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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0871; Airspace Docket No. 20–AGL–32]

RIN 2120–AA66

Amendment of Class D and Class E Airspace and Revocation of Class E Airspace; Muskegon, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D and Class E airspace and revokes the Class E airspace designated as an extension to Class D and Class E surface areas at Muskegon County Airport, Muskegon, MI. This action is the result of an airspace review caused by the decommissioning of the Muskegon VHF omnidirectional range (VOR) navigation aid as part of the VOR Minimum Operational Network (MON) Program. The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, April 22, 2021. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class D airspace, the Class E surface airspace, and the Class E airspace extending upward from 700 feet above the surface, and revokes the Class E airspace designated as an extension to Class D and Class E surface areas at Muskegon County Airport, Muskegon, MI, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (85 FR 67319; October 22, 2020) for Docket No. FAA–2020–0871 to amend the Class D and Class E airspace and revoke the Class E airspace designated as an extension to Class D and Class E surface areas at Muskegon County Airport, Muskegon, MI. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class D and E airspace designations are published in paragraph 5000, 6002, 6004, and 6005, respectively, of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71:

Amends the Class D airspace to within a 4.3-mile (increased from a 4.2-mile) radius of Muskegon County Airport, Muskegon, MI; updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database; and replaces the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

Amends the Class E surface area to within a 4.3-mile (increased from a 4.2-mile) radius of Muskegon County Airport; removes the extension as it is no longer required; and replaces the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

Revokes the Class E airspace area designated as an extension to Class D and Class E surface areas at Muskegon County Airport as it is no longer required;

And amends the Class E airspace extending upward from 700 feet above the surface at Muskegon County Airport by removing the Muskegon VORTAC and associated extensions as they are no longer required; removes the extensions southeast and northwest of the airport as they are no longer required; and updates geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is the result of an airspace review caused by the decommissioning of the Muskegon VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

FAA Order 7400.11, Airspace Designations and Reporting Points, is

published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

■ 1. The authority citation for part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 5000. Class D Airspace.

* * * * *

AGL MI D Muskegon, MI [Amended]

Muskegon County Airport, MI
(Lat. 43°10′04″ N, long. 86°14′08″ W)

That airspace extending upward from the surface to and including 3,100 feet MSL within a 4.3-mile radius of Muskegon County Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002. Class E Airspace Areas Designated as a Surface Area.

* * * * *

AGL MI E2 Muskegon, MI [Amended]

Muskegon County Airport, MI
(Lat. 43°10′04″ N, long. 86°14′08″ W)

Within a 4.3-mile radius of the Muskegon County. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airman. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004. Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AGL MI E4 Muskegon, MI [Remove]

Paragraph 6005. Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth.

* * * * *

AGL MI E5 Muskegon, MI [Amended]

Muskegon County Airport, MI
(Lat. 43°10′04″ N, long. 86°14′08″ W)
Grand Haven Memorial Airpark, MI
(Lat. 43°02′03″ N, long. 86°11′53″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the Muskegon County Airport, and within a 6.4-mile radius of the Grand Haven Memorial Airpark.

Issued in Fort Worth, Texas, on January 13, 2021.

Martin A. Skinner,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2021–01019 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0759; Airspace Docket No. 20–ACE–20]

RIN 2120–AA66

Amendment of Class D and Class E Airspace and Establishment of Class E Airspace; Fort Riley and Manhattan, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D and Class E airspace at Marshall AAF, Fort Riley, KS, and Manhattan Regional Airport, Manhattan, KS, and establishes Class E airspace extending upward from 700 feet above the surface at Marshall AAF and Freeman Field, Junction City, KS. This action is the result of airspace reviews due to the decommissioning of the Calvary and McDowell Creek non-directional beacons (NDBs). The names and geographic coordinates of the airports and navigational aids are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, April 22, 2021. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class D airspace, Class E surface airspace, Class E airspace area designated as an extension to Class D and Class E surface airspace, and Class E airspace extending upward from 700 feet above the surface at Manhattan Regional Airport, Manhattan, KS; amends the Class D and Class E surface airspace at Marshall AAF, Fort Riley, KS; and establishes Class E airspace extending upward from 700 feet above the surface at Marshall AAF and Freeman Field, Junction City, KS, to support instrument flight rule operations at these airports.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (85 FR 52289; August 25, 2020) for Docket No. FAA–2020–0759 to amend the Class D and Class E airspace at Marshall AAF, Fort Riley, KS, and Manhattan Regional Airport, Manhattan, KS, and establish Class E airspace extending upward from 700 feet above the surface at Marshall AAF and Freeman Field, Junction City, KS. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment was received and the following is provided in response.

The person submitting the comment incorrectly interpreted the NPRM and presumed that the proposed airspace changes would lower the altitudes and change the current flight paths that the aircraft flying to and from Marshall AAF and Manhattan Regional Airport are currently utilizing; however, this is not the case. These airspace changes are updating the airspace and bringing it into compliance with current FAA orders and directives, but are not changing the flight paths or altitudes that the aircraft are currently using. As neither the altitudes nor flight paths of the aircraft are being changed by this airspace amendment as presumed by the commenter, no changes or further action is required in response.

Class D and E airspace designations are published in paragraph 5000, 6002, 6004, and 6005, respectively, of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

Subsequent to publication and during the FAA charting review, a typographical error was found in the geographic coordinates for the Fort Riley VOR (''long. 96°15′40″W'' vice ''long. 96°51′40″W'') in the Class D and E airspace legal descriptions; a typographic error was found in the Fort Riley, KS, Class E airspace extending upward from 700 feet above the surface airspace legal description header (''IA'' vice ''KS''); a reciprocal radial (''216°'' vice ''036°'') was incorrectly listed in the Fort Riley, KS, Class D and Class E airspace legal descriptions; it was discovered that some airspace extensions listed in the Manhattan, KS, Class E airspace area designated as an extension to Class D and Class E surface airspace and the Fort Riley, KS, and Manhattan, KS, Class E airspace extending upward from 700 feet above the surface airspace legal descriptions were covered by other extensions or Class E airspace and are not required; and there was an omission to the exclusionary language in the Manhattan, KS, Class E airspace area designated as an extension to Class D and Class E surface airspace. As these corrections and the removal of the airspace extensions, which were being added to the existing airspace, do not change the airspace as proposed, they are incorporated into this rule.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71:

Amending the Class D airspace to within a 3.9-mile radius (increased from a 3.7-mile radius) of Marshall AAF, Fort Riley, KS; adding an extension 1.1 miles each side of the 036° radial (corrected from 216°) from the Fort Riley VOR extending from the 3.9-mile radius to 4.7 miles southwest of the airport; adding an extension 1 mile each side of the 220° bearing from the airport extending from the 3.9-mile radius to 4 miles southwest of the airport; updating the name (previously Marshall Army Airfield) and geographic coordinates of the airport to coincide with the FAA's aeronautical database; removing the cities associated with the airports to comply with changes to FAA Order 7400.2M, Procedures for Handling Airspace Matters; and replacing the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

Amending the Class D airspace to within a 4.3-mile radius (increased from a 4.2-mile radius) of Manhattan Regional Airport, Manhattan, KS; removing the Manhattan VOR/DME and McDowell Creek NDB from the airspace legal description as they are not required; updating the name (previously Manhattan Municipal Airport) and geographic coordinates of the airport to coincide with the FAA's aeronautical database; and replacing the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

Amending the Class E surface area to within a 3.9-mile radius (increased from a 3.7-mile radius) of Marshall AAF; removing the current extension from the Fort Riley VOR, as it is no longer required; removing the Calvary NDB and associated extension from the airspace legal description; adding an extension 1.1 miles each side of the 036° (corrected from 216°) radial from the Fort Riley VOR extending from the 3.9-mile radius to 4.7 miles southwest of the airport; adding an extension 1 mile each side of the 220° bearing from the airport extending from the 3.9-mile radius to 4 miles southwest of the airport; updating the name (previously Marshall Army Airfield) and geographic coordinates of the airport to coincide with the FAA's aeronautical database; removing the cities associated with the airports to comply with changes to FAA Order 7400.2M; and replacing the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

Amending the Class E surface area to within a 4.3-mile radius (increased from a 4.2-mile radius) of Manhattan Regional Airport; updating the name (previously Manhattan Municipal Airport) and geographic coordinates of the airport to coincide with the FAA's aeronautical database; and adding part-

time verbiage to the airspace legal description that was previously omitted;

Amending the Class E airspace area designated as an extension to Class D and Class E surface airspace at Manhattan Regional Airport by removing the McDowell NDB and associated extensions from the airspace legal description; removing the extension to the southeast of the VOR/DME, as it is no longer needed; adding an extension 1.3 miles each side of the 042° radial from the Manhattan VOR/DME extending from the 4.3-mile radius of the airport to 5.2 miles northeast of the airport; adding an extension 2.4 miles each side of the 211° radial from the Manhattan VOR/DME extending from the 4.3-mile radius of the airport to 7 miles southwest of the Manhattan VOR/DME; and updating the name (previously Manhattan Municipal Airport) and geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Establishing Class E airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Marshall AAF; and within a 6.4-mile radius of Freeman Field, Junction City, KS, excluding that airspace within Restricted Areas R–3602A and R–3602B;

And amending the Class E airspace extending upward from 700 feet above the surface within a 6.8-mile radius (increased from a 6.7-mile radius) of Manhattan Regional Airport; removing the McDowell NDB and associated extensions from the airspace legal description; removing the extensions southeast of the VOR/DME, as they are no longer required; removing the HATAN OM and Manhattan Municipal Airport ILS and associated extensions, as they are no longer required; adding an extension 4 miles each side of the 040° bearing from the airport extending from the 6.8-mile radius of the airport to 10.6 miles northeast of the airport; removing the extension northeast of the VOR/DME (This extension was previously amended in the NPRM, but is covered by the previous listed extension.) as it is no longer required; and updating the name (previously Manhattan Municipal Airport) and geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is due to airspace reviews caused by the decommissioning of the Calvary and McDowell Creek NDBs, which provided navigational information to the instrument procedures at these airports.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

■ 1. The authority citation for part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 5000. Class D Airspace.

* * * * *

ACE KS D Fort Riley, KS [Amended]

Marshall AAF, KS
(Lat. 39°03′10″ N, long. 96°45′52″ W)
Freeman Field, KS
(Lat. 39°02′36″ N, long. 96°50′36″ W)
Fort Riley VOR
(Lat. 38°58′13″ N, long. 96°51′40″ W)

That airspace extending upward from the surface to and including 3,600 feet MSL within a 3.9-mile radius of the Marshall AAF, and within 1.1 miles each side of the 036° radial from the Fort Riley VOR extending from the 3.9-mile radius of Marshall AAF to 4.7 miles southwest of Marshall AAF, and within 1 mile each side of the 220° bearing from Marshall AAF extending from the 3.9 mile radius of Marshall AAF to 4 miles southwest of Marshall AAF excluding that airspace within Restricted Area R–3602B and excluding that airspace within a 1-mile radius of Freeman Field. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

ACE KS D Manhattan, KS [Amended]

Manhattan Regional Airport, KS
(Lat. 39°08′28″ N, long. 96°40′19″ W)

That airspace extending upward from the surface to and including 3,600 feet MSL within a 4.3-mile radius of Manhattan Regional Airport excluding that airspace within the Fort Riley, KS, Class D airspace and Class E surface airspace areas and excluding that airspace within Restricted Area R–3602B. This Class D airspace area is effective during the specific dates and times established in advanced by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002. Class E Airspace Areas Designated as a Surface Area.

* * * * *

ACE KS E2 Fort Riley, KS [Amended]

Marshall AAF, KS
(Lat. 39°03′10″ N, long. 96°45′52″ W)
Freeman Field, KS
(Lat. 39°02′36″ N, long. 96°50′36″ W)
Fort Riley VOR
(Lat. 38°58′13″ N, long. 96°51′40″ W)

That airspace extending upward from the surface within a 3.9-mile radius of the Marshall AAF, and within 1.1 miles each side of the 036° radial from the Fort Riley VOR extending from the 3.9-mile radius of Marshall AAF to 4.7 miles southwest of Marshall AAF, and within 1 mile each side of the 220° bearing from Marshall AAF extending from the 3.9 mile radius of Marshall AAF to 4 miles southwest of Marshall AAF excluding that airspace within Restricted Area R–3602B and excluding that airspace within a 1-mile radius of Freeman Field. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will

thereafter be continuously published in the Chart Supplement.

* * * * *

ACE KS E2 Manhattan, KS [Amended]

Manhattan Regional Airport, KS
(Lat. 39°08′28″ N, long. 96°40′19″ W)

That airspace extending upward from the surface within a 4.3-mile radius of Manhattan Regional Airport excluding that airspace within the Fort Riley, KS, Class D airspace and Class E surface airspace areas and excluding that airspace within Restricted Area R–3602B. This Class E airspace area is effective during the specific dates and times established in advanced by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004. Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ACE KS E4 Manhattan, KS [Amended]

Manhattan Regional Airport, KS
(Lat. 39°08′28″ N, long. 96°40′19″ W)
Manhattan VOR/DME
(Lat. 39°08′44″ N, long. 96°40′07″ W)

That airspace extending upward from the surface within 1.3 miles each side of the 042° radial from the Manhattan VOR/DME extending from the 4.3-mile radius of the Manhattan Regional Airport to 5.2 miles northeast of the airport, and within 2.4 miles each side of the 211° radial from the Manhattan VOR/DME extending from the 4.3-mile radius of the Manhattan Regional Airport to 7 miles southwest of the Manhattan VOR/DME excluding that airspace within the Fort Riley, KS, Class D airspace and Class E surface airspace areas and excluding that airspace within Restricted Area R–3602B.

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

* * * * *

ACE KS E5 Fort Riley, KS [Establish]

Marshall AAF, KS
(Lat. 39°03′10″ N, long. 96°45′52″ W)
Freeman Field, KS
(Lat. 39°02′36″ N, long. 96°50′36″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Marshall AAF, and within a 6.4-mile radius of Freeman Field excluding that airspace within Restricted Areas R–3602A and R–3602B.

* * * * *

ACE KS E5 Manhattan, KS [Amended]

Manhattan Regional Airport, KS
(Lat. 39°08′28″ N, long. 96°40′19″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the Manhattan Regional Airport, and within 4 miles each side of the 040° bearing from the Manhattan Regional Airport extending from the 6.8-mile radius of the airport to 10.6 miles northeast of the airport excluding that airspace within Restricted Areas R–3602A and R–3602B.

Issued in Fort Worth, Texas, on January 13, 2021.

Martin A. Skinner,

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

[FR Doc. 2021–01020 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0459]

RIN 1625–AA00

Safety Zone; Tanapag Harbor, Saipan, CNMI

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a annually recurring safety zone for navigable waters within Tanapag Harbor, Saipan. This safety zone will encompass the designated swim course for the Escape from Managaha swim event in the waters of Tanapag Harbor, Saipan, Commonwealth of the Northern Mariana Islands. This action is necessary to protect all persons and vessels participating in this marine event from potential safety hazards associated with vessel traffic in the area. Race participants, chase boats, and organizers of the event will be exempt from the safety zone. Entry of persons or vessels into the safety zone is prohibited unless authorized by the Captain of the Port (COTP) Guam.

DATES: This rule is effective February 22, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0459 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Chief Petty Officer Robert Davis, Sector Guam, U.S. Coast Guard, by telephone at (671) 355–4866, or email at *WWMGuam@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The purpose of this rule is to ensure the safety of the participants and the navigable waters in the safety zone before, during, and after the scheduled swim event. In response, on November 20, 2020, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; Tanapag Harbor, Saipan, CNMI (85 FR 74304–74306). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this safety zone. During the comment period that ended December 21, 2020, we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under its authority in 46 U.S.C 70034 (previously 33 U.S.C. 1231). The Captain of the Port (COTP) Guam has determined that potential hazards exist, and the purpose of this rule is to protect all persons and vessels participating in this marine event from potential safety hazards associated with vessel traffic in the area.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published November 20, 2020. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a annual recurring safety zone from 5:00 a.m. until 8:30 a.m. on a Saturday or Sunday between February and April. The safety zone will cover all navigable waters within 100-yard radius of race participants in Tanapag Harbor, Saipan. This rulemaking would prohibit persons and vessels not involved in the event from being in the safety zone unless authorized by the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone, which will impact a small designated area of Tanapag Harbor for 3.5 hours. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received 00 comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 3.5 hours that will prohibit entry within 100-yards of swim participants. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—SAFETY ZONE; TANAPAG HARBOR, SAIPAN, CNMI

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.1417 to read as follows:

165.1417 Safety Zone; Tanapag Harbor, Saipan, CNMI.

(a) *Location.* The following area, within the Guam Captain of the Port (COTP) Zone (See 33 CFR 3.70–15), all navigable waters within a 100-yard radius of race participants for Escape for Managaha Swim in Tanapag Harbor, Saipan. Race participants, chase boats, and organizers of the event will be exempt from the safety zone.

