevant deadline in paragraph (d)(2) of this section. The Administrator or the Participating State Director will act on the submissions in accordance with the procedures in paragraph (d)(2) of this section.

(1) *Application and alternative liner demonstration submission requirements.* To obtain approval under this paragraph (d), the owner or operator of the CCR surface impoundment must submit all of the following:

(i) *Application.* The owner or operator of the CCR surface impoundment must submit a letter to the Administrator or the Participating State Director, announcing their intention to submit a demonstration under paragraph (d)(1)(ii) of this section. The application must include the location of the facility and identify the specific CCR surface impoundment for which the demonstration will be made. The letter must include all of the following:

(A) A certification signed by the owner or operator that the CCR unit is in full compliance with this subpart except for § 257.71(a)(1);

(B) Documentation supporting the certification required under paragraph (d)(1)(i)(A) of this section that includes all the following:

(*1*) Documentation that the groundwater monitoring network meets all the requirements of § 257.91. This must include documentation that the existing network of groundwater monitoring wells is sufficient to ensure detection of any groundwater contamination resulting from the impoundment, based on direction of flow, well location, screening depth and other relevant factors. At a minimum, the documentation must include all of the following:

(*i*) Map(s) of groundwater monitoring well locations in relation to the CCR unit(s) that depict the elevation of the potentiometric surface and the direction(s) of groundwater flow across the site;

(*ii*) Well construction diagrams and drilling logs for all groundwater monitoring wells;

(*iii*) Maps that characterize the direction of groundwater flow accounting for temporal variations; and

(*iv*) Any other data and analyses the owner or operator of the CCR surface impoundment relied upon when determining the design and location of the groundwater monitoring network.

(*2*) Documentation that the CCR surface impoundment remains in detection monitoring pursuant to § 257.94 as a precondition for submitting an application. This includes documentation that the groundwater monitoring program meets the requirements of §§ 257.93 and 257.94. Such documentation includes data of constituent concentrations, summarized in table format, at each groundwater monitoring well monitored during each sampling event, and documentation of the most recent statistical tests conducted, analyses of the tests, and the rationale for the methods used in these comparisons. As part of this rationale, the owner or operator of the CCR surface impoundment must provide all data and analyses relied upon to comply with each of the requirements of this part;

(*3*) Documentation that the unit meets all the location restrictions under §§ 257.60 through 257.64;

(*4*) The most recent structural stability assessment required at § 257.73(d); and

(*5*) The most recent safety factor assessment required at § 257.73(e).

(C) Documentation of the design specifications for any engineered liner components, as well as all data and analyses the owner or operator of the CCR surface impoundment relied on when determining that the materials are suitable for use and that the construction of the liner is of good quality and in-line with proven and accepted engineering practices.

(D) Facilities with CCR surface impoundments located on properties adjacent to a water body must demonstrate that there is no reasonable probability that a complete and direct transport pathway (*i.e.,* not mediated by groundwater) can exist between the impoundment and any nearby water body. If the potential for such a pathway is identified, then the unit would not be eligible to submit a demonstration. If ongoing releases are identified, the owner or operator of the CCR unit must address these releases in accordance with § 257.96(a); and

(E) Upon submission of the application and any supplemental materials submitted in support of the application to the Administrator or the Participating State Director, the owner or operator must place the complete application in the facility's operating record as required by § 257.105(f)(14).

(ii) *Alternate Liner Demonstration Package.* The completed alternate liner demonstration package must be certified by a qualified professional engineer. The package must present evidence to demonstrate that, based on the construction of the unit and surrounding site conditions, there is no reasonable probability that operation of the surface impoundment will result in concentrations of constituents listed in appendix IV to this part in the uppermost aquifer at levels above a groundwater protection standard. For each line of evidence, as well as any other data and assumptions incorporated into the demonstration, the owner or operator of the CCR surface impoundment must include documentation on how the data were collected and why these data and assumptions adequately reflect potential contaminant transport from that specific impoundment. The alternate liner demonstration at a minimum must contain all of the following lines of evidence:

(A) *Characterization of site hydrogeology.* A characterization of the variability of site-specific soil and hydrogeology surrounding the surface impoundment that will control the rate and direction of contaminant transport from the impoundment. The owner or operator must provide all of the following as part of this line of evidence:

(*1*) Measurements of the hydraulic conductivity in the uppermost aquifer from all monitoring wells associated with the impoundment(s) and discussion of the methods used to obtain these measurements;

(*2*) Measurements of the variability in subsurface soil characteristics collected from around the perimeter of the CCR surface impoundment to identify regions of substantially higher conductivity;

(*3*) Documentation that all sampling methods used are in line with recognized and generally accepted practices that can provide data at a spatial resolution necessary to adequately characterize the variability

of subsurface conditions that will control contaminant transport;

(*4*) Explanation of how the specific number and location of samples collected are sufficient to capture subsurface variability if:

(*i*) Samples are advanced to a depth less than the top of the groundwater table or 20 feet beneath the bottom of the nearest water body, whichever is greater, and/or

(*ii*) Samples are spaced further apart than 200 feet around the impoundment perimeter;

(*5*) A narrative description of site geological history; and

(*6*) Conceptual site models with cross-sectional depictions of the site environmental sequence stratigraphy that include, at a minimum:

(*i*) The relative location of the impoundment with depth of ponded water noted;

(*ii*) Monitoring wells with screening depth noted;

(*iii*) Depiction of the location of other samples used in the development of the model;

(*iv*) The upper and lower limits of the uppermost aquifer across the site;

(*v*) The upper and lower limits of the depth to groundwater measured from monitoring wells if the uppermost aquifer is confined; and

(*vi*) Both the location and geometry of any nearby points of groundwater discharge or recharge (*e.g.,* surface water bodies) with potential to influence groundwater depth and flow measured around the unit.

(B) *Potential for infiltration.* A characterization of the potential for infiltration through any soil-based liner components and/or naturally occurring soil that control release and transport of leachate. All samples collected in the field for measurement of saturated hydraulic conductivity must be sent to a certified laboratory for analysis under controlled conditions and analyzed using recognized and generally accepted methodology. Facilities must document how the selected method is designed to simulate on-site conditions. The owner or operator must also provide documentation of the following as part of this line of evidence:

(*1*) The location, number, depth, and spacing of samples relied upon is supported by the data collected in paragraph (d)(1)(ii)(A) of this section and is sufficient to capture the variability of saturated hydraulic conductivity for the soil-based liner components and/or naturally occurring soil;

(*2*) The liquid used to pre-hydrate the samples and measure long-term hydraulic conductivity reflects the pH and major ion composition of the CCR surface impoundment porewater;

(*3*) That samples intended to represent the hydraulic conductivity of naturally occurring soils (*i.e.,* not mechanically compacted) are handled in a manner that will ensure the macrostructure of the soil is not disturbed during collection, transport, or analysis; and

(*4*) Any test for hydraulic conductivity relied upon includes, in addition to other relevant termination criteria specified by the method, criteria that equilibrium has been achieved between the inflow and outflow, within acceptable tolerance limits, for both electrical conductivity and pH.

(C) *Mathematical model to estimate the potential for releases.* Owners or operators must incorporate the data collected for paragraphs (d)(1)(ii)(A) and (d)(1)(ii)(B) of this section into a mathematical model to calculate the potential groundwater concentrations that may result in downgradient wells as a result of the impoundment. Facilities must also, where available, incorporate the national-scale data on constituent concentrations and behavior provided by the existing risk record. Application of the model must account for the full range of site current and potential future conditions at and around the site to ensure that high-end groundwater concentrations have been effectively characterized. All of the data and assumptions incorporated into the model must be documented and justified.

(*1*) The models relied upon in this paragraph (d)(1)(ii)(C) must be well-established and validated, with documentation that can be made available for public review.

(*2*) The owner or operator must use the models to demonstrate that, for each constituent in appendix IV of this part, there is no reasonable probability that the peak groundwater concentration that may result from releases to groundwater from the CCR surface impoundment throughout its active life will exceed the groundwater protection standard at the waste boundary.