(b) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a

Federal, State, and local officer designated by or assisting the Captain of the Port (COTP) Sector Guam in the enforcement of the safety zone.

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

(2) This safety zone is closed to all persons and vessel traffic, except as may be permitted by the COTP or a designated on-scene representative.

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

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

(d) *Enforcement period.* This safety zone will be enforced at a specified date between February and April. The Coast Guard will provide advance notice of enforcement and a broadcast notice to mariners to inform public of specific date.

Dated: January 12, 2021.

Christopher M. Chase,

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

[FR Doc. 2021–01084 Filed 1–19–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 100

RIN 0906–AB24

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

AGENCY: Public Health Service, Health Resources and Services Administration (''HRSA''), Department of Health and Human Services (''HHS'' or the ''Department'').

ACTION: Final rule.

SUMMARY: The Secretary finalizes the proposed rule to amend the Vaccine Injury Table (Table) by regulation. This final rule will have effect only for petitions for compensation under the National Vaccine Injury Compensation Program (VICP) filed after this final rule become effective. This final rule does not impact COVID–19 vaccines or PREP Act immunity for Covered Persons (as defined in the PREP Act) who manufacture, distribute, order, or administer COVID–19 vaccines.

DATES: This final rule is effective on February 22, 2021.

FOR FURTHER INFORMATION CONTACT: Please visit the National Vaccine Injury Compensation Program's website, *https://www.hrsa.gov/vaccinecompensation/,* or contact Tamara Overby, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Room 08N146B, 5600 Fishers Lane, Rockville, MD 20857; by email at *vaccinecompensation@hrsa.gov;* or by telephone at (855) 266–2427.

SUPPLEMENTARY INFORMATION: This is a final rule by which HHS amends the provisions of 42 CFR 100.3 by removing Shoulder Injury Related to Vaccine Administration, vasovagal syncope, and Item XVII from the Vaccine Injury Table.

I. Background and Purpose

Vaccination is one of the best ways to protect against potentially harmful diseases that can be very serious, may require hospitalization, or even be deadly. Almost all individuals who are vaccinated have no serious reactions.[1] Nonetheless, in the 1980s, Congress became concerned that a small number of children who received immunizations had serious reactions to them, and it was not always possible to predict which children would have reactions, or what reactions they would have.[2] Claimants alleging vaccine-related injuries in civil litigation encountered a time-consuming, expensive, and often inadequate system.[3] Moreover, increased litigation against vaccine manufacturers resulted in difficulties in their ability to secure affordable product liability insurance, stabilize vaccine prices and supply, and enter the market.[4]

Therefore, Congress enacted the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99—660 (42 U.S.C. 300aa–1 *et seq.*) (''Vaccine Act'' or ''the Act''), which established the National Vaccine Injury Compensation Program (VICP). The objectives of the VICP are to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines to be federally compensated. Petitions for compensation under the VICP are filed in the United States Court of Federal Claims (Court), rather than the civil tort system, with a copy served on the Secretary, who is the Respondent. The U.S. Department of Justice (DOJ) represents HHS in Court, and the Court, acting through judicial officers called Special Masters, makes the final decision as to eligibility for, and the type and amount of, compensation.

To gain entitlement to compensation under this Program, a petitioner must establish that a vaccine-related injury or death has occurred, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating what is referred to as a ''Table injury.'' That is, a petitioner may show that the vaccine recipient (1) received a vaccine covered under the Act; (2) suffered an injury of the type enumerated in the regulations at 42 CFR 100.3—the ''Vaccine Injury Table'' (Table)—corresponding to the vaccination in question; and (3) that the onset of such injury took place within the time period specified in the Table. If so, the injury is presumed to have been caused by the vaccine, and the petitioner is entitled to compensation (assuming that other requirements are satisfied), unless the respondent affirmatively shows that the injury was caused by some factor unrelated to the vaccination (*see* 42 U.S.C. 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B), and 300aa–14(a)).

42 U.S.C. 300aa–14(c) and (e) permit the Secretary to revise the Table. The Table currently includes 17 vaccine categories, with 16 categories for specific vaccines, as well as the corresponding illnesses, disabilities, injuries, or conditions covered, and the requisite time period when the first symptom or manifestation of onset or of significant aggravation after the vaccine administration must begin to receive the Table's legal presumption of causation. The final category of the Table, ''Item

[1] National Vaccine Injury Compensation Program, Health Resources & Servs. Admin., *https://www.hrsa.gov/vaccine-compensation/index.html* (last reviewed Jan. 2020).

[2] H.R. Rep. No. 99–908, pt. 1, at 6 (1986). Even though in rare instances individuals may have adverse reactions to vaccines, the Centers for Disease Control and Prevention (CDC) recommends that individuals be vaccinated against a wide range of illnesses and diseases. *See* Recommended Vaccines by Age. Ctrs. for Disease Control & Prevention, *https://www.cdc.gov/vaccines/vpd/vaccines-age.html* (last reviewed Nov. 22, 2016).

[3] H.R. Rep. No. 99–908, at 6.

[4] *See id.* at 4–6.

XVII,'' includes ''[a]ny new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage.'' [5] Two injuries—Shoulder Injury Related to Vaccine Administration (SIRVA) and vasovagal syncope—are listed as associated injuries for this category. Through this general category, new vaccines recommended by the CDC for routine administration to children and subject to an excise tax are deemed covered under the VICP prior to being added to the Table as a separate vaccine category through Federal rulemaking.

The Department previously issued a notice of proposed rulemaking that proposed to remove SIRVA, vasovagal syncope, and Item XVII from the Vaccine Injury Table found at 42 CFR 100.3. The Department did so for the reasons set forth in the proposed rule.[6]

Pursuant to the Vaccine Act, HHS provided the proposed revisions to the Vaccine Table to the ACCV.[7] The ACCV considered the proposed changes set forth in the proposed rule on March 6, 2020 and May 18, 2020. Four members of the ACCV also held a workgroup meeting on April 3, 2020 to discuss the proposed changes. On July 16, 2020, the proposed rule went on public display, with a comment period that ended on January 12, 2021.[8] On November 9, 2020, the Department held a public hearing pursuant to 42 U.S.C. 300aa–14(c)(1) via teleconference to discuss the proposed rule.[9]

The Department now finalizes the proposed rule to remove SIRVA and vasovagal syncope from the Table found at 42 CFR 100.3(a) and to remove the corresponding descriptions of those injuries—''Qualifications and Aids to Interpretation'' (QAI)—from 42 CFR 100.3(c). This decision is based upon a review of the relevant statutory provisions and the scientific literature, as well as the Department's experience since SIRVA and vasovagal syncope were added to the Table. The Department also finalizes its proposal to remove Item XVII from the Table found at 42 CFR 100.3(a), because the Department has serious concerns that Item XVII is contrary to applicable law, for the reasons set forth below. The Department finalizes this final rule for the reasons set forth in the proposed rule. This final rule does not impact COVID–19 vaccines or PREP Act immunity for Covered Persons (as defined in the PREP Act) who manufacture, distribute, order, or administer COVID–19 vaccines.

II. Discussion of, and Response to, Public Comments

What follows is a summary of the public comments the Department received on the notice of proposed rulemaking for this rule, which had a comment period that ended on January 12, 2021, and the comments received at the public hearing on the proposed rule. The Department received 763 comments on the proposed rule. Commenters included patients, family and friends of patients, vaccine lawyers, rehabilitation counselors, nurses, doctors, legal clinics, law firms, law schools, biotech trade associations, pharmacist acclimations, drug store associations, and non-profits. The majority of commenters made statements in opposition to the proposed rule, although some commenters supported the proposed rule.

The public hearing was conducted on November 9, 2020 from 10:00 a.m. till 3 p.m. via Adobe connect teleconference. 34 comments were provided during the public hearing on the proposed rule. Commenters included those who experienced SIRVA injuries, doctors, vaccine lawyers, representatives from vaccine legal clinics, law professors, representatives from biotechnical associations, and representatives from vaccine information associations. All commenters who spoke at the public hearing were in opposition to the proposed rule. Below are summaries of the comments and the Department's responses.

Section I: Comments Regarding Vaccines in General

Comment: Many commenters expressed concerns over the safety of vaccines in general. Some believe that all chemicals in vaccines are harmful to the body and cause bone and organ deterioration. Some believe that all vaccines should be stopped entirely. Others called for a complete moratorium on vaccines until all negative side effects are gone. Some commenters believe that vaccine and pharmaceutical companies are evil and have bought the government to push unsafe vaccines. They stress that vaccines are useless and unsafe and the very fact that the VICP is in existence proves that vaccines are unsafe.

Response: Vaccines are one of the greatest success stories in public health. Through use of vaccines, we have eradicated smallpox and nearly eliminated wild polio virus. The number of people who experience the devastating effects of preventable infectious diseases like measles, diphtheria, and whooping cough is at an all-time low. The United States has a long-standing vaccine safety program that closely and constantly monitors the safety of vaccines. Before vaccines are approved by the Food and Drug Administration (FDA), they are tested and studied extensively by scientists to help ensure they are safe and effective. After vaccines are approved, a critical part of the vaccine safety program is that the Centers for Disease Control and Prevention (CDC)'s Immunization Safety Office (ISO) and FDA monitor for possible vaccine side effects and conduct studies to determine whether health problems are caused by vaccines. CDC's ISO data show that the current U.S. vaccine supply is the safest in history.[10] Also, regulating clinical research and reviewing the safety of vaccines are responsibilities of the FDA, not the VICP, and changes in vaccine research and how vaccines are studied and tested are beyond the scope of this final rule.

Comment: Some commenters described bad reactions they, or their children, personally experienced from a range of vaccines to argue that there should be an end to mandated vaccines for children.

Response: The Department sympathizes with all those who have experienced negative reactions to vaccines. Vaccination is one of the best ways to protect against potentially harmful diseases that can be very serious, may require hospitalization, or even be deadly. Almost all individuals who are vaccinated have no serious reactions.[11] Nonetheless, in the 1980s, Congress became concerned that a small number of children who received immunizations had serious reactions to them, and it was not always possible to predict which children would have reactions, or what reactions they would have.[12] Therefore, Congress enacted the

[5] 42 CFR 100.3(a).

[6] *See* 85 FR 43794 (July 20, 2020) (''proposed rule'').

[7] The Department first provided the proposed revisions to the Table and requested recommendations and comments by the ACCV on or about February 15, 2020.

[8] National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 85 FR 43794 (July 20, 2020).

[9] *https://www.regulations.gov/document?D=HRSA-2020-0002-0373.*

[10] *http://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html.*

[11] National Vaccine Injury Compensation Program, Health Resources & Servs. Admin., *https://www.hrsa.gov/vaccine-compensation/index.html* (last reviewed Jan. 2021).

[12] H.R. Rep. No. 99–908, pt. 1, at 6 (1986). Even though in rare instances individuals may have adverse reactions to vaccines, the Centers for Disease Control and Prevention (CDC) recommends

National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. 300aa–1 *et seq.*) (Vaccine Act), which established the National Vaccine Injury Compensation Program (VICP). The objectives of the VICP are to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines to be federally compensated.

While the federal government recommends that individuals be vaccinated against a wide range of illnesses and diseases, it does not mandate them. Each state decides which vaccines are required for child's enrollment and attendance at a childcare facility or school in that state. Vaccination requirements and allowable exemptions vary by state.[13]

Comment: Commenters believe that there should be no vaccines that contain metals, formaldehyde, preservatives, fetal tissue, and other potentially harmful ingredients to humans.

Response: That is beyond the scope of this final rule. For more information on the contents of vaccines and their safety, please see *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-us-licensed-vaccines.*

Comment: Some commenters believe that vaccines are an attempt to supersede their rights as parents, and this regulation should be abandoned.

Response: The federal government is not trying to supersede parent's rights. The purpose of vaccines are to eradicate diseases and to reduce the number of people who experience the devastating effects of preventable infectious diseases like measles, diphtheria, and whooping cough. This regulation does not address parents' rights with respect to their children.

Comment: A commenter expressed anger about the Gardasil HPV vaccine causing injury and death.

Response: There is a safe and effective HPV vaccine that can prevent the infections that most commonly cause cancer. Gardasil 9 (human papillomavirus 9-valent vaccine, recombinant; 9vHPV) was approved by the FDA for use in 2014. The safety of Gardasil 9 was studied in clinical trials with more than 15,000 participants before it was licensed and continues to be monitored. Gardasil 9 protects against 9 types of cancer-causing HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. For more information on the HPV vaccine, side effects, and who should and should not receive this vaccine, see *https://www.cdc.gov/vaccinesafety/vaccines/hpv-vaccine.html.*

Comment: Some commenters asked to make vaccines optional. They believe that vaccines should not be mandated. Commenters believe that all vaccines should be voluntary. Many commenters contended that they are not. Many expressed a strong desire against being forced to get any vaccine, specifically the COVID–19 vaccine.

Response: State laws establish vaccination requirements for school children and some state healthcare workers. Revision of state laws and requirements are not within the scope of this final rule.

Comment: Some commenters expressed concern that their jobs made it mandatory to have vaccines. They believe that since their jobs make it mandatory, all related injuries should be compensated by the government.

Response: Employment requirements are beyond the scope of this final rule.

Comment: Some commenters believe that all of the studies supporting vaccines are biased and created out of fear of the ''vaccine lobby.''

Response: Vaccines are one of the greatest success stories in public health. Through use of vaccines, we have eradicated smallpox and nearly eliminated wild polio virus. The number of people who experience the devastating effects of preventable infectious diseases like measles, diphtheria, and whooping cough is at an all-time low. The United States has a long-standing vaccine safety program that closely and constantly monitors the safety of vaccines. Before vaccines are approved by the Food and Drug Administration (FDA), they are tested and studied extensively by scientists to help ensure they are safe and effective. After vaccines are approved, a critical part of the vaccine safety program is that the Centers for Disease Control and Prevention (CDC)'s Immunization Safety Office (ISO) and FDA monitor for possible vaccine side effects and conduct studies to determine whether health problems are caused by vaccines. CDC's ISO data show that the current U.S. vaccine supply is the safest in history.[14] Also, regulating clinical research and reviewing the safety of vaccines are responsibilities of the FDA, not the VICP, and changes in vaccine research and how vaccines are studied and tested are beyond the scope of this final rule.

Section II: COVID–19 Vaccine Comments

Comment: Some commenters expressed concern that the proposed rule did not add the COVID–19 vaccine to the Table. Some commenters believe that the Notice of Proposed Rulemaking would stop the automatic addition of the COVID–19 vaccine to the Vaccine Injury Table. Some believe the COVID–19 vaccine should be added to the Table to make the general public feel better about taking the vaccine; they believe that the change in the Table will increase fear of vaccination. Some commenters believe that since the COVID–19 vaccine is not included on the Table, it is unsafe. Others are concerned that the Government will mandate the COVID–19 vaccine, and that the changes to the Table are an attempt by the government to shield itself from any responsibility to compensate for COVID–19 vaccine related injuries. Other commenters asked if someone was injured by the COVID–19 vaccine, how would they be compensated.

Response: This final rule has zero impact on inclusion of the COVID–19 vaccine on the Table. The COVID–19 vaccine can separately be added to the Table, but the Department needs to follow the process specified in 42 U.S.C. 300aa–14(c)–(d) to do so. This includes that the ACCV recommend that the COVID–19 vaccine be added, or opine on the Department's recommendation to add the COVID–19 vaccine to the Table. Prior to COVID–19 vaccines being added to the Table, injuries resulting from these vaccines can be compensated under the Countermeasures Injury Compensation Program (CICP).

The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP and filing a claim are available at the toll-free number 1–855–266–2427 or the CICP's website, *https://www.hrsa.gov/cicp/.*

Comment: Commenters believe that it is suspicious that the Administration is trying to remove injuries from the Table ''secretly'' during the COVID–19 pandemic. Other commenters suggested that the Department should not remove SIRVA from the Table at a time when millions more vaccines are being administered against COVID–19.

Response: The Department respectfully disagrees that injuries are

that individuals be vaccinated against a wide range of illnesses and diseases. See Recommended Vaccines by Age. Ctrs. for Disease Control & Prevention, *https://www.cdc.gov/vaccines/vpd/vaccines-age.html* (last reviewed Jan. 2021).

[13] More information about state vaccination requirements for daycare and school entry can be found at *https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html* (last reviewed Jan. 2021).

[14] *http://www.cdc.gov/vaccin19esafety/ensuringsafety/history/index.html.*

being removed from the Table ''secretly.'' The ACCV publicly discussed the proposal on March 6, 2020 and May 18, 2020. Recordings of both discussions are publicly available at *https://www.hrsa.gov/advisory-committees/vaccines/meetings.html.* The Department subsequently published the Notice of Proposed Rulemaking in the **Federal Register** and provided a 180-day public comment period. It also held a public hearing on the proposed rule on November 9, 2020. The fact that the commenters were able to comment on the proposed rule indicates that SIRVA and vasovagal syncope are not being removed ''secretly.'' This final rule has zero impact on the COVID–19 vaccine, which is not currently on the Table. Those injured by the COVID–19 vaccine can recover from the CICP if they satisfy the statutory and regulatory prerequisites.

Comment: A commenter expressed anger about the COVID–19 vaccine altering the very DNA of its recipient.

Response: This comment is outside the scope of this rulemaking. The Department notes, though, that COVID–19 mRNA vaccines do not affect or interact with DNA in any way.[15]

Comment: Some commenters asked the Department to consider giving people stimulus checks in exchange for receiving the COVID–19 vaccine.

Response: Whether to provide stimulus checks for receiving the COVID–19 vaccine is outside the scope of this final rule.

Comment: One commenter asked the Department to reconsider removing SIVRA and vasovagal syncope from the Table because nurses, and those on the medical front line, need protection from liability, especially considering the overwhelming year they have had due to the COVID–19 pandemic.

Response: The Department thanks front-line workers for the tremendous work they have done over the past year. This final rule does not impact PREP Act immunity for Covered Persons (as defined in the PREP Act) who manufacture, distribute, order, or administer COVID–19 vaccines. Under the PREP Act and the Secretary's March 10, 2020 PREP Act declaration, as amended, during the effective period of the declaration, Covered Persons are immune from suit and liability (absent willful misconduct) under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.[16]

Section III: General Support for the Proposed Rule

Comment: Some commenters believe that there is no good rationale to include adverse events that are due to the physical administration of the vaccine rather than the effects of the contents. Commenters believe keeping those events covered by the program actually waters down the intent of the program and pulls away resources from the people who were actually affected by the vaccines themselves.

Response: The Department agrees.

Comment: Some commenters believe that the high number of SIRVA and vasovagal syncope cases submitted to the VICP has led to a falsely elevated number of reported side effects and reinforcing the ''fear'' of receiving vaccines by those who may be uninformed.

Response: The Department agrees. Since the scientific literature indicates that SIRVA and vasovagal syncope results from poor vaccination technique and the act of injection, rather than the vaccine components, removing SIRVA and vasovagal syncope from the Table would more accurately reflect the number of reported side effects actually caused by vaccine components. Such claims, which are not associated with vaccines or their components, therefore erroneously suggest that vaccines are less safe than they in fact are.

Comment: Some commenters believe that SIRVA and vasovagal syncope cases submitted to the VICP has also has contributed to a delayed process in awarding monies to those with valid claims related to the vaccine itself.

Response: The Department agrees.

Comment: Some commenters believe the federal government is not the place to lodge a complaint related to the administration of a vaccine. The appropriate place to do this is through the traditional court system or through practitioner licensing boards. They believe that current use and the number of claims for shoulder injury in adults are against the intent and spirit of the original law.

Response: The Department thanks the commenters for these comments. It is the Department's belief that Congress intended for the Vaccine Act's compensation system to be used for unavoidable injuries and illnesses that cannot be predicted in advance and can occur without fault. SIRVA and vasovagal syncope are generally not those types of injuries or illnesses. With proper injection technique, SIRVA is likely preventable. The scientific literature also suggests that those administering vaccines can take steps to significantly reduce the likelihood of vasovagal syncope.

Section IV: General Concerns

Comment: Many commenters believed that vaccine or pharmaceutical companies should be solely liable for all negative side effects caused by their vaccines. They called for the repeal of the laws which grant vaccine manufactures immunity.

Response: The National Childhood Vaccine Injury Act of 1986 was passed by Congress. To repeal the Act would require a statutory amendment and thus is not within the scope of this final rule.

Comment: Some commenters fear that the proposed rule will disband the entire VICP.

Response: This final rule is not disbanding the VICP. For the most part, this final rule reverts to the status quo as of January 2017. The one additional change, removing Item XVII, is being done because the Secretary has serious concerns that Item XVII does not comport with applicable law. All vaccines currently on the Table, and the vast majority of injuries currently on the Table, will remain on the Table after this final rule becomes effective.

Comment: Many commenters stated that the National Vaccine Injury Compensation Program covers injuries caused not only by the contents of the vaccine, but also the administration of the vaccine. They stated that but for the vaccine, there would not be a faulty administration, and there would not be a SIRVA injury. Many other commenters stated that all injuries, whether caused by the contents of the vaccine or by faulty administration of the vaccine, should be covered by the VICP. Commenters stated that HHS incorrectly interpreted the Vaccine Act to preclude claims involving ''negligence by the vaccine administrator.'' This commenter stated that contrary to the HHS interpretation of the Act, legislative history shows that Congress expressly indicated that it sought to broadly cover all injuries or death associated with vaccine administrations.

Response: The Secretary respectfully disagrees with the comment that whether or not SIRVA is caused by faulty administration the VICP should cover the injuries. The Department has concluded that the Vaccine Act should be read as not applying to cover injuries, like SIRVA and vasovagal syncope, which involve negligence by the vaccine

[15] More information about how COVID–19 mRNA vaccines work can be found at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html.*

[16] 42 U.S.C. 247d–6d; *see also* Fourth Amendment to the Secretary's PREP Act Declaration, 85 FR79,190, 79,195 (Dec. 9, 2020).

administrator. The Vaccine Act is ambiguous in how it handles such injuries, and in the Department's view there are strong reasons to exclude them from coverage under the Act's compensation scheme.

The Act creates a compensation program ''for a vaccine-related injury or death.'' 42 U.S.C. 300aa–11(a)(1). Under the Act, ''only . . . a person who has sustained a vaccine-related injury or death'' can recover. 42 U.S.C. 300aa–11(a)(9). The Act defines ''[v]accine-related injury or death'' as ''an illness, injury, condition, or death *associated with* one or more of the *vaccines* set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.'' 42 U.S.C. 300aa–33(5) (emphasis added); *see also Dean* v. *HHS,* No. 16–1245V, 2018 WL 3104388, at * 9 (Fed. Cl. Spec. Mstr. May 29, 2018) (defining ''vaccine'' as ''any substance designed to be administered to a human being for the prevention of 1 or more diseases'') (quoting 26 U.S.C. 4132(a)(2)). Thus, the compensation program covers injuries ''associated with'' the vaccine itself.

SIRVA is not a vaccine, and it is not an injury caused by a vaccine antigen, but by administration of the vaccine by the health care provider. The Department does not think the term ''associated with'' was meant to sweep in injuries caused by negligent administration of the vaccine. Although the Act permits petitioners to recover for Vaccine Table injuries without demonstrating causation in individual cases, the term ''associated with'' nevertheless requires that the injury, in general, be causally related to the vaccine itself. This is clear both from dictionary definitions of ''associated,'' which means ''related, connected, or combined together'' (Merriam-Webster.com Dictionary, Merriam-Webster, *https://www.merriam-webster.com/dictionary/associated.* Accessed 10 Jul. 2020), and from the text of the Act itself, *see, e.g.,* 42 U.S.C. 300aa–22(b)(1) (focusing on injuries that ''resulted'' from vaccine side effects); 42 U.S.C. 300aa–13(a)(1)(B) & (2)(B) (excluding ''trauma'' that has ''no known relation to the vaccine involved'').

Importantly, in the key operative provisions discussed above, the phrase ''associated with'' is linked to the vaccine itself, not to the technique in administering the vaccine. *See Decker* v. *Nw. Envtl. Def. Ctr.,* 568 U.S. 597, 611 (2013) (in interpreting phrase ''associated with industrial activity,'' the key consideration is the scope of ''industrial activity''; the ''statute does not foreclose a more specific definition by the agency'' and ''a reasonable interpretation . . . could . . . require the discharges to be related in a direct way to operations at 'an industrial plant' ''); *Chevron, U.S.A., Inc.* v. *Nat. Resources Def. Council, Inc.,* 467 U.S. 837, 861 (1984) (''[T]he meaning of a word must be ascertained in the context of achieving particular objectives, and the words associated with it may indicate that the true meaning of the series is to convey a common idea.'').

That basic requirement is not met with SIRVA and vasovagal syncope. While the act of being vaccinated may be a but-for cause of those injuries, the injury is not associated with the vaccine itself because, with proper administration technique, those injuries will not result from the vaccine. Rather, SIRVA and vasovagal syncope result from the use of improper—that is, negligent—administration technique.

There are several indicators in the language and structure of the Vaccine Act that show it was not meant to cover negligent administration of the vaccine.

First, as the Federal Circuit has explained, troubling issues arise if the Act were to apply to ''negligence facially unrelated to the vaccine's effects.'' *Amendola* v. *Sec., Dept. of Health & Human Servs.,* 989 F.2d 1180, 1187 (Fed. Cir. 1993). It could include, for example, ''the doctor's negligent dropping of an infant patient'' or use of contaminated equipment. *Id.* at 1186–87. The better reading of the statute is that it does not reach this far.

Second, the definition of vaccine-related injury carves out ''an adulterant or contaminant *intentionally added* to such a vaccine. 42 U.S.C. 300aa–33(5) (emphasis added). By excluding from the definition those injuries associated with an adulterant or contaminant intentionally added to the vaccine, Congress indicated its intent to permit suit only where the injury was caused by the components of the vaccine itself, not individual fault. Relatedly, in the provisions setting forth the standard for awarding compensation, Congress specified that an award is not appropriate when injury was ''due to factors unrelated to the administration of the vaccine,'' and further defined that phrase to include ''trauma . . . which have no known relation to the vaccine involved.'' 42 U.S.C. 300aa–13(a)(1)(B) & (2)(B). In other words, Congress excluded compensation for injuries that were not related ''to the vaccine involved.''

Third, the statutory scheme requires that the patient ''received a vaccine set forth in the Vaccine Injury Table,'' 42 U.S.C. 300aa–11(c)(1)(A), tying compensation to the receipt of a specific listed vaccine. *See* 42 U.S.C. 300aa–11(c)(1)(C)(i) (speaking to an injury aggravated ''*in association with the vaccine* referred to'' on the Vaccine Injury Table); 42 U.S.C. 300aa–11(c)(1)(C)(ii)(I) (for conditions not on the Vaccine Injury Table, allowing proof that the condition ''was caused by a vaccine'' on the Table); 42 U.S.C. 300aa–11(c)(1)(C)(ii)(II) (same). But negligent administration can occur without regard to the specific vaccine and, as noted above, can encompass anything from negligent needle placement to ''the doctor's negligent dropping of an infant patient.'' *Amendola,* 989 F.2d at 1186–87. Congress strongly signaled that it was focused on compensation for harm caused by the vaccine by requiring that the Table list the vaccines themselves and the types of injuries the vaccines themselves would cause.

Fourth, in the provision preempting state tort liability, Congress protected manufacturers from liability when the injury ''resulted from side effects that were unavoidable even though the vaccine was properly prepared . . .'' 42 U.S.C. 300aa–22(b)(1). This language shows Congress wanted to preserve a state tort remedy for certain avoidable injuries, such as those caused by negligent vaccine administration. Given that the Vaccine Act seeks to replace state tort remedies for the injuries it covers, this reinforces the conclusion that the Act does not reach SIRVA and vasovagal syncope.

Fifth, Congress provided for health care providers who administer vaccines to record detailed information about the vaccination, including the date of administration; the manufacturer; the name of the provider; and other identifying information. 42 U.S.C. 300aa–25. This information is well suited to a program designed to compensate for injuries associated with the vaccine itself, since it provides the key details about the vaccine provided and when. But this reporting requirement is woefully inadequate if the Program was designed to compensate for negligence by the provider, which would require maintaining careful records regarding the actual administration of the vaccine.

In setting up the original Vaccine Injury Table, Congress referenced conditions ''resulting from the administration of such vaccines.'' 42 U.S.C. 300a–14(a). But this phrase was not designed to define the scope of the program or the Table; instead, Congress directed the Secretary to add conditions

to the Table if they were ''associated with such vaccines.'' 42 U.S.C. 300aa–14(e)(1)(B) & (2)(B). And it is telling that Congress included nothing similar to SIRVA or other injuries caused by negligent vaccine administration in the original Table, rather than injuries associated with the vaccine components themselves. Finally, that Congress asked the Secretary to ''make or assure improvements'' in the ''administration'' of vaccines, 42 U.S.C. 300aa–27(a)(2), among many areas of improvement in the vaccination process, does not imply that the compensation program covers negligent administration.

Perhaps for some or all of these reasons, state courts have found that injuries arising from negligent administration of a vaccine are not ''vaccine-related injuries'' under 42 U.S.C. 300aa–33(5), and therefore are not preempted by the Vaccine Act. *See, e.g., Neddeau* v. *Rite Aid of Conn.,* 2015 WL 5133151, at *3 (Super. Ct. Conn. July 28, 2015) (state court action did not allege a ''vaccine-related'' injury and therefore was not barred by the Vaccine Act, because plaintiff's allegation that the administrator struck the needle too high was an allegation that her injuries ''were caused by negligence in the physical process of injecting the vaccine, not by the effects of the vaccine''); *Nwosu ex rel. Ibrahim* v. *Adler,* 969 So. 2d 516, 519 (Ct. App. Fla. 2007) (claim arising from a physician's negligent injection of a vaccine was not a ''vaccine-related injury,'' and adding that ''[i]t is true that had the child not been vaccinated, she would not have been injured. However, her injury as alleged, does not flow from the inoculant injected into her body [so] it is not the type of injury covered under the Act'').

The Table should only include injuries caused by a vaccine or its components, not the manner in which the vaccine was administered. Thus, a petitioner must have an injury or death ''associated'' with the vaccine, not one resulting from poor injection technique or other improper administration of the vaccine. The Department believes SIRVA and vasovagal claims should not be included on the Table and cannot be based on causation in fact, because they are not injuries associated with vaccines or their components, nor are they unavoidable injuries or illnesses that cannot be predicted in advance, or that can occur without fault.

Comment: Some commenters asked that this final rule be postponed until the new administration enters office, arguing that it is unfair to change the VICP in the final days of President Trump's administration.

Response: Past practice has often been to finalize rules that are ready for finalization without waiting for the incoming Administration to take office.[17] This is consistent with the Department's desire to as expeditiously as possible ensure the Table complies with applicable law.

Comment: Many commenters took issue with the Department's assertion in the proposed rule that retaining SIRVA and vasovagal syncope injuries on the Table will encourage frivolous petitions for compensation and add to DOJ's caseload.

Response: The proposed rule explained in detail how DOJ's caseload has increased since SIRVA and vasovagal syncope were added to the Table. DOJ had informed the Department that, out of 2,214 SIRVA claims filed since 2017, DOJ had identified 27 cases in which altered medical records have been filed, some of which involved changes to the site of vaccination.