(*3*) The demonstration must include the peak groundwater concentrations modeled for all constituents in appendix IV of this part attributed both to the impoundment in isolation and in addition to background.

(D) Upon submission of the alternative liner demonstration to the Administrator or the Participating State Director, the owner or operator must place the complete demonstration in the facility's operating record as required by § 257.105(f)(15).

(2) *Procedures for adjudicating requests*—(i) *Deadline for application submission.* The owner or operator must submit the application under paragraph (d)(1)(i) of this section to EPA or the Participating State Director for approval no later than November 30, 2020.

(ii) *Deadline for demonstration submission.* If the application is approved the owner or operator must submit the demonstration required under paragraph (d)(1)(ii) of this section to EPA or the Participating State Director for approval no later than November 30, 2021.

(A) *Extension due to analytical limitations.* If the owner or operator cannot meet the demonstration deadline due to analytical limitations related to the measurement of hydraulic conductivity, the owner or operator must submit a request for an extension no later than September 1, 2021 that includes a summary of the data that have been analyzed to date for the samples responsible for the delay and an alternate timeline for completion that has been certified by the laboratory. The extension request must include all of the following:

(*1*) A timeline of fieldwork to confirm that samples were collected expeditiously;

(*2*) A chain of custody documenting when samples were sent to the laboratory;

(*3*) Written certification from the lab identifying how long it is projected for the tests to reach the relevant termination criteria related to solution chemistry, and

(*4*) Documentation of the progression towards all test termination metrics to date.

(B) *Length of extension.* If the extension is granted, the owner or operator will have 45 days beyond the timeframe certified by the laboratory to submit the completed demonstration.

(C) *Extension due to analytical limitations for chemical equilibrium.* If the measured hydraulic conductivity has not stabilized to within acceptable tolerance limits by the time the termination criteria for solution chemistry are met, the owner or operator must submit a preliminary demonstration no later than September 1, 2021 (with or without the one-time extension for analytical limitations).

(*1*) In this preliminary demonstration, the owner or operator must submit a justification of how the bounds of uncertainty applied to the available measurements of hydraulic conductivity ensure that the final value is not underestimated.

(*2*) EPA will review the preliminary demonstration to determine if it is

complete and, if so, will propose to deny or to tentatively approve the demonstration. The proposed determination will be posted in the docket on *www.regulations.gov* and will be available for public comment for 30 days. After consideration of the comments, EPA will issue its decision on the application within four months of receiving a complete preliminary demonstration.

(*3*) Once the final laboratory results are available, the owner or operator must submit a final demonstration that updates only the finalized hydraulic conductivity data to confirm that the model results in the preliminary demonstration are accurate.

(*4*) Until the time that EPA approves this final demonstration, the surface impoundment must remain in detection monitoring or the demonstration will be denied.

(*5*) If EPA tentatively approved the preliminary demonstration, EPA will then take action on the newly submitted final demonstration using the procedures in paragraphs (d)(2)(iv) through (vi) of this section.

(*6*) The public will have 30 days to comment but may comment only on the new information presented in the complete final demonstration or in EPA's tentative decision on the newly submitted demonstration.

(D) Upon submission of a request for an extension to the deadline for the demonstration due to analytical limitations pursuant to paragraph (d)(2)(ii)(A) of this section, the owner or operator must place the alternative liner demonstration extension request in the facility's operating record as required by § 257.105(f)(16).

(E) Upon submission of a preliminary demonstration pursuant to paragraph (d)(2)(ii)(C) of this section, the owner or operator must place the preliminary demonstration in the facility's operating record as required by § 257.105(f)(17).

(iii) *Application review*—(A) EPA will evaluate the application and may request additional information not required as part of the application as necessary to complete its review. Submission of a complete application will toll the facility's deadline to cease receipt of waste until issuance of a final decision under paragraph (d)(2)(iii)(C) of this section. Incomplete submissions will not toll the facility's deadline and will be rejected without further process.