Section V: SIRVA-Specific Comments

Comment: Many commenters stated that according to medical literature, not all SIRVA is related to improper injection technique, and some or all cases of SIRVA result from the antigen itself, not just the needle placement in the bursa. These commenters stated that this undermines the Department's justification for removing SIRVA from the Vaccine Injury Table. They also state that HHS was incorrect to suggest that ''there is nearly uniform agreement in the scientific community that SIRVA is caused by improper vaccine administration, rather than by the vaccine itself.'' Other commenters stated that since medical literature is split on the cause of SIRVA, it should be left on the table until further research can be done.

Response: There is nearly uniform agreement in the scientific community that SIRVA is caused by improper vaccine administration, rather than by the vaccine itself.[18] Since the 2017 Final Rule was promulgated, additional scientific research concluded that subdeltoid or subacromial bursitis and other shoulder lesions are ''more likely to be the consequence of a poor injection technique (site, angle, needle size, and failure to take into account [a] patient's characteristics, *i.e.,* sex, body weight, and physical constitution),'' rather than ''antigens or adjuvants contained in the vaccines that would trigger an immune or inflammatory response.'' [19] The Department has not seen compelling peer-reviewed publications, submitted either by the commenters or otherwise, that calls into question this conclusion. Indeed, SIRVA stands for shoulder injury *related to vaccine administration.*

Comment: Many commenters wrote about their SIRVA injuries and experiences with treatment and therapy. Many received or were in the process of receiving compensation through the VICP. They stressed the pain and suffering they went through due to a badly administered vaccine and asked for SIRVA to remain on the Table. They believe they deserve just compensation

[17] For example, fifty-six (56) new rules were finalized in the final two (2) full days of the previous Administration. *See* **Federal Register**, *https://www.federalregister.gov/documents/search?conditions%5Bpublication_date%5D%5Bgte%5D=1%2F18%2F2017&conditions%5Bpublication_date%5D%5Blte%5D=1%2F20%2F2017&conditions%5Btype%5D%5B%5D=RULE.*

[18] *See* Barnes MG, Ledford C, Hogan K. A ''needling'' problem: shoulder injury related to vaccine administration. J Am Board Fam Med. 2012 Nov-Dec;25(6):919–22; Cross GB, Moghaddas J, Buttery J, Ayoub S, Korman TM. Don't aim too high: Avoiding shoulder injury related to vaccine administration. Aust Fam Physician. 2016 May;45(5):303–6.

[19] Martín Arias, K.H., Fadrique, R., Sáinz Gil, M., and Salgueiro-Vazquez, M.E., Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations, *Vaccine,* 2017;35:4870–4876. *See also* Bancsi A, Houle SKD, Grindrod KA. Shoulder injury related to vaccine administration and other injection site events. *Can. Fam. Physician.* 2019 Jan;65(1):40–42 (explaining that SIRVA ''is a preventable occurrence caused by the injection of a vaccine into the shoulder capsule rather than the deltoid muscle''); Macomb CV, Evans MO, Dockstater JE, Montgomery JR, Beakes DE. Treating SIRVA Early With Corticosteroid Injections: A Case Series. Mil Med. 2019 Oct 17 (noting that SIRVA does not occur unless the vaccine is mistakenly given in the shoulder capsule). Another recent study reviewed the Vaccine Adverse Event Reporting System (VAERS) database from July 2010 to June 2017 for reports of atypical shoulder pain and dysfunction following injection of inactivated influenza vaccine (IIV). *See* B.F. Hibbs, C.S. Ng, O. Museru *et al.,* Reports of atypical shoulder pain and dysfunction following inactivated influenza vaccine, Vaccine Adverse Event Reporting System (VAERS), 2010–2017, *Vaccine.* The review found that, of the 266 reports where contributing factors for the injury were reported, 216 (81.2%) described the vaccination as being given ''too high'' on the arm. Other reports described improper or poor administration technique (*e.g.,* bone strikes, ''administered in tendon''), uneven position between vaccinator and the patient (*e.g.,* vaccinator standing while patient sitting), vaccination needle too long, and others (*e.g.,* difficulty injecting vaccine). A small minority of reports also indicated the patient had a history of thyroid dysfunction or diabetes. It is possible that certain injuries characterized as SIRVA occur when an immunologically active substance designed to trigger an inflammatory response (*i.e.,* the vaccine antigen) is injected into an area where the inflammatory response can cause joint damage (*i.e.,* the bursa or tendons) as opposed to an area where the inflammatory response will not cause joint damage or permanent harm (*i.e.,* the deltoid muscle). Such injuries are fairly characterized as resulting from the vaccination technique, since they would not have occurred if the injection occurred in the proper part of the body.

for their SIRVA injury through the VICP. These commenters stressed that the compensation is needed for treatments, pain and suffering, lost wages, and to help cover expenses while they are unable to work. They stressed that their SIRVA injuries make employment or career advancement extremely difficult, and many could no longer work in their chosen fields.

Response: The Department sympathizes with those who suffered an injury, but it is the Department's belief that Congress intended for the Vaccine Act's compensation system to be used for unavoidable injuries and illnesses that cannot be predicted in advance and can occur without fault. SIRVA is generally not that type of injury or illness. Moreover, under this final rule, those with SIRVA injuries are not barred from suing those who injured them in state court. Those injured still have an opportunity to be compensated by the faulty party.

Comment: Many commenters asked what their recourse for SIRVA injuries would be if it is removed from the Table. Many other commenters believe that removal of SIRVA from the Table will eliminate any recourse for patients of improperly administered vaccines.

Response: Under this final rule, those with SIRVA injuries are not barred from suing those who injured them in state court (or in federal court if the requirements for diversity jurisdiction under 28 U.S.C. 1332 are satisfied).

Comment: Many commenters believe that vaccine administration by poorly trained and minimally qualified staff is what leads to a high number of SIRVA cases, so the Government should provide more training, guidelines, and supervision of medical staff and companies that administer vaccines. These commenters suggest mandating more vaccine administration training and certification. Some suggested that funds from the VICP should be set aside to train providers with the proper technique of vaccine administration. They believe that unless there is more regulation for continuous training on injection administration, SIRVA should not be removed from the table.

Response: The Department agrees that SIRVA is caused by improper vaccine administration. The Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner, but the Department also wants to incentivize those who administer vaccines to do so properly. Doing so will improve public confidence in vaccinations. Removing SIRVA from the Table further incentivizes learning proper administration technique. The Department agrees that proper vaccine administration is critical to ensure that vaccination is safe and effective. CDC provides recommendations on vaccine administration technique, many of which can be found at *https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html.*

Comment: Some commenters opposed removing SIRVA from the Table, but stress that since the injury is caused by faulty administration, the person administering the vaccine and causing the injury should be held accountable.

Response: While the Department disagrees with the suggestion to keep SIRVA on the Table, the Department understands the desire to hold accountable those who cause injury by using faulty administration. If those who administer vaccines can be held liable when a patient suffers from SIRVA as a result of the administration of the vaccine, those who administer vaccines will have greater incentive to use proper injection technique. The Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner, but awarding no-fault compensation from the VICP to those with SIRVA and vasovagal syncope claims lessens the incentive to take appropriate precautions. Since Vaccine Act proceedings are generally sealed and not made available to the public, vaccine administrators may be left unaware that they used an improper technique. If SIRVA and vasovagal syncope are included in the Table, petitioners will continue to seek to recover from the VICP, where they can recover more easily because they need not prove causation, rather than from those who failed to properly administer the vaccine.

Comment: A commenter suggested increasing the VICP tax to help cover all SIRVA injuries and support more administration training.

Response: The Department lacks the authority to increase the VICP tax, and this is beyond the scope of this final rule.

Comment: Some commenters threatened that if SIRVA is removed from the Table, they will wage a campaign to discourage the public at large from receiving flu vaccines.

Response: Flu vaccines have a good safety record. Hundreds of millions of Americans have safely received flu vaccines over the past 50 years, and there has been extensive research supporting the safety of flu vaccines. A flu vaccine is the first and best way to reduce your chances of getting the flu and spreading it to others. CDC recommends that everyone 6 months of age and older receive a flu vaccine every year. More information on the safety of flu vaccines can be found at *https://www.cdc.gov/flu/prevent/general.htm.* The Department anticipates that this final rule may result in fewer individuals suffering from SIRVA or vasovagal syncope, because it will better incentivize those administering vaccines to use proper injection technique.

Comment: Commenters believe the general public should be better informed about the risk of SIRVA. Some suggestions included an ad campaign, or informational pamphlets handed out before vaccine injection. One commenter suggested that all patients should receive the entire list of ingredients of all vaccines before they consent to the vaccine.

Response: All healthcare providers (as defined in the Vaccine Act) are required by the Vaccine Act (42 U.S.C. 300aa–26) to give the appropriate VIS or Vaccine Information Statement to the patient (or parent or legal representative) prior to every administration of specific vaccines. A VIS or Vaccine Information Statement is a document, produced by CDC, that informs vaccine recipients—or their parents or legal representatives—about the benefits and risks of a vaccine they are receiving. Such materials shall be revised ''(1) after notice to the public and 60 days of comment thereon, and (2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.'' 42 U.S.C. 300aa–26(b). Since the aforementioned statutory required steps were not taken prior to the proposed rule, the commenter's suggestions are outside the scope of this final rule. Further information about vaccine ingredients can be found at *https://www.cdc.gov/vaccines/vac-gen/additives.htm.*

Comment: Many commenters stress that HHS has drastically changed its position since March 21, 2017 when it adopted the Final Rule adding SIRVA to the Vaccine Injury Table. Commenters point to past Departmental interpretations of SIRVA and vasovagal syncope, and the inclusion of these injuries as covered under the VICP. They argue that the Department does not have an adequate bases for changing

its interpretation of these injuries. Moreover, the Department has concluded that there are strong policy reasons for now removing SIRVA from the Table.

Response: As discussed above, it is the Department's belief that vasovagal syncope is not a ''vaccine-related injury'' and therefore should not be included on the Table or compensable under the VICP. 42 U.S.C. 300aa–11, 300aa–14(e), and the inclusion of the injury in 2017 was incorrect.

Comment: Many commenters believe that SIRVA should remain on the table because ''No evidence has been presented by DHHS justifying the removal of these injuries.''

Response: The scientific literature indicates that SIRVA likely results from poor vaccination technique, rather than the vaccine or its components alone. The notice of proposed rulemaking that preceded the Final Rule characterized SIRVA as an ''adverse event following vaccination thought to be related to the technique of intramuscular percutaneous injection (the procedure where access to a muscle is obtained by using a needle to puncture the skin) into an arm resulting in trauma from the needle and/or the unintentional injection of a vaccine into tissues and structures lying underneath the deltoid muscle of the shoulder.'' [20] The IOM similarly concluded that ''the injection, and not the contents of the vaccine, contributed to the development of deltoid bursitis.'' [21] Indeed, the primary case series relied upon by the Department in promulgating the proposed rule and Final Rule found that the medical literature supports the possibility that SIRVA may result from inappropriate needle length and/or injection technique.[22] There is nearly uniform agreement in the scientific community that SIRVA is caused by improper vaccine administration, rather than by the vaccine itself.[23] Since the Final Rule was promulgated, additional scientific research concluded that subdeltoid or subacromial bursitis and other shoulder lesions are ''more likely to be the consequence of a poor injection technique (site, angle, needle size, and failure to take into account [a] patient's characteristics, *i.e.,* sex, body weight, and physical constitution),'' rather than ''antigens or adjuvants contained in the vaccines that would trigger an immune or inflammatory response.'' [24]

Comment: Some commenters stated that HHS's justification for removing SIRVA from the VICP does not comport with best available science, because, although HHS correctly states that SIRVA and syncope are considered to be adverse injuries following direct trauma from an injection point, ''negligent administration'' and ''poor vaccination technique'' are not exclusively connected with the onset of SIRVA and syncope-related injuries. Commenters stated that the agency did not consider that serious injuries may occur following the onset of SIRVA or a syncope-related event.

Response: It is possible that serious injuries may occur following the onset of SIRVA or a syncope-related event, but the scientific literature suggests such injuries generally result from the act of injection, rather than the vaccine or its components. That negligent administration or poor vaccination technique may also be connected with other injuries does not change the Department's conclusions.

Comment: Some commenters stated that SIRVA injuries are not as rare as the Department states. They state that due to lack of information, many SIRVA injuries are not recognized or reported.

Response: The Department did not state that SIRVA injuries are rare.

Comment: Some commenters argue that medical literature supports that SIRVA alone cannot result from negligent administration of a vaccine, because these injuries are a combination of both (1) the needle placed into the subacromial bursa and (2) the vaccine components that are needed to cause the immune response, resulting in SIRVA.

Response: It is possible that certain injuries characterized as SIRVA occur when an immunologically active substance designed to trigger an inflammatory response (*i.e.,* the vaccine antigen) is injected into an area where the inflammatory response can cause joint damage (*i.e.,* the bursa or tendons) as opposed to an area where the inflammatory response will not cause joint damage or permanent harm (*i.e.,* the deltoid muscle). Such injuries are fairly characterized as resulting from the vaccination technique, since they would not have occurred if the injection occurred in the proper part of the body.

Section VI: Vasovagal Syncope Specific Concerns

Comment: Some commenters shared their negative experiences with vasovagal syncope. One commenter said he was left alone after receiving a vaccine, which resulted in severe injuries to his face and causing him to need extensive medical treatment. He stated that the VICP is the only recourse to financial compensation for pain and suffering, since Texas malpractice laws make it difficult to obtain compensation.

Response: The Department sympathizes with those who suffered an injury, but it is the Department's belief that Congress intended for the Vaccine Act's compensation system to be used for unavoidable injuries and illnesses

[20] National Vaccine Injury Compensation: Revision to the Vaccine Injury Table (''2015 Proposed Rule''), 80 FR 45132, 45136 (July 29, 2015) (emphasis supplied); *see also* Adverse Effects of Vaccines: Evidence and Causality (''IOM Report''), at 620, *available at https://www.nap.edu/catalog/13164/adverse-effects-of-vaccines-evidence-and-causality.*

[21] IOM Report at 620. SIRVA is a medicolegal term, not a medical diagnosis, that is meant to capture a broad array of potential shoulder injuries. However the IOM only made findings concerning deltoid bursitis.

[22] Atanasoff S, Ryan T, Lightfoot R, and Johann Liang R, 2010, Shoulder injury related to vaccine administration (SIRVA), *Vaccine* 28(51): 8049–52 (recommending that injections avoid the top third of the deltoid muscle to avoid shoulder injury).

[23] *See* Barnes MG, Ledford C, Hogan K. A ''needling'' problem: Shoulder injury related to vaccine administration. J Am Board Fam Med. 2012 Nov-Dec; 25(6):919–22; Cross GB, Moghaddas J, Buttery J, Ayoub S, Korman TM. Don't aim too high: Avoiding shoulder injury related to vaccine administration. Aust Fam Physician. 2016 May; 45(5):303–6.

[24] Martín Arias, K.H., Fadrique, R., Sáinz Gil, M., and Salgueiro-Vazquez, M.E., Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations, *Vaccine,* 2017; 35: 4870–4876. *See also* Bancsi A, Houle SKD, Grindrod KA. Shoulder injury related to vaccine administration and other injection site events. *Can. Fam. Physician.* 2019 Jan; 65(1): 40–42 (explaining that SIRVA ''is a preventable occurrence caused by the injection of a vaccine into the shoulder capsule rather than the deltoid muscle''); Macomb CV, Evans MO, Dockstater JE, Montgomery JR, Beakes DE. Treating SIRVA Early With Corticosteroid Injections: A Case Series. Mil Med. 2019 Oct 17 (noting that SIRVA does not occur unless the vaccine is mistakenly given in the shoulder capsule). Another recent study reviewed the Vaccine Adverse Event Reporting System (VAERS) database from July 2010 to June 2017 for reports of atypical shoulder pain and dysfunction following injection of inactivated influenza vaccine (IIV). *See* B.F. Hibbs, C.S. Ng, O. Museru *et al.,* Reports of atypical shoulder pain and dysfunction following inactivated influenza vaccine, Vaccine Adverse Event Reporting System (VAERS), 2010–2017, *Vaccine.* The review found that, of the 266 reports where contributing factors for the injury were reported, 216 (81.2%) described the vaccination as being given ''too high'' on the arm. Other reports described improper or poor administration technique (*e.g.,* bone strikes, ''administered in tendon''), uneven position between vaccinator and the patient (*e.g.,* vaccinator standing while patient sitting), vaccination needle too long, and others (*e.g.,* difficulty injecting vaccine). A small minority of reports also indicated the patient had a history of thyroid dysfunction or diabetes. It is possible that certain injuries characterized as SIRVA occur when an immunologically active substance designed to trigger an inflammatory response (*i.e.,* the vaccine antigen) is injected into an area where the inflammatory response can cause joint damage (*i.e.,* the bursa or tendons) as opposed to an area where the inflammatory response will not cause joint damage or permanent harm (*i.e.,* the deltoid muscle). Such injuries are fairly characterized as resulting from the vaccination technique, since they would not have occurred if the injection occurred in the proper part of the body.

that cannot be predicted in advance and can occur without fault. Vasovagal syncope is generally not that type of injury or illness. Scientific and medical literature support the conclusion that syncope may be caused by the act of vaccination, but not its contents.[25] Texas state malpractice laws are beyond the scope of this final rule.

Comment: Some commenters stated that contrary to the Department's position that vasovagal syncope is not a vaccine-related injury, the IOM found ''sufficient mechanistic evidence supporting the conclusion that syncope is 'directly related to vaccine administration,' '' and that the CDC has reported people fainting after receiving nearly all vaccines. While the commenters agree that steps can be taken to reduce the risk of syncope, they state that it should remain on the Injury Table.

Response: The IOM found insufficient epidemiologic evidence of an association between the injection of a vaccine and syncope, but it found sufficient mechanistic evidence supporting the conclusion that syncope is ''directly related to vaccine administration.'' [26] The IOM explained that evidence it examined as part of its review suggested ''that the injection, and not the contents of the vaccine, contributed to the development of syncope.'' [27] In addition, because syncope is an injury related *solely* to the injection of a vaccine, the Department did not add syncope to the 2017 revisions to the Table as an injury for vaccines that are not administered by injection, such as oral polio and rotavirus vaccine.

Comment: One commenter stated that removing syncope from the table would go against three decades of precedent and the weight of the medical evidence.

Response: The Department respectfully disagrees. Vasovagal syncope was not added to the Table until 2017. From the inception of the Table until 2017, vasovagal syncope is not included.

Section VII: Comments Regarding Item VII

Comment: Some commenters are concerned that removing Item XVII from the Table will remove an avenue to add new vaccines to the Table.

Response: The Department is removing Item XVII from the table because it has serious concerns that Item XVII is contrary to law, including the procedures described in the Vaccine Act for amending the Table. Specifically, to the extent that Item XVII provides a unilateral mechanism for adding injuries and vaccines to the Table, it may be inconsistent with the Vaccine Act. The Vaccine Act provides a method for adding new vaccines to the Table, and it is far from clear that the approach in Item XVII complies with that method. The Vaccine Act provides that the Secretary may promulgate regulations to modify the Table, but in doing so, he ''shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.'' [28] Moreover, the Table cannot be revised unless ''the Secretary has first provided to the [ACCV] a copy of the proposed regulation or revision, requested recommendations and comments by the [ACCV], and afforded the [ACCV] at least 90 days to make such recommendations.'' [29] Item XVII, by contrast, suggests that vaccines are added to the Table once the CDC recommends them for routine administration to children and an excise tax is imposed, even prior to notice and public comment or comments from the ACCV.[30] This may be inconsistent with the rulemaking requirements of the Administrative Procedure Act 5 U.S.C. 553, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* various Executive Orders that cabin rulemaking (see, *e.g.,* Executive Order 12866), and the Vaccine Act.

Moreover, even with the removal of Item XVII, new vaccines may be added to the Table under 42 U.S.C. 300aa–14(d), when appropriate.

Comment: One commenter stated that HHS's argument that Item XVII is unlawful is without merit. Article I of the Constitution provides Congress the authority to delegate responsibilities to independent agencies, and the Vaccine Act expressly provides that HHS shall amend the Vaccine Injury Table to include any CDC vaccine recommended for routine childhood use within two years. According to this commenter, Congress provided the CDC with an autonomous role in the VICP process, and its recommendations are separate from administrative action by HHS. Therefore, commenters stated that Item XVII is lawful.

Response: The Vaccine Act provides that the Secretary may promulgate regulations to modify the Table, but in doing so, he ''shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.'' [31] Moreover, the Table cannot be revised unless ''the Secretary has first provided to the [ACCV] a copy of the proposed regulation or revision, requested recommendations and comments by the [ACCV], and afforded the [ACCV] at least 90 days to make such recommendations.'' [32] Item XVII, by contrast, suggests that vaccines are added to the Table once the CDC recommends them for routine administration to children and an excise tax is imposed, even prior to notice and public comment or comments from the ACCV.

Comment: One commenter stated that Item XVII does have merit, especially because it streamlines the process to allow for quicker inclusions of important vaccines. This commenter stated that this is especially important and timely due to the impact of the COVID–19 pandemic and the need to provide quick compensation for COVID–19 vaccine-related injuries or deaths. Removing Item XVII would just frustrate the stated purpose of the Vaccine Act.

Response: The Department appreciates the desire to quickly add vaccines to the Table. However Congress in 42 U.S.C. 300aa–14 specified the procedures that must be followed to amend the Table. In addition, an excise tax would have to be imposed.

Comment: A few commenters opposed the removal of the mechanism to add vaccines to the Table under item XVII. According to the commenters, the proposed rule would stop the automatic addition of COVID–19 and other new vaccines to the VICP, which could potentially delay or permanently prevent the COVID–19 vaccine from being covered under the VICP, and subjecting administrators to lawsuits in the future. Commenters suggested that

[25] 80 FR 45,137 (The IOM found that one case report suggested that ''the injection, and not the contents of the vaccine, contributed to the development of syncope''). *See also* IOM Report at 18 (''injection of vaccine, independent of the antigen involved, can lead to'' syncope); Miller, E. and Woo, E.J. Time to prevent injuries from postimmunization syncope, Nursing, 2006 36 (12): 20.

[26] 80 FR 45137.

[27] 80 FR 45137. *See also* IOM Report.

[28] 42 U.S.C. 300aa–14(c)(1).

[29] 42 U.S.C. 300aa–14(d).

[30] The language in Item XVII also raises Constitutional concerns. Item XVII in effect allows CDC to add vaccines to the Table so long as the Secretary publishes notice of coverage. The Office of Legal Counsel has previously opined that a statute that sought to authorize the CDC director to take certain action unilaterally was inconsistent with the Executive Powers Clause. (Statute Limiting The President's Authority To Supervise The Director Of The Centers For Disease Control In The Distribution Of An AIDS Pamphlet, 12 U.S. Op. Off. Legal Counsel 47, 48, 1988 WL 390999, at * 1). For the same reasons, it is not clear that the CDC director, as an inferior officer, has the authority to unilaterally add vaccines to the Table without the approval of the Secretary.

[31] 42 U.S.C. 300aa–14(c)(1).

[32] 42 U.S.C. 300aa–14(d).

this policy change is seemingly at odds with the actions undertaken by HHS to expand liability protections for administrators under authorities granted in the PREP Act.

Response: The Department appreciates the desire to quickly add vaccines to the Table. However Congress in 42 U.S.C. 300aa–14 specified the procedures that must be followed to amend the Table. In addition, an excise tax would have to be imposed. During the effective period of the Secretary's COVID–19 PREP Act declaration, Covered Persons are already immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of FDA-approved or FDA-licensed COVID–19 vaccines (unless they engage in willful misconduct that causes death or serious physical injury). *See* 42 U.S.C. 247d–6d.

Section VIII: Miscellaneous Comments

Comment: A commenter asked that the license for the Hepatitis B Vaccine be revoked until further safety studies are done.

Response: This is beyond the scope of this final rule. For more information on the safety of this vaccine, see *https://www.cdc.gov/hepatitis/hbv/bfaq.htm#bFAQd04; https://www.cdc.gov/vaccines/hcp/vis/vis-statements/hep-b.html.*

Comment: Some commenters believe that all vaccines should be automatically added to the VICP. Other commenters asked for specific vaccines to be added to the Table immediately.

Response: In 42 U.S.C. 300aa–14(c)–(d), Congress specified procedures that the Department must follow to add vaccines to the Table. In revising the Table, the Department must follow these procedures. The Department notes, though, that if a vaccine is in a category of vaccines that is already covered by the VICP, then the new vaccine product is already covered even before the date of licensure. For example, hepatitis B vaccines are covered under the Program under Category VIII of the Vaccine Injury Table. If a new hepatitis B vaccine is licensed in the U.S., it is already automatically covered under the VICP. Adding specific vaccines to the Table in this final rule is likely impermissible under the Administrative Procedure Act and the logical outgrowth doctrine. Such vaccines could be added in a separate rulemaking.

Comment: Many commenters stressed that vaccines should be changed so they do not need to be administered with a shot.

Response: This is beyond the scope of this final rule.

Comment: Some commenters believed that any and all mandatory vaccines should be covered. Specifically, a commenter expressed her anger over a ''mandatory'' TD shot to travel out of the country.

Response: There are no vaccination requirements for visitors to the United States, and U.S. residents traveling abroad do not need any vaccines to reenter the United States. Many vaccines are recommend by the CDC and primary care doctors when travelling outside the United States, but they are not mandatory under federal law.[33]

Comment: One commenter said it was unfair that the Table does not include heart conditions, because they were diagnosed with Pericarditis 24 hours after receiving the DMMR vaccine.

Response: To gain entitlement to compensation under the VICP, a petitioner must establish that a vaccine-related injury or death has occurred, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating what is referred to as a ''Table injury.'' That is, a petitioner may show that the vaccine recipient (1) received a vaccine covered under the Act; (2) suffered an injury of the type enumerated in the regulations at 42 CFR 100.3—the ''Table''—corresponding to the vaccination in question; and (3) that the onset of such injury took place within the time period specified in the Table. If so, the injury is presumed to have been caused by the vaccine, and the petitioner is entitled to compensation (assuming that other requirements are satisfied), unless the respondent affirmatively shows that the injury was caused by some factor unrelated to the vaccination (*see* 42 U.S.C. 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B), and 300aa–14(a)). Whether to add heart conditions to the Table is beyond the scope of this final rule.

Comment: A commenter expressed concern that CDC guidelines for vaccine administration are not followed, which is leading to SIRVA and vasovagal syncope. Some commenters believe that pharmacies should not be allowed to administer vaccines if injuries such as SIRVA and Vasovagal Syncope are occurring.

Response: The Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner, but the Department also wants to incentivize those who administer vaccines to do so properly. Doing so will improve public confidence in vaccinations. Removing SIRVA from the Table further incentivizes learning proper administration technique. The Department agrees that proper vaccine administration is critical to ensure that vaccination is safe and effective. CDC provides recommendations on vaccine administration technique, many of which can be found at *https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html.* Whether pharmacists should be allowed to vaccinate is beyond the scope of this final rule.

Comment: One commenter believed that instead of removing SIRVA and vasovagal syncope from the Table, a new department should be created to deal exclusively with injuries caused by vaccine administration.

Response: Only Congress, not the Department, has the authority to create a new department to deal exclusively with injuries caused by vaccine administration.

Comment: One commenter suggested that vaccine companies should be mandated to set apart part of their profits to help fund the National Vaccine Injury Compensation Program (VICP).

Response: The source of funding for the VICP is the Vaccine Injury Compensation Trust Fund (Trust Fund). The Trust Fund is already funded by an excise tax on each dose of vaccines recommended by the CDC for routine administration to children. To the extent that the commenter is proposing a change to the funding mechanism for the VICP, effectuating such a change is beyond the scope of this final rule.

Comment: Some commenters believed that all those injured should be able to go to their local court and file claims.

Response: Under 42 U.S.C. 300aa–11(a)(2), no person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or

[33] For more information on Vaccines recommended for international travel: *https://wwwnc.cdc.gov/travel/destinations/traveler/none/united-states#:~:text=There%20are%20no%20vaccination%20requirements,reenter%20the%20United%20States.* (last viewed Jan. 2021).

death, unless the person has first filed a petition in the Court. This is mandated by statute, and the Department does not have the authority to change this.

Comment: Some commenters believe that removing SIRVA and Vasovagal syncope will result in burdensome and time consuming litigation that is unfair to those injured since they would have to provide evidentiary support in state court. They also believe that the claims will clog up federal, state, and local courts. Other commenters suggested that removing these injuries from the VICP will lead to claim suppression because many individuals will not have the resources to pursue their claims in court.

Response: It is the Department's position that if SIRVA and vasovagal syncope were removed from the Table, individuals could still file SIRVA and vasovagal syncope claims in state court, or Federal district court if they satisfy the requirements of 28 U.S.C. 1332 or 28 U.S.C. 1367. Once in those court, petitioners would be required to prove causation between the manner of administration and the claimed injury.

Further, this final rule is unlikely to unduly burden the civil tort system. The Department conducted a search in the WestLaw legal database for cases in state court that contained both the terms ''SIRVA'' and ''vaccine,'' and found only 20 hits, at least two of which were cases involving an entity named SIRVA and not the injury. It is possible that some additional cases were filed in federal district court. Nonetheless, the Department believes based on this data that any additional burden on the civil tort system, which would be dispersed across States and not concentrated in any one or few States, from removing SIRVA and vasovagal syncope from the Table and reverting to the status quo as of January 2017 will be minimal.

Comment: Some commenters worry that removing SIRVA and vasovagal syncope from the Table will result in doctors and pharmacists being unwilling to administer vaccines because they fear personal liability.

Response: The Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner, but the Department also wants to incentivize those who administer vaccines to do so properly.[34] Doing so will improve public confidence in vaccinations. Many physicians and pharmacists were willing to administer vaccines prior to SIRVA and vasovagal syncope's addition to the Table in 2017. In addition, certain pharmacists are already immune from suit and liability for claims for loss caused by, arising out of, relating to, or resulting from the administration of certain childhood vaccines to individuals ages three through 18 for the duration of the Secretary's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19.[35]

Comment: Commenters suggest that the tax on flu vaccines that sustain the VICP fund should be returned to the doctors, pharmacists, and other vaccine administrators so that individuals injured by administration can sue the provider directly.

Response: The source of funding for the VICP is the Trust Fund. The Trust Fund is funded by an excise tax on each dose of vaccines recommended by the CDC for routine administration to children. To the extent that the commenter is proposing a change to the funding mechanism for the VICP, effectuating such a change is beyond the scope of this final rule.

Comment: Some commenters asked that all time limits for injuries be removed from the VICP.

Response: Revision of the statute of limitations would require a statutory amendment and thus is not within the scope of this final rule.

Comment: Many commenters wrote about their personal negative reactions to vaccine components.

Response: These comments are outside the scope of this rulemaking, since the scientific literature indicates that SIRVA and vasovagal syncope results from poor vaccination technique and the act of injection, rather than the vaccine components.

Comment: Some commenters asked that vaccine injury reporting be significantly improved to reflect all injuries caused by vaccine components. Some asked that reporting to the Vaccine Adverse Event Reporting System (VAERS) be mandatory. A commenter referenced the Harvard Pilgrim Health Care report which found that less than 1 percent of vaccine adverse events are reported.

Response: This final rule concerns the VICP, which is distinct from the Vaccine Adverse Event Reporting System. As such, these comments are outside the scope of this final rule.

Comment: Two commenters opposed removing SIRVA from the Table because they stated that they have seen compensation greatly help those injured by providing resources for rehab treatment.

Response: The Department sympathizes with those who suffered an injury, but it is the Department's belief that Congress intended for the Vaccine Act's compensation system to be used for unavoidable injuries and illnesses that cannot be predicted in advance and can occur without fault. SIRVA is generally not that type of injury or illness. Moreover, under this final rule, those with SIRVA injuries are not barred from suing those who injured them in state court. Those injured still have an opportunity to be compensated.