(B) If the application is determined to be incomplete, EPA will notify the facility. The owner or operator must place the notification of an incomplete application in the facility's operating record as required by § 257.105(f)(18).

(C) EPA will publish a proposed decision on complete applications in a docket on *www.regulations.gov* for a 20-day comment period. After consideration of the comments, EPA will issue its decision on the application within sixty days of receiving a complete application.

(D) If the application is approved, the deadline to cease receipt of waste will be tolled until an alternate liner demonstration is determined to be incomplete or a final decision under paragraph (d)(2)(vi) of this section is issued.

(E) If the surface impoundment is determined by EPA to be ineligible to apply for an alternate liner demonstration, and the facility lacks alternative capacity to manage its CCR and/or non-CCR wastestreams, the owner or operator may apply for an alternative closure deadline in accordance with the procedures in § 257.103(f). The owner or operator will be given four months from the date of the ineligibility determination to apply for the alternative closure provisions in either § 257.103(f)(1) or (f)(2), during which time the facility's deadline to cease receipt of waste will be tolled.

(F) Upon receipt of a decision on the application pursuant to paragraph (d)(2)(iii)(C) of this section, the owner or operator must place the decision on the application in the facility's operating record as required by § 257.105(f)(19).

(iv) *Demonstration review.* EPA will evaluate the demonstration package and may request additional information not required as part of the demonstration as necessary to complete its review. Submission of a complete demonstration package will continue to toll the facility's deadline to cease receipt of waste into that CCR surface impoundment until issuance of a final decision under paragraph (d)(2)(vi) of this section. Upon a determination that a demonstration is incomplete the tolling of the facility's deadline will cease and the submission will be rejected without further process.

(v) *Proposed decision on demonstration.* EPA will publish a proposed decision on a complete demonstration package in a docket on *www.regulations.gov* for a 30-day comment period.

(vi) *Final decision on demonstration.* After consideration of the comments, EPA will issue its decision on the alternate liner demonstration package within four months of receiving a complete demonstration package. Upon approval the facility may continue to operate the impoundment as long as the impoundment remains in detection monitoring. Upon detection of a statistically significant increase over background of a constituent listed on appendix III to this part, the facility must proceed in accordance with the requirements of paragraph (ix) of this section.

(vii) *Facility operating record requirements.* Upon receipt of the final decision on the alternate liner demonstration pursuant to paragraph (vi) of this section, the owner or operator must place the final decision in the facility's operating record as required by § 257.105(f)(20).

(viii) *Effect of Demonstration Denial.* If EPA determines that the CCR surface impoundment's alternate liner does not meet the standard for approval in this paragraph (d), the owner or operator must cease receipt of waste and initiate closure as determined in EPA's decision. If the owner or operator needs to obtain alternate capacity, they may do so in accordance with the procedures in § 257.103. The owner or operator will have four months from the date of EPA's decision to apply for an alternative closure deadline under either § 257.103(f)(1) or (f)(2), during which time the facility's deadline to cease receipt of waste will be tolled.

(ix) *Loss of authorization*–(A) The owner or operator of the CCR unit must comply with all of the following upon determining that there is a statistically significant increase over background levels for one or more constituents listed in appendix III to this part pursuant to § 257.94(e):

(*1*) In addition to the requirements specified in this paragraph (d), comply with the groundwater monitoring and corrective action procedures specified in §§ 257.90 through 257.98;

(*2*) Submit the notification required by § 257.94(e)(3) to EPA within 14 days of placing the notification in the facility's operating record as required by § 257.105(h)(5);

(*3*) Conduct intra-well analysis on each downgradient well to identify any trends of increasing concentrations as required by paragraph (d)(2)(ix)(B) of this section. The owner and operator must conduct the initial groundwater sampling and analysis for all constituents listed in appendix IV to this part according to the timeframes specified in § 257.95(b);

(*4*) The owner or operator may elect to pursue an alternative source demonstration pursuant to § 257.94(e)(2) that a source other than the CCR unit caused the contamination, or that the statistically significant increase resulted from error in sampling, analysis, statistical evaluation, or natural variation in groundwater quality, provided that such alternative source

demonstration must be conducted simultaneously with the sampling and analysis required by paragraph (d)(2)(ix)(A)(*3*) of this section. If the owner or operator believes that a successful demonstration has been made, the demonstration must be submitted to EPA for review and approval. The owner or operator must place the demonstration in the facility's operating record within the deadlines specified in § 257.94(e)(2) and submit the demonstration to EPA within 14 days of placing the demonstration in the facility's operating record.