Comment: Many commenters believe that the proposed rule changes are contrary to the legislative intent behind the creation of the vaccine injury compensation program, namely providing fair and prompt compensation to those individuals that have suffered well recognized injuries related to certain vaccines whilst shielding the pharmaceutical and medical industries from significant exposure.

Response: The Department explained in the proposed rule[36] and elsewhere herein why this final rule is consistent with Congressional intent.

Comment: Some commenters stated that it was the intention of Congress to centralize claims for compensation out of hundreds of tort venues to a centralized administrative compensation system, and removing SIRVA and vasovagal syncope is contrary to that congressional intent.

Response: The Department explained in the proposed rule[37] and elsewhere herein why this final rule is consistent with Congressional intent. SIRVA and vasovagal syncope are not the sorts of injuries that Congress intended for inclusion in the Table.

Comment: Many commenters believe that the proposed rule change will result in exposing pharmaceutical companies to liability and will inadvertently ''chill'' vaccine production.

Response: For the most part, this final rule merely reverts to the status quo as of January 2017. In fact, the vaccination rate has gone down slightly since SIRVA and vasovagal syncope were added to

[34] *See* Frakes, M., & Jena, A.B. (2016). Does Medical Malpractice Law Improve Health Care Quality?. *Journal of public economics,* 143, 142–158. *https://doi.org/10.1016/j.jpubeco.2016.09.002* (Finding ''evidence suggesting that treatment quality may improve upon reforms that expect physicians to adhere to higher quality clinical standard'').

[35] *See* 85 FR 52,136, 52140 (Aug. 24, 2020).

[36] *See* 85 FR 43,796–43,797.

[37] *See* 85 FR 43,796–43,797.

the Table,[38] so it seems unlikely that this final rule will ''chill'' vaccine production.

Comment: Many commenters stated that there is no data supporting the Department's position that the trust fund is running out of money. These commenters state that without this data, HHS should not change the Vaccine Injury Table.

Response: SIRVA claims are diminishing the Trust Fund.[39] The Department did not state that the Trust Fund is running out of money. The Department is finalizing this final rule for a combination of legal and policy reasons explained herein and in the proposed rule, not solely because any particular claims are diminishing the Trust Fund.

Comment: Many commenters do not believe that reducing the caseload of the VICP is a plausible justification to change the Injury Table. Others believe that the VICP should just hire more people to help process the caseload.

Response: The Department is finalizing this final rule for a combination of legal and policy reasons explained herein and in the proposed rule, not solely because of caseload concerns.

Comment: Some commenters stated that limiting VICP claims would be harmful to families because if individuals and their families are inadequately compensated for injuries or death, they can be economically harmed. These costs could also be passed on to taxpayers when injured individuals and their families are forced to resort to extreme measures such as filing for bankruptcy.

Response: If SIRVA and vasovagal syncope were removed from the Table, individuals could still file SIRVA and vasovagal syncope claims in state court.[40]

Comment: Some commenters stated that HHS's interpretation of Section 300aa–11(a)(2)(A) of the Vaccine Act is flawed because it interprets ''associated with the vaccine'' to mean that the injury must come from the vaccine itself instead of from the administration of the vaccine. The Department relies on a dictionary definition of ''associated with'' to conclude that it means ''related, connected, or combined together,'' but does not explain why this definition forecloses cases in which the vaccine ''combine[s] together'' with its administration to bring about the illness. Furthermore, the phrase ''associated with the administration of the vaccine'' is not qualified. Congress could have said ''associated with the *non-negligent* administration of the vaccine'' or ''associated with the *proper* administration of the vaccine.'' Commenters suggested that if (as HHS states in the proposed rule) Congress intended to cover only those injuries associated with some ''antigen,'' then lawmakers would have used that word somewhere in the Act.

Commenters stated that according to the tort law principles in which the Vaccine Act is grounded, ''legal cause'' often implicates the combined effects of two or more forces, each constituting a substantial factor in bringing about the harm, and imposes liability upon each person or thing responsible for those forces. Therefore, consistent with tort law principles, a SIRVA claimant can be found to have ''sustained a vaccine-related injury'' when a third party's negligent administration of the vaccine acts concurrently with the contents of needle, *i.e.,* the vaccine, which combined effect is in turn a substantial factor in bringing about the petitioner's harm. The commenter stated that this is consistent with the definition of ''associated with.''

Response: Cases where the vaccine ''combine[s] together'' with its administration to bring about the illness are fairly characterized as resulting from the administration technique, since they would not have occurred if the administration were proper. The fact that Congress could have said ''non-negligent'' administration of the vaccine or ''associated with the ''proper'' administration of the vaccine'' does not call into question the Department's careful examination of, and analysis of, the relevant statutory terms, which is informed by the Department's expertise in this subject matter.

Comment: Some commenters disagree with the Department's reasoning that ''associated with'' does not include injuries caused by negligent administration of the vaccine. They point to 42 U.S.C. 30aa–11 which they contend specifically provides for ''administration'' of the vaccine. They state that the Act refers to ''administration of the vaccine'' 17 times. Other commenters list prior interpretation of the act to be inconsistent with the Department's ''new'' interpretation.

Response: The Vaccine Act does in certain places refer to ''administration of'' or the ''administrator'' of the vaccine. But the Department thinks that those usages were not meant to suggest the Program covers negligence in the administration of the vaccine, but served other purposes. At most, these usages render the statute ambiguous with respect to needle injuries. In Section 300aa–11(a)(2)(A), the statute precludes suits against ''a vaccine administrator,'' but this reference does not define the scope of the compensation program—instead, it protects administrators from suits ''arising from a vaccine-related injury or death associated with the administration of a vaccine.'' This language is not entirely clear, as it appears to impose two distinct qualifications that both must be met but are worded slightly differently. It may be a belt and suspenders approach to ensure that vaccine administrators are protected from tort claims like in *Amendola,* where the vaccine itself was properly administered and caused the injury, but the petitioner alleged the administrator was negligent in deciding to give the vaccine. *See* 989 F.2d at 1186 (holding Vaccine Program does not exclude cases of ''negligence in deciding, for example, whether to administer an otherwise satisfactory vaccine''). The important point is that the first qualification—''arising from a vaccine-related injury''—is also included here and, Congress defined this requirement to include only injuries associated with the vaccine itself. *See also* 42 U.S.C. 300aa–11(b)(1)(A) (referencing individuals who ''died as the result of the administration of a vaccine'' but only if the individual sustained a ''vaccine-related injury''). In setting up the original Vaccine Injury Table, Congress referenced conditions ''resulting from the administration of such vaccines.'' 42 U.S.C. 300a–14(a). But this phrase was not designed to define the scope of the program or the Table; instead, Congress directed the Secretary to add conditions to the Table if they were ''associated with such vaccines.'' 42 U.S.C. 300aa–14(e)(1)(B) & (2)(B). And it is telling that Congress included nothing similar to SIRVA or other injuries caused by negligent vaccine administration in the original Table, rather than injuries associated with the vaccine components themselves. Finally, that Congress asked the Secretary to ''make or assure improvements'' in the ''administration'' of vaccines, 42 U.S.C. 300aa–27(a)(2), among many areas of improvement in the vaccination process, does not imply that the compensation program covers negligent administration.

Furthermore, state courts have found that injuries arising from negligent administration of a vaccine are not ''vaccine-related injuries'' under 42

[38] *See, e.g., https://www.cdc.gov/flu/fluvaxview/coverage-1718estimates.htm; https://www.cdc.gov/nchs/data/hus/2018/031.pdf.*

[39] 85 FR 43,798.

[40] Or Federal district court if they satisfy the requirements of 28 U.S.C. 1332 or 28 U.S.C. 1367.

U.S.C. 300aa–33(5), and therefore are not preempted by the Vaccine Act. *See, e.g., Neddeau* v. *Rite Aid of Conn.,* 2015 WL 5133151, at *3 (Super. Ct. Conn. July 28, 2015) (state court action did not allege a ''vaccine-related'' injury and therefore was not barred by the Vaccine Act, because plaintiff's allegation that the administrator struck the needle too high was an allegation that her injuries ''were caused by negligence in the physical process of injecting the vaccine, not by the effects of the vaccine''); *Nwosu ex rel. Ibrahim* v. *Adler,* 969 So. 2d 516, 519 (Ct. App. Fla. 2007) (claim arising from a physician's negligent injection of a vaccine was not a ''vaccine-related injury,'' and adding that ''[i]t is true that had the child not been vaccinated, she would not have been injured. However, her injury as alleged, does not flow from the inoculant injected into her body [so] it is not the type of injury covered under the Act'').

The Table should only include injuries caused by a vaccine or its components, not the manner in which the vaccine was administered. Thus, a petitioner must have an injury or death ''associated'' with the vaccine, not one resulting from poor injection technique or other improper administration of the vaccine.

Comment: One commenter stated that to the extent that negligence may well be a component of some SIRVA injuries, categorically excluding these as vaccine-related injuries would make sense only if one could show that negligence alone causes SIRVA. The commenter asserts that medical literature shows that all SIRVA injuries necessarily involve an inflammatory, immune reaction in the deltoid/bursa region. (*See Vaccine-related Shoulder Discomfort,* M. Bordor & E. Montalvo; *Shoulder injury related to vaccine administration,* S. Atanasoff, et al.)

Response: SIRVA stands for shoulder injury *related to vaccine administration.* The Department does not necessarily agree that the scientific literature shows that all SIRVA injuries necessarily involve an inflammatory, immune reaction in the deltoid/bursa region. It is possible that certain injuries characterized as SIRVA occur when an immunologically active substance designed to trigger an inflammatory response (*i.e.,* the vaccine antigen) is injected into an area where the inflammatory response can cause joint damage (*i.e.,* the bursa or tendons) as opposed to an area where the inflammatory response will not cause joint damage or permanent harm (*i.e.,* the deltoid muscle). Such injuries are fairly characterized as resulting from the vaccination technique, since they would not have occurred if the injection occurred in the proper part of the body.

Comment: Some commenters provided critical reviews of the research cited by HHS in the proposed rule. One commenter stated that the medical and scientific literature cited by the Department is contrary to (or at best inconclusive of) the proposition that SIRVA is caused solely by the physical conduct attributable to the person administering the vaccine.

Response: The Department respectfully disagrees, and maintains the view espoused in the proposed rule. The Department correctly characterized the literature in the proposed rule.

Comment: One commenter stated that HHS wrongfully stated that the standard of proof for establishing entitlement of a SIRVA claim is too low or lenient, leading to the filing of dubious or frivolous claims without providing any evidence of this in the proposed rule. This commenter stated that the suspicion of activity is not proper justification for the Department's proposed policy change. The commenter also stated that the Department's claim that there has been a dramatic increase in SIRVA claims is meaningless without context, such as an increase in the number of flu vaccines administered from the 2016/2017 flu season to the 2018/2019 flu season. This commenter also pointed out that the there is no evidence that SIRVA claims are diminishing the Trust Fund, because according to the US Treasury Bulletin for March 2020, the balance of the Trust Fund at the end of FY 2019 was $3.95 billion, up from $3.85 billion at the end of FY 2018.

Response: DOJ informs the Department that, as of the time of the proposed rule, out of 2,214 SIRVA claims filed since 2017, DOJ had identified 27 cases in which altered medical records have been filed, some of which involved changes to the site of vaccination. The proposed rule noted that the vaccination rate had decreased slightly since SIRVA was added to the Table,[41] yet SIRVA claims have risen dramatically in recent years. The Department is finalizing this final rule for a combination of legal and policy reasons explained herein and in the proposed rule, not solely because any particular claims are diminishing the Trust Fund.

Comment: Some commenters stated that if SIRVA is removed from the Vaccine Injury Table, it will have to be covered by malpractice insurance, which could unnecessarily drive up the costs of delivering vaccines and reduce the number of people willing to administer them.

Response: It is not clear this was problematic in the United States before SIRVA and vasovagal syncope were added to the Table in 2017, and the Department has been unable to locate any evidence that insurance has materially declined due to the addition of SIRVA and vasovagal syncope to the Table. Moreover, the vaccination rate has gone down slightly between when SIRVA and vasovagal syncope were added to the Table and the time of the proposed rule.[42]

Comment: A commenter asked that if SIRVA and vasovagal syncope are removed from the Table, all claims filed before the Final Rule be allowed to continue through the National Vaccine Injury Compensation Program.

Response: This final rule applies to claims filed after the effective date of this final rule.

Comment: A commenter stated that in the 34 years since the Vaccine Act was passed by Congress, HHS has only ever added to the Injury Table, and that it is deeply troubling and potentially against the intent of the Act to remove injuries from the Table.

Response: The Vaccine Act explicitly provides that the Secretary can ''delete from'' the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided. 42 U.S.C. 300aa–14(c)(3). Therefore, this final rule is consistent with the statutory text and Congressional intent.

Comment: Some commenters stated that the Department's contention that SIRVA should be removed, in part, because patient records were altered in 27 out of 2,214 cases is unsupportable. They state that the average fraudulent health care claims, according to the National Health Care Anti-Fraud Association, is 3%, which is higher than the reported fraud in the SIRVA records, which is 1.2%. One commenter points out that, as of January 1, 2020, the Court requires that all medical records be certified under the Pre-Assignment Review Order, which greatly reduces the chance of fraudulent records.

Response: DOJ had identified 27 cases in which altered medical records have been filed, some of which involved changes to the site of vaccination. However, it is possible there were additional instances that DOJ did not uncover. The Department is finalizing this final rule because of a combination of legal and policy reasons stated herein and in the proposed rule, not solely because of fraud.

[41] 85 FR 43,801 n.33.

[42] 85 FR 43,801.

Comment: Some commenters stated that removing coverage for SIRVA and syncope is inconsistent with the Program's twin purposes of creating a simplified means of recovery for those injured by the administration of vaccines and providing liability protection to vaccine administrators and manufacturers. Commenters state that the policy objective is triggered by the immunization and does not vary with whether the claimed injury is a consequence of the contents versus the administration process.

Response: The Department agrees that the VICP seeks to create a simplified means of recovery and provide certain liability protection to vaccine administrators and manufacturers. But it only seeks to do so for injuries encompassed by the Vaccine Act. The Act creates a compensation program ''for a vaccine-related injury or death.'' 42 U.S.C. 300aa–11(a)(1). Under the Act, ''only . . . a person who has sustained a vaccine-related injury or death'' can recover. 42 U.S.C. 300aa–11(a)(9). The Act defines ''[v]accine-related injury or death'' as ''an illness, injury, condition, or death *associated with* one or more of the *vaccines* set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.'' 42 U.S.C. 300aa–33(5) (emphasis added); *see also Dean* v. *HHS,* No. 16–1245V, 2018 WL 3104388, at * 9 (Fed. Cl. Spec. Mstr. May 29, 2018) (defining ''vaccine'' as '' 'any substance designed to be administered to a human being for the prevention of 1 or more diseases' '') (quoting 26 U.S.C. 4132(a)(2)). Thus, the compensation program covers injuries ''associated with'' the vaccine itself.

SIRVA is not a vaccine, and it is not an injury caused by a vaccine antigen, but by administration of the vaccine by the health care provider. The Department does not think the term ''associated with'' was meant to sweep in injuries caused by negligent administration of the vaccine. Although the Act permits petitioners to recover for Vaccine Table injuries without demonstrating causation in individual cases, the term ''associated with'' nevertheless requires that the injury, in general, be causally related to the vaccine itself. This is clear both from dictionary definitions of ''associated,'' which means ''related, connected, or combined together'' (Merriam-Webster.com Dictionary, Merriam-Webster, *https://www.merriam-webster.com/dictionary/associated.* Accessed 10 Jul. 2020), and from the text of the Act itself, *see, e.g.,* 42 U.S.C. 300aa–22(b)(1) (focusing on injuries that ''resulted'' from vaccine side effects); 42 U.S.C. 300aa–13(a)(1)(B) & (2)(B) (excluding ''trauma'' that has ''no known relation to the vaccine involved'').