(*5*) The alternative source demonstration must be posted to the facility's publicly accessible CCR internet site and submitted to EPA within 14 days of completion. EPA will publish a proposed decision on the alternative source determination on *www.regulations.gov* for a 20-day comment period. After consideration of the comments, EPA will issue its decision. If the alternative source demonstration is approved, the owner or operator may cease conducting the trend analysis and return to detection monitoring. If the alternative source demonstration is denied, the owner or operator must either complete the trend analysis or cease receipt of waste. Upon receipt of the final decision on the alternative source demonstration, the owner or operator must place the final decision in the facility's operating record as required by § 257.105(f)(22).

(B) *Trend analysis.* (*1*) Except as provided for in § 257.95(c), the owner or operator must collect a minimum of four independent samples from each well (background and downgradient) on a quarterly basis within the first year of triggering assessment monitoring and analyze each sample for all constituents listed in appendix IV to this part. Consistent with 257.95(b), the first samples must be collected within 90 days of triggering assessment monitoring. After the initial year of sampling, the owner or operator must then conduct sampling as prescribed in § 257.95(d)(1). After each sampling event, the owner or operator must update the trend analysis with the new sampling information.

(*2*) The owner or operator of the CCR surface impoundment must apply an appropriate statistical test to identify any trends of increasing concentrations within the monitoring data. For normally distributed datasets, linear regression will be used to identify trends and determine the associated magnitude. For non-normally distributed datasets, the Mann-Kendall test will be used to identify trends and the Theil-Sen trend line will be used to determine the associated magnitude. If a trend is identified, the owner or operator of the CCR surface impoundment will use the upper 95th percentile confidence limit on the trend line to estimate future concentrations. The owner or operator will project this trendline into the future for a duration set to the maximum number of years established in § 257.102 for closure of the surface impoundment.

(*3*) A report of the results of each sampling event, as well as the final trend analysis, must be posted to the facility's publicly accessible CCR internet site and submitted to EPA within 14 days of completion. The trend analysis submitted to EPA must include all data relied upon by the facility to support the analysis. EPA will publish a proposed decision on the trend analysis on *www.regulations.gov* for a 30-day comment period. After consideration of the comments, EPA will issue its decision. If the trend analysis shows the potential for a future exceedance of a groundwater protection standard, before the closure deadlines established in § 257.102, the CCR surface impoundment must cease receipt of waste by the date provided in the notice.

(C) If the trend analysis demonstrates the presence of a statistically significant trend of increasing concentration for one or more constituents listed in appendix IV of this part with potential to result in an exceedance of any groundwater protection standard before closure is complete, or if at any time one or more constituents listed in appendix IV of this part are detected at a statistically significant level above a groundwater protection standard, the authorization will be withdrawn. The provisions at § 257.96(g)(3) do not apply to CCR surface impoundments operating under an alternate liner demonstration. Upon receipt of a decision that the alternate liner demonstration has been withdrawn, the owner or operator must place the decision in the facility's operating record as required by § 257.105(f)(24).

(D) The onus remains on the owner or operator of the CCR surface impoundment at all times to demonstrate that the CCR surface impoundment meets the conditions for authorization under this section. If at any point, any condition for qualification under this section has not been met, EPA or the Participating State Director can without further notice or process deny or revoke the owner or operator's authorization under paragraph (d)(2)(ix) of this section.

■ 3. Amend § 257.101 by revising paragraph (a)(3) to read as follows:

§ 257.101 Closure or retrofit of CCR units.