Importantly, in the key operative provisions discussed above, the phrase ''associated with'' is linked to the vaccine itself, not to the technique in administering the vaccine. *See Decker* v. *Nw. Envtl. Def. Ctr.,* 568 U.S. 597, 611 (2013) (in interpreting phrase ''associated with industrial activity,'' the key consideration is the scope of ''industrial activity''; the ''statute does not foreclose a more specific definition by the agency'' and ''a reasonable interpretation . . . could . . . require the discharges to be related in a direct way to operations at 'an industrial plant' ''); *Chevron, U.S.A., Inc.* v. *Nat. Resources Def. Council, Inc.,* 467 U.S. 837, 861 (1984) (''[T]he meaning of a word must be ascertained in the context of achieving particular objectives, and the words associated with it may indicate that the true meaning of the series is to convey a common idea.'').

That basic requirement is not met with SIRVA and vasovagal syncope. While the act of being vaccinated may be a but-for cause of those injuries, the injury is not associated with the vaccine itself because, with proper administration technique, those injuries will not result from the vaccine. Rather, SIRVA and vasovagal syncope result from the use of improper—that is, negligent—administration technique.

There are several indicators in the language and structure of the Vaccine Act that show it was not meant to cover negligent administration of the vaccine.[43]

Comment: Many commenters stated that the proposed rule is not supported by the cited financial concerns; that SIRVA payouts in the last three years only account for 1% of the $4 billion life-to-date total that the program has paid for claims for all injuries. They contend that the fund has enough money to support SIRVA claims. Other commenters pointed out that the awards paid out on an annual basis has substantially decreased, while the fund has increased in size. Some commenters contend that financial concerns is not a proper basis to remove an injury from the Table.

Response: The Department is finalizing this final rule for a combination of legal and policy reasons explained herein and in the proposed rule, not solely because any particular claims are diminishing the Trust Fund.

Comment: Many commenters stated that the Department should not move forward with this final rule since the ACCV voted against the rule changes.

Response: The Department is grateful to the ACCV for its time spent considering the proposed changes and for providing its comments. However, the Department found the ACCV's comments not adequately persuasive.[44] For reasons stated herein and in the proposed rule, the Department believes that credible scientific and medical evidence supports this final rule.

Comment: Some commenters stated that removing SIRVA and vasovagal syncope from the Table will have the negative effective of reducing the amount of providers who are willing to administer vaccinations, thereby lowering the overall number of people vaccinated. A few commenters also stated that the legislative history of the Vaccine Act shows that Congress took steps to provide protections for healthcare providers. These commenters suggest that removing SIRVA from the Vaccine Injury Table would be contrary to Congressional intent and undercut key purposes of the Vaccine Act.

Response: The Department respectfully disagrees. The Department has been unable to locate any evidence that premiums have materially declined due to the addition of SIRVA and vasovagal syncope to the Table. Moreover, the vaccination rate has gone down slightly since SIRVA and vasovagal syncope were added to the Table.[45] In addition, certain pharmacists are already immune from suit and liability for claims for loss caused by, arising out of, relating to, or resulting from the administration of certain childhood vaccines to individuals ages three through 18 for the duration of the Secretary's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19.[46]

Comment: Some commenters disagree with the Department's statement that the present regime lessens the incentive of vaccine administrators to take appropriate precautions during administration. They state that that health care providers, including pharmacists, are highly trained, skilled professionals that seek to provide high quality care to their patients, and are not likely to be negligent in the care they provide because of their knowledge of

[43] *See* 85 FR 43,796, 43,797.

[44] *See* 85 FR 43,801–43,802 for a detailed discussion of why the Department did not find the ACCV's comments to be adequately persuasive.

[45] *See, e.g., https://www.cdc.gov/flu/fluvaxview/coverage1718estimates.htm; https://www.cdc.gov/nchs/data/hus/2018/031.pdf.*

[46] *See* 85 FR 52,136, 52140 (Aug. 24, 2020).

liability protection. Further they list several instances where civil action can be filed under the Act (under 42 U.S.C. 300aa–21(a), the patient/petitioner may reject the Federal Claims judgment and pursue a civil action; the vaccine administered is not listed in the Table; the injury sustained is not listed in the Table; the injury/illness did not last 6 months). Commenters argue that health care providers are bound by their ethical, moral, and legal duties to protect public health and no other consideration eliminates or lessens that commitment.

Response: The Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner. The Department has taken many steps during the COVID–19 pandemic to increase the universe of individuals who can safely vaccinate. Ensuring vaccines are administered safely will increase public confidence in vaccinations. Since Vaccine Act proceedings are generally sealed and not made available to the public, vaccine administrators may be left unaware that they used an improper technique.[47] 42 U.S.C. 300aa–21(a) does not materially change the analysis, because there are not many instances where an individual would go through the VICP process, fail to recover, and then be able to recover in state court. There are also not many instances where a petitioner would elect to forgo his or her recovery from the VICP to sue in state court, since it is not often that an individual could recover more in state court, and there are risks inherent in state court litigation.

Comment: One commenter who serves on the Advisory Commission on Childhood Vaccines stated that a representative from HHS should have come to talk to the Commission about the proposed rule. This commenter stated that additional evidence should have been provided by HHS at the May 2020 meeting of the Commission, but HHS was not involved in the meeting. The commenter stated that it was the responsibility of HHS to provide sufficient evidence to justify its recommendation, not the job of the Commission to provide sufficient evidence to support its rejection. Another commenter stated that by not adopting the recommendation of the Commission, HHS risks undermining the integrity of the Federal Advisory Committee Act (FACA) process and the willingness of qualified experts to serve on such committees.

Response: The proposal provided to the ACCV before the May 2020 meeting, which synthesized the views of many within the Department, was the Department's best explanation for why it was proposing the changes to the Table. The Department's proposed regulation provided to the ACCV provided ample scientific and legal justification. The Department is grateful to the ACCV for its time spent considering the proposed changes and for providing its comments, but it would raise constitutional concerns if a federal Agency had to accept the recommendations of a FACA.

Comment: A few commenters stated that there is no evidence to support that the Department's position that ''SIRVA petitions are likely to unnecessarily risk reductions in the funding available for children and others who sustain unavoidable vaccine-related injury or death'' because the taxes collected by vaccine manufacturers and paid into the Trust Fund have exceeded outflows for every year except Fiscal Year 2013. Commenters also stated that this reasoning ignores the fact that some SIRVA claims involve children.

Response: It stands to reason that if large sums are paid to SIRVA petitioners, that risks reducing funding available for others who sustain unavoidable vaccine-related injuries or deaths. At the time of the proposed rule, over 99.2% of SIRVA cases (3,034 out of 3,057) filed since FY 2010 were filed by adults.[48]

Comment: Some commenters urge the VICP and the CICP to merge together to promote unity and clarity.

Response: Revision of the formation and organization of the VICP and the CICP would require a statutory amendment and thus is not within the scope of this final rule.

Comment: Many commenters stated that patients, healthcare providers, vaccine administrators, and vaccine manufactures do not support the Notice of Proposed Rulemaking.

Response: For the legal and policy reasons stated herein and in the proposed rule, the Department is finalizing this final rule. The Department notes, in addition, that non-SIRVA cases, including those filed on behalf of children, are adversely affected as resources are stretched or diverted to litigate SIRVA cases.

Comment: Many commenters state that even before SIRVA was added to the Table in 2017, individuals were able to receive compensation from the VICP for their SIRVA related injuries. Commenters point to VICP cases in which the Vaccine Court held that a causal connection between the administration of the vaccine and the consequential injury is sufficient proof for an award under the Vaccine Act. Comments stated that the Department's change in policy is contrary to the Congressional Intent of the Act and would have a devastating effect upon parties' ability to recover for their injuries.

Response: Prior to SIRVA's addition to the Table, SIRVA claims were sometimes awarded due to a combination of the government resolving the claims without litigating them to conclusion, and public statements by the Department suggesting SIRVA was a cognizable injury. The proposal to add SIRVA to the Table was in the works for several years before the 2015 notice of proposed rulemaking was published, and there was a great deal of public discussion about it at the ACCV and at the Court of Federal Claims' annual judicial conference. The Department has in the past not always contested cases alleging injuries that have been proposed for addition to the Table if the case as pleaded fulfilled the criteria for entitlement to compensation. However, for the reasons discussed in the proposed rule and this final rule, including the Department's review of the statute and more recent scientific literature, the Department no longer believes such claims should be included on the Table or can be based on causation in fact, because they are not injuries associated with vaccines or their components, nor are they unavoidable injuries or illnesses that cannot be predicted in advance, or that can occur without fault.

Comment: Several commenters stated that HHS switched its position in this rulemaking without adequately considering the input of the Advisory Commission on Childhood Vaccines which unanimously rejected the rule change, and without discussing the change with the CDC's Advisory Committee for Immunization Practices (ACIP), HHS's own National Vaccine Advisory Committee (NVAC), the National Foundation for Infectious Disease (NFID), and the Institute of Vaccine Safety at Johns Hopkins whose epidemiologists have consulted closely with the Program since its inception.

Response: The Department is grateful to the ACCV for its time spent considering the proposed changes and for providing its comments. The Department considered the ACCV's

[47] 85 FR 43,802.

[48] 85 FR 43,798.

comments.[49] However, the Department found the ACCV's comments not adequately persuasive. The Department has also considered public comments from a wide variety of perspectives during the two public hearings and 180-day public comment period on the proposed rule.

Comment: A few commenters stated that they believe the reason for HHS's policy change is to reduce the Department's workload, which has increased due to the large number of SIRVA cases. Commenters stated that workload concerns are not a valid reason for making a policy change. Some commenters added that the change would not actually make the system more efficient, but would rather shift the burden of SIRVA cases to the civil tort system.

Response: The Department has set forth herein and in the proposed rule a series of legal and policy reasons for finalizing this final rule. The Department believes based on the examined data that any additional burden on the civil tort system, which would be dispersed across States and not concentrated in any one or few States, from removing SIRVA and vasovagal syncope from the Table and reverting to the status quo as of January 2017 will be minimal.[50]

Comment: One commenter warned that this rule could result in the increase in the cost of vaccines, as more medical providers are exposed to liability.

Response: With respect to SIRVA and vasovagal syncope, this final rule will revert to the status quo as of January 2017. In addition, certain pharmacists are already immune from suit and liability for claims for loss caused by, arising out of, relating to, or resulting from the administration of certain childhood vaccines to individuals ages three through 18 for the duration of the Secretary's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19.[51]

Comment: One commenter disagreed with the Department's contention that by excluding from the definition those injuries associated with an adulterant or contaminant intentionally added to the vaccine, Congress intended to permit suit only where the injury was caused by the components of the vaccine itself. The commenter states that the Department is applying the doctrine of *ejusdem generis* (*i.e.,* where general words follow an enumeration of two or more things, they apply only to persons or things of the same general kind or class specifically mentioned). However, here, an adulterant and contaminant are *exceptions* instead of enumerations. Therefore, the commenter contends that the Department's interpretation of Congress' intent is not supported.

Response: The Department respectfully disagrees. There are several indicators in the language and structure of the Vaccine Act that show it was not meant to cover negligent administration of the vaccine.[52]

Comment: One commenter stated that the Department mischaracterized current SIRVA cases when it said ''petitioners in such cases often prevail because of the low burden of proof and because it is not necessary to prove causation.'' The commenter said that litigation records show complex cases in which the Department of Justice ''vigorously'' advocated for the DHHS.

Response: The Department agrees that the Department of Justice generally vigorously advocates for the Department. But the burden of proof on petitioners is low, and petitioners generally need not prove causation.

Comment: One commenter stated that the proposed rule change may disproportionately and severely affect minority communities, since many do not have the same access to quality care; the time, energy, and know-how to navigate a complex legal system; and the resources to access compensation.

Response: Aiding minority communities was not posited as a reason to add SIRVA or vasovagal syncope to the Table when they were added in 2017.[53] In any event, this final rule will alleviate the Department's significant legal concerns about whether the current Table comports with applicable law.

Comment: Some commenters stated that HRSA is attempting to undo the lengthy and thorough legal and medical analysis it performed when it promulgated the Rule that put both vasovagal syncope and SIRVA on the Vaccine Injury Table in 2017.

Response: This final rule is the product of a lengthy and thorough legal and scientific analysis, including an analysis of scientific literature published after finalization of the 2017 Final Rule.

Comment: One commenter argued that the Vaccine Act has a subrogation clause which permits the Federal government to seek recompense if the VICP compensates a claim, but determines later that a health care professional was negligent in administering a vaccine. Thus, injury claims resulting from the administration of vaccines should still be eligible for VICP compensation.

Response: This subrogation provision does not properly incentivize the vaccine administrator, since it is unlikely that the Federal government would assert many claims against administrators, given the burden and expense compared to the relatively small potential recovery for the Federal government. Individuals would have a greater incentive to assert such claims if the administrator were negligent.

Comment: Some commenters stated that the Department incorrectly relies on *Amendola* v. *Sec., Dept. of Health & Human Servs.,* 989 F.2d 1180 (Fed. Cir. 1993) to say that issues would arise if the Vaccine Act were interpreted to cover injuries caused by negligent administration. Commenters contend that the Federal Circuit Judge stated ''Congress clearly intended by the amendment to apply the Act to pediatricians who administered a vaccine as well as to the manufacture who made it,'' and ''[w]e see no basis for drawing a bright line that excludes erroneous judgment calls by the administrator, as well as negligent contamination.'' One commenter concludes that *Amendola,* in fact, confirms that the Vaccine Act protects both vaccine administrators and manufactures.

Response: The Department respectfully disagrees with this characterization of *Amendola.* As the Federal Circuit has explained, troubling issues arise if the Act were to apply to ''negligence facially unrelated to the vaccine's effects.'' *Amendola* v. *Sec., Dept. of Health & Human Servs.,* 989 F.2d 1180, 1187 (Fed. Cir. 1993). It could include, for example, ''the doctor's negligent dropping of an infant patient'' or use of contaminated equipment. *Id.* at 1186–87. The better reading of the statute is that it does not reach this far.

Comment: One commenter argued that the state tort liability preemption in Subpart B merely covers the remedies available to patients after they have gone through the VICP, not that Congress intended to ''preserve a state tort remedy for certain avoidable injuries, such as those caused by negligent vaccine administration.''

Response: Congress protected manufacturers from liability when the injury ''resulted from side effects that were unavoidable even though the vaccine was properly prepared. . .'' 42 U.S.C. 300aa–22(b)(1). This language shows Congress wanted to preserve a

[49] *See* 85 FR 43,801–02 (discussing the ACCV's comments in depth).

[50] 85 FR 43,804.

[51] *See* 85 FR 52,136, 52140 (Aug. 24, 2020).

[52] *See* 85 FR 43,796–97.

[53] *See* 85 FR 6294.

state tort remedy for certain avoidable injuries, such as those caused by negligent vaccine administration. Given that the Vaccine Act seeks to replace state tort remedies for the injuries it covers, this reinforces the conclusion that the Act does not reach SIRVA and vasovagal syncope.

Comment: One commenter disagreed with the Department's position that recordkeeping and reporting requirements are ''woefully inadequate if the Program was designed to compensate for negligence by the provider,'' since physicians are subject to myriad state laws and regulations governing medical records. The commenter stated that Congress authorized HHS to promulgate additional recordkeeping requirements if need be.

Response: The text and structure of the Vaccine Act show that it was not meant to cover negligent administration of the vaccine. That some state laws and regulations govern medical records is besides the point.

Comment: Many commenters argued that this rule is an unconscionable attempt to alleviate HHS's backlog of pending cases, and that the public would be better served if the Department was to hire additional personal to handle case management.

Response: The Department respectfully disagrees. The Department has set forth a series of legal and policy reasons for this final rule both herein and in the proposed rule.

III. Statutory Authority

The primary statutory authority for this rulemaking is 42 U.S.C. 300aa–14. 42 U.S.C 300aa–14(c)(1) provides that the ''Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, he shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.'' 42 U.S.C. 300aa–14(c)(3), in turn, provides: ''A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.''