(a) * * *

(3) The timeframe specified in paragraph (a)(1) of this section does not apply if the owner or operator complies with the alternate liner demonstration provisions specified in § 257.71(d) or the alternative closure procedures specified in § 257.103.

* * * * *

■ 4. Amend § 257.102 by revising (d)(3)(ii) introductory text to read as follows:

§ 257.102 Criteria for conducting the closure or retrofit of CCR units.

* * * * *

(d) * * *

(3) * * *

(ii) The owner or operator may select an alternative final cover system design, provided the alternative final cover system is designed and constructed to meet the criteria in paragraphs (d)(3)(ii)(A) through (C) of this section. The design of the final cover system must be included in the written closure plan required by paragraph (b) of this section.

* * * * *

■ 5. Amend § 257.103 by revising paragraphs (f)(1)(vi) introductory text, (f)(3)(i)(A) and (f)(3)(i)(C) to read as follows:

§ 257.103 Alternative closure requirements.

* * * * *

(f) * * *

(1) * * *

(vi) *Maximum time frames.* All CCR surface impoundments covered by paragraph (f)(1) must cease receiving waste by the deadlines specified in paragraphs (f)(1)(vi)(A) and (B) of this section and close in accordance with the timeframes in § 257.102(e) and (f).

* * * * *

(3) * * *

(i) * * *

(A) Except as provided by § 257.71(d)(2)(iii)(E) and (viii), the owner or operator must submit the demonstration required under paragraph (f)(1)(iv) of this section, for an alternative deadline to cease receipt of waste pursuant to paragraph (f)(1) of this section, to the Administrator or the Participating State Director for approval no later than November 30, 2020.

* * * * *

(C) Except as provided by § 257.71(d)(2)(iii)(E) and (viii), the owner or operator must submit the demonstration required under

paragraph (f)(2)(v) of this section to the Administrator for approval no later than November 30, 2020.

* * * * *

■ 6. Amend § 257.105 by adding paragraphs (f)(14) through (23) to read as follows:

§ 257.105 Recordkeeping requirements.

* * * * *

(f) * * *

(14) The application and any supplemental materials submitted in support of the application as required by § 257.71(d)(1)(i)(E).

(15) The alternative liner demonstration as required by § 257.71(d)(1)(ii)(D).

(16) The alternative liner demonstration extension request as required by § 257.71(d)(2)(ii)(D).

(17) The documentation prepared for the preliminary demonstration as required by § 257.71(d)(2)(ii)(E).

(18) The notification of an incomplete application as required by § 257.71(d)(2)(iii)(B).

(19) The decision on the application as required by § 257.71(d)(2)(iii)(F).

(20) The final decision on the alternative liner demonstration as required by § 257.71(d)(2)(vii).

(21) The alternative source demonstration as required under § 257.71(d)(2)(ix)(A)(*4*).

(22) The final decision on the alternative source demonstration as required under § 257.71(d)(2)(ix)(A)(*5*).

(23) The final decision on the trend analysis as required under § 257.71(d)(2)(ix)(B)(*3*).

(24) The decision that the alternative source demonstration has been withdrawn as required under § 257.71(d)(2)(ix)(C).

* * * * *

■ 7. Amend § 257.106 by adding paragraphs (f)(13) through (23).

§ 257.106 Notification requirements.

* * * * *

(f) * * *

(13) Provide notification of the availability of the application and any supplemental materials submitted in support of the application specified under § 257.105(f)(14).

(14) Provide notification of the availability of the alternative liner demonstration specified under § 257.105(f)(15).

(15) Provide notification of the availability of the alternative liner demonstration extension request specified under § 257.105(f)(16).

(16) Provide notification of the availability of the documentation prepared for the preliminary demonstration specified under § 257.105(f)(17).

(17) Provide notification of the availability of the notification of an incomplete application specified under § 257.105(f)(18).

(18) Provide notification of the availability of the decision on the application specified under § 257.105(f)(19).

(19) Provide notification of the availability of the final decision on the alternative liner demonstration specified under § 257.105(f)(20).

(20) Provide notification of the availability of the alternative source demonstration specified under § 257.105(f)(21).

(21) Provide notification of the availability of the final decision on the alternative source demonstration specified under § 257.105(f)(22).

(22) Provide notification of the final decision on the trend analysis specified under § 257.105(f)(23).

(23) Provide notification of the decision that the alternative source demonstration has been withdrawn specified under § 257.105(f)(24).

* * * * *

■ 8. Amend § 257.107 by adding paragraphs (f)(13) through (23).

§ 257.107 Publicly accessible internet site requirements.

* * * * *

(f) * * *

(13) The application and any supplemental materials submitted in support of the application specified under § 257.105(f)(14).

(14) The alternative liner demonstration specified under § 257.105(f)(15).

(15) The alternative liner demonstration specified under § 257.105(f)(16).

(16) The documentation prepared for the preliminary demonstration specified under § 257.105(f)(17).

(17) The notification of an incomplete application specified under § 257.105(f)(18).

(18) The decision on the application specified under § 257.105(f)(19).

(19) The final decision on the alternative liner demonstration specified under § 257.105(f)(20).

(20) The alternative source demonstration specified under § 257.105(f)(21).

(21) The final decision on the alternative source demonstration specified under § 257.105(f)(22).

(22) The final decision on the trend analysis specified under § 257.105(f)(23).

(23) The decision that the alternative source demonstration has been withdrawn specified under § 257.105(f)(24).

* * * * *

[FR Doc. 2020–23327 Filed 11–10–20; 8:45 am]

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Part VIII

The President

Proclamation 10116—National Apprenticeship Week, 2020
Proclamation 10117—World Freedom Day, 2020

Federal Register
Vol. 85, No. 219
Thursday, November 12, 2020

Presidential Documents

Title 3—

The President

Proclamation 10116 of November 6, 2020

National Apprenticeship Week, 2020

By the President of the United States of America

A Proclamation

Apprenticeships provide American workers tangible skills and an industry-recognized credential. They strengthen our Nation's economy and help millions of men and women provide for their families without taking on the financial burden of student loans and other related debt. During National Apprenticeship Week, we celebrate the American workers who create a brighter future for themselves and their families through apprenticeships, and we further our commitment to bolstering opportunity as we continue our economic comeback.

For decades, politicians and bureaucrats in Washington neglected workers, shipped jobs overseas, and abandoned essential manufacturing industries. When I took office, I reversed these policies and pledged to always put the American economy, labor force, and worker first. Under my leadership, we have cut taxes, removed burdensome regulations on businesses, and renegotiated our trade deals, all of which led to historic job creation and economic growth. Apprenticeships are a pillar of our effort to continue this trend, and my Administration remains committed to supporting initiatives that empower Americans and prepare our workers to compete and thrive in a 21st-century economy.

Since taking office, my Administration has worked tirelessly to empower more Americans with the benefits of apprenticeships and the skills they provide. In June of 2017, I signed an Executive Order on Expanding Apprenticeships in America. Under my leadership, the Department of Labor has awarded $80 million across 42 States and territories for occupational skills education for American students and workers, 800,000 Americans have joined apprenticeship programs, and we are well on the way to meeting my goal of 1 million new apprentices by September of next year. In Fiscal Year 2019 alone, we registered more than 250,000 new apprentices in vital industries, including advanced manufacturing, financial services, educational services, transportation, healthcare, and informational technology. My Administration also recently launched the Industry-Recognized Apprenticeship Program model, which provides opportunities for industry-led, market-driven training that expands workforce development and opens windows to well-paying jobs in high-demand industries. In recognition of our Nation's obligation to our military men and women, my Administration has also expanded the United Services Military Apprenticeship Program across all branches, providing apprenticeship opportunities to our service members while they are still on active duty to help them prepare for prosperous and fulfilling lives after their time in uniform.

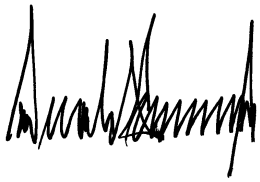
My Administration will also continue to work with industry partners to provide workers with the skills they need to succeed in today's economy through the Pledge to America's Workers. This initiative recently proved essential as our Nation confronted the unprecedented challenges of the coronavirus pandemic. As part of our ongoing response, we launched the largest industrial mobilization since World War II, and thousands of new apprentices answered the call for skilled labor in key sectors like manufacturing, healthcare, cybersecurity, and information technology. These efforts

demonstrate that, when government allows the free market to respond, the spirit of the American worker and the strength and resolve of America's economy will overcome any challenge.

This week, we recommit to bolstering economic opportunity through apprenticeships. I encourage individuals, business leaders, and government officials to support hardworking Americans and their families through expanding apprenticeship education and training, recognizing the essential role apprenticeships play in sustaining our national economy.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 8 through November 14, 2020, as National Apprenticeship Week.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of November, in the year of our Lord two thousand twenty, and of the Independence of the United States of America the two hundred and forty-fifth.



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Presidential Documents

Proclamation 10117 of November 6, 2020

World Freedom Day, 2020

By the President of the United States of America

A Proclamation

On World Freedom Day, we commemorate the historic fall of the Berlin Wall in 1989, which liberated the people of East Germany from the grip of tyranny. This watershed event marked the triumph of freedom and liberty for hundreds of millions of people who rejected the oppression of Soviet communism and its Marxist-Leninist ideology. Today, we celebrate the blessings of freedom in Germany and across the world, and reaffirm our Nation's support for all who wish to be free.

Following World War II, the Soviet Union built an Iron Curtain between the East and West, isolating the city of West Berlin and shutting off the free flow of goods and people. Determined to prevent the light of liberty from being extinguished, our Nation stood with the United Kingdom and France against the Soviet demand that the West withdraw from Berlin. To defeat this demand for surrender, the United States Air Force and our allies fearlessly airlifted food, fuel, and supplies to the starving people of West Berlin, and together, we were resolved to restore freedom to the German people.

For almost 30 years, the Berlin Wall symbolized the divide between the free world and communism. On its eastern side, the rights that democratic societies hold dear—the fundamental freedoms of religion, speech, the press, association, and petition—were replaced by forced secularism, oppressive censorship, monolithic propaganda, and inhumane division. Hundreds of brave Germans died attempting to escape this brutal fate, as the Stasi used landmines, armed watchtowers, and barbed wire to intimidate those who dreamed of freedom and to kill and harm those who braved any attempt to escape. Those whose escapes failed, those who facilitated successful or attempted crossings, and those who crossed the Stasi in some other way were tortured, imprisoned, and executed in horrifying violations of human dignity and rights.

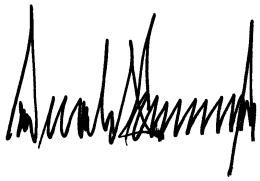
The United States always stood resolutely with the victims and survivors of the evil ideology that controlled East Germany and East Berlin. Our valiant response to Soviet oppression in Germany defined the Cold War, from President John F. Kennedy's declaration, ''Ich bin ein Berliner,'' in 1963 to President Ronald Reagan's momentous call, ''Mr. Gorbachev, tear down this wall!'' in 1987. Our founding principles of individual, God-given unalienable rights, human dignity, and equality of opportunity were embraced by the millions held in Soviet bondage, and ultimately won the ideological battle of the Cold War. As a result, we are able to celebrate Germany's reunification today, reaffirm our alliance, and recognize German contributions to modern day peace and prosperity.

This World Freedom Day, we honor all those who fought for freedom, endured injustice, and bravely resisted totalitarianism before the fall of the Berlin Wall. We also reassert our longstanding commitment to combat tyranny, uplift the voices of those held captive by communist regimes, and halt the spread of this brutal ideology at home and around the world.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution

and the laws of the United States, do hereby proclaim November 9, 2020, as World Freedom Day. I call upon the people of the United States to observe this day with appropriate ceremonies and activities, reaffirming our dedication to freedom and democracy.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of November, in the year of our Lord two thousand twenty, and of the Independence of the United States of America the two hundred and forty-fifth.



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