IV. Statutory and Regulatory Requirements

A. Executive Orders 12866, 13563, and 13771: Regulatory Planning and Review

E.O. 12866 and E.O. 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 supplements and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866, which emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations that are ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues require special analysis. The Department anticipates that the final rule will save limited compensation funds under the National Vaccine Injury Compensation Program. Specifically, it will reduce the amount of program funds spent on program administration, reduce the amount of funds paid out to those with SIRVA or vasovagal syncope claims, and ensure that funds awarded from the VICP are awarded to individuals whose claims arise from vaccine-related injuries, which is consistent with the original intent of the VICP. Moreover, the Department anticipates that the final rule may result in fewer individuals suffering from SIRVA or vasovagal syncope, because it will better incentivize those administering vaccines to use proper injection technique. If those who administer vaccines can be held liable when a patient suffers from SIRVA or vasovagal syncope as a result of the administration of the vaccine, those who administer vaccines will have greater incentive to use proper injection technique. In addition, the final rule may also limit the ability of those opposed to vaccinations to cite to the high number of SIRVA awards to misleadingly suggest that vaccines are less safe than they truly are.

The Department considered, as an alternative to the proposed rule and this final rule, issuing a notice of proposed rulemaking that would revise the definition of SIRVA so that those with true shoulder injuries were able to recover while reducing the number of less appropriate claims. However, the Department concluded that removing SIRVA from the Table is preferable. If SIRVA is removed from the Table, those with actual SIRVA injuries would still be able to recover in state court. Removal is preferable to redefining SIRVA, because it better addresses the vaccine hesitancy concern, is more in line with the Vaccine Act and Congressional intent, and incentivizes learning and utilizing proper administration technique. Indeed, because Vaccine Act proceedings are generally sealed and not made available to the public, vaccine administrators often are left unaware that they used an improper technique.

The Department also considered, as alternatives to this final rule, not removing one or more of (1) SIRVA, (2) vasovagal syncope, or (3) Item XVII from the Table. For the reasons discussed herein and in the proposed rule, the Department rejected these alternatives.

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 one year, or adversely or 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 must be prepared for major rules with economically significant effects ($100 million or more in any one year), and a ''significant'' regulatory action is subject to Office of Management and Budget (OMB) review. As discussed below regarding the anticipated effects, these changes are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of ''economically significant'' under Executive Order 12866. OMB has waived review over this final rule.

B. Economic and Regulatory Impact

In accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities. Between FY 2017 and FY 2019, the VICP on average paid out $30,893,481.90 per year to petitioners alleging SIRVA claims. The VICP on average paid out $124,489.56 per year to petitioners alleging vasovagal syncope claims. When this final rule goes into effect, the Department anticipates that small entities will not actually pay these amounts, because fewer SIRVA and vasovagal syncope claims would be filed if petitioners had to prove causation. In addition, vaccines are often administered by non-small entities, so even if total amounts paid approximated the amounts paid on average between FY 2017 and FY 2019, claims against small entities would be less. It is the Department's belief that should the amounts paid equal the amounts annually paid out of the VICP between FY 2017 and FY 2019, and such claims are paid in full by small entities, these amounts will not constitute a significant impact on a substantial number of small entities for purposes of the RFA.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $154 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The Department has determined that this final rule will not result in expenditures by State, local, and tribal governments, or by the private sector, of $154 million or more in any one year. Accordingly, the Department has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

The provisions of this rule will also not negatively affect family well-being or the following family elements: family safety; family stability; marital commitment; parental rights in the education, nurture and supervision of their children; family functioning; disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

On January 30, 2017, the White House issued Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs. 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. This final rule partially repeals prior regulations and is not expected to increase incremental costs, so it is not anticipated to be a regulatory or deregulatory action under Executive Order 13771.

As stated above, this final rule modifies the Vaccine Injury Table to ensure that the Table complies with applicable law, the Table is consistent with medical and scientific literature, those administering vaccines have additional incentive to use proper injection technique, and the VICP has sufficient funds to adequately compensate those injured by vaccines listed in the Table.

C. Executive Order 12988: Civil Justice Reform

The agency has reviewed this rule under Executive Order 12988 on Civil Justice Reform and has determined that this final rule complies with this Executive Order.

V. Summary of Impacts

This final rule has the effect of removing injuries from the Table that are not encompassed by the provisions of the Vaccine Act and that are reducing the pool of funds available to those injured by vaccines or vaccine components. It therefore aligns the Table with the Department's understanding of Congress' intent and public policy in favor of compensating those harmed by injuries associated with the vaccine or vaccine components, and particularly children who have suffered such harm. The rule also has the effect of ensuring that the limited compensation resources available under the National Vaccine Injury Compensation Program are provided to those with vaccine-related injuries or deaths. In addition, because of the large volume of SIRVA claims, removing SIRVA from the Table will reduce the amount of program funds spent on program administration and ensure that funds awarded from the VICP are awarded to individuals whose claims arise from vaccine-related injuries, which is consistent with the Department's interpretation of the original intent of the VICP.

The final rule also better incentivizes those who administer vaccines to use proper injection technique. It may also help correct misleading and erroneous suggestions that vaccines are not safe. Because COVID–19 and the COVID–19 vaccines are not currently on the Table, the Department does not believe this rule will have an impact on patients with COVID–19 or the COVID–19 vaccines.

Moreover, the rule is unlikely to unduly burden the civil tort system. The Department conducted a search in the WestLaw legal database for cases in state court that contained both the terms ''SIRVA'' and ''vaccine,'' and found only 20 hits, at least two of which were cases involving an entity named SIRVA and not the injury.[54] It is possible that some additional cases were filed in federal district court. Nonetheless, the Department believes based on this data that any additional burden on the civil tort system, which will be dispersed across States and not concentrated in any one or few States, from removing SIRVA and vasovagal syncope from the Table and reverting to the status quo as of January 2017 will be minimal.

A. Executive Order 13132—Federalism

HHS has reviewed this final rule in accordance with E.O. 13132 regarding federalism and has determined that it does not have ''federalism implications.'' This final rule will not ''have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and

[54] *https://1.next.westlaw.com/Search/Results.html?query=%22sirva%22%20%26%20%22vaccine%22&jurisdiction=ALLSTATES&saveJuris=False&contentType=CASE&querySubmissionGuid=i0ad6ad3f000001733a44933a7bf4372d&startIndex=1&searchId=i0ad6ad3f000001733a44933a7bf4372d&kmSearchIdRequested=False&simpleSearch=False&isAdvancedSearchTemplatePage=False&skipSpellCheck=False&isTrDiscoverSearch=False&thesaurusSearch=False&thesaurusTermsApplied=False&ancillaryChargesAccepted=False&proviewEligible=False&eventingTypeOfSearch=FRM&transitionType=Search&contextData=%28sc.Search%29.*

responsibilities among the various levels of government.''

B. Collection of Information

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) (PRA) requires that OMB approve all collections of information by a federal agency from the public before they can be implemented. This final rule is projected to have no impact on current reporting and recordkeeping burden, as the amendments finalized in this rule will not impose any data collection requirements under the PRA.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.

Accordingly, 42 CFR part 100 is amended as set forth below:

PART 100—VACCINE INJURY COMPENSATION

■ 1. The authority citation for 42 CFR part 100 continues to read as follows:

Authority: Secs. 312 and 313 of Public Law 99–660 (42 U.S.C. 300aa–1 note); 42 U.S.C. 300aa–10 to 300aa–34; 26 U.S.C. 4132(a); and sec. 13632(a)(3) of Public Law 103–66.

■ 2. In § 100.3, revise paragraph (a) and remove paragraphs (c)(10) and (13) and (e)(8). The revision reads as follows:

§ 100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660, 100 Stat. 3779 (42 U.S.C. 300aa–1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa–14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the Qualifications and Aids to Interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the Qualifications and Aids to Interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).

TABLE 1 TO PARAGRAPH (a)—VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (*e.g.,* DTaP, DTP, DT, Td, or TT).	A. Anaphylaxis	≤4 hours.
	B. Brachial Neuritis	2–28 days (not less than 2 days and not more than 28 days).
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (*e.g.*, DTP, DTaP, P, DTP-Hib).	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	≤72 hours.
III. Vaccines containing measles, mumps, and rubella virus or any of its components (*e.g.,* MMR, MM, MMRV).	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	5–15 days (not less than 5 days and not more than 15 days).
IV. Vaccines containing rubella virus (*e.g.,* MMR, MMRV).	A. Chronic arthritis	7–42 days (not less than 7 days and not more than 42 days).
V. Vaccines containing measles virus (*e.g.,* MMR, MM, MMRV).	A. Thrombocytopenic purpura	7–30 days (not less than 7 days and not more than 30 days).
	B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient.	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive.	≤12 months.
VI. Vaccines containing polio live virus (OPV).	A. Paralytic Polio.	
	—in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection.	
	—in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
VII. Vaccines containing polio inactivated virus (*e.g.,* IPV).	A. Anaphylaxis	≤4 hours.
VIII. Hepatitis B vaccines	A. Anaphylaxis	≤4 hours.
IX. Haemophilus influenzae type b (Hib) vaccines.	No Condition Specified.	Not applicable.
X. Varicella vaccines	A. Anaphylaxis	≤4 hours.
	B. Disseminated varicella vaccine-strain viral disease.	
	—Vaccine-strain virus identified	Not applicable.

TABLE 1 TO PARAGRAPH (a)—VACCINE INJURY TABLE—Continued

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
	—If strain determination is not done or if laboratory testing is inconclusive.	7–42 days (not less than 7 days and not more than 42 days).
	C. Varicella vaccine-strain viral reactivation	Not applicable.
XI. Rotavirus vaccines	A. Intussusception	1–21 days (not less than 1 day and not more than 21 days).
XII. Pneumococcal conjugate vaccines.	No Condition Specified.	Not applicable.
XIII. Hepatitis A vaccines	No Condition Specified.	Not applicable.
XIV. Seasonal influenza vaccines	A. Anaphylaxis	≤4 hours.
	B. Guillain-Barré Syndrome	3–42 days (not less than 3 days and not more than 42 days).
XV. Meningococcal vaccines	A. Anaphylaxis	≤4 hours.
XVI. Human papillomavirus (HPV) vaccines.	A. Anaphylaxis	≤4 hours.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–01211 Filed 1–19–21; 8:45 am]

BILLING CODE 4165–15–P

Proposed Rules

Federal Register
Vol. 86, No. 12
Thursday, January 21, 2021

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1166; Project Identifier AD–2020–00906–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 737–9 airplanes. This proposed AD was prompted by a report of missing sealant on the left and right wing leading edge outboard blowout door. This proposed AD would require doing a fluid seal contact inspection and a detailed inspection for missing sealant on the blowout door and applying sealant if necessary. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by March 8, 2021.

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

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

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1166.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1166; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Chris Baker, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3552; email: *christopher.r.baker@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–1166; Project Identifier AD–2020–00906–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Chris Baker, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3552; email: *christopher.r.baker@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA proposes to adopt a new AD for The Boeing Company Model 737–9 airplanes having line numbers 6834, 6852, 6872, 6899, 6917, 6935, 7096, 7173, 7196, 7201, 7208, 7216, 7246, 7253, 7261, 7268, 7306, 7316, 7338, 7348, 7361, 7384, 7388, 7394, and 7428. The FAA received a report indicating that the application of sealant on the left wing and right wing leading edge outboard blowout door was missed during the airplane manufacturing process on some Model 737–9 airplanes. The missing sealant is intended to act as a fuel barrier. In the event of a substantial fuel leak from the wing box, missing sealant could result in an unintended drain path allowing fuel to come into contact with the engine. This condition, if not addressed, could lead to a large ground fire.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 737–57A1350 RB, dated April 23, 2020. The service

information specifies procedures for doing a fluid seal contact inspection and a detailed inspection of the left and right wing leading edge outboard blowout door, at the inboard and outboard ends of the hinge, for missing sealant and applying sealant, if necessary.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishment of the actions identified in Boeing Alert Requirements Bulletin 737–57A1350 RB, dated April 23, 2020, described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1166.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 14 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	4 work-hours × $85 per hour = $340	$0	$340	$4,760

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
Up to 4 work-hours × $85 per hour = Up to $340	Up to $100	Up to $440.

The FAA has included all known costs in this cost estimate. According to the manufacturer, however, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

The Boeing Company: Docket No. FAA–2020–1166; Project Identifier AD–2020–00906–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by March 8, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 737–9 airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin 737–57A1350 RB, dated April 23, 2020.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a report of missing sealant on the left and right wing

leading edge outboard blowout door. The FAA is issuing this AD to address the missing sealant, which is intended to act as a fuel barrier. In the presence of a substantial fuel leak from the wing box, the unintended drain path could allow fuel to come into contact with the engine. This condition, if not addressed, could lead to a large ground fire.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD, at the applicable times specified in the Compliance paragraph of Boeing Alert Requirements Bulletin 737–57A1350 RB, dated April 23, 2020, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–57A1350 RB, dated April 23, 2020.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 737–57A1350, dated April 23, 2020, which is referred to in Boeing Alert Requirements Bulletin 737–57A1350 RB, dated April 23, 2020.

(h) Exception to Service Information Specifications

Where Boeing Alert Requirements Bulletin 737–57A1350 RB, dated April 23, 2020, refers to ''the Original Issue date of Requirements Bulletin 737–57A1350 RB,'' this AD requires using ''the effective date of this AD.''

(i) Alternative Methods of Compliance (AMOCs)

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

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(j) Related Information

(1) For more information about this AD, contact Chris Baker, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3552; email: *christopher.r.baker@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on December 17, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–01160 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1174; Project Identifier MCAI–2019–00135–E]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG (Type Certificate Previously Held by Rolls-Royce Deutschland GmbH, Formerly BMW Rolls-Royce GmbH) Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Rolls-Royce Deutschland Ltd & Co KG (RRD) BR700–710A1–10, BR700–710A2–20 and BR700–710C4–11 model turbofan engines. This proposed AD was prompted by an investigation by RRD, which revealed a quality escape during the high-pressure turbine (HPT) stage 1 disk rim cooling air hole manufacturing process. This proposed AD would require removing affected HPT disks from service prior to reaching specified compliance times or at the next engine shop visit, whichever occurs first. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by March 8, 2021.

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

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

For service information identified in this NPRM, contact Rolls-Royce Deutschland Ltd & Co KG, Eschenweg 11, Dahlewitz 15827, Germany; phone: +49 0 33 7086 1200; email: *rrd.techhelp@rolls-royce.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1174; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Wego Wang, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington MA 01803; phone: (781) 238–7134; fax: (781) 238–7199; email: *wego.wang@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2020–1174; Project Identifier MCAI–2019–00135–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR

11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Wego Wang, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2019–0299, dated December 10, 2019 (referred to after this as ''the MCAI''), to address the unsafe condition on these products. The MCAI states:

> An occurrence was reported of an HPT stage 1 disc burst on an industrial gas turbine engine. Subsequent investigation revealed a quality escape during HPT stage 1 disc rim cooling air hole manufacturing process. A review revealed that 28 HPT stage 1 discs were subject to a similar quality escape, two of which have been recovered and removed from service. The consequence of this manufacturing error is that the affected parts can no longer safely reach their Declared Safe Cyclic Life (DSCL).
>
> This condition, if not corrected, may lead to failure of an affected part, possibly resulting in release of high-energy debris, with consequent damage to, and/or reduced control of, the aeroplane. To address this potentially unsafe condition, RRD issued the NMSB, providing instructions to remove the engine from service for in-shop replacement of the affected part.
>
> For the reasons described above, this [EASA] AD reduces the DSCL for the affected parts, requires identification of the affected parts and removal from service of each affected engine for replacement of the affected part. This [EASA] AD also prohibits (re)installation of affected parts.

You may obtain further information by examining the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1174.

FAA's Determination

This product has been approved by EASA and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this NPRM because the agency evaluated all the relevant information provided by EASA and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed RRD Alert Non-Modification Service Bulletin (NMSB) SB–BR700–72–A900659, Revision 1, dated November 5, 2019 (the NMSB). The NMSB provides the part numbers and serial numbers for affected HPT disks, the serial numbers for all engines with an affected HPT disk installed, and instructions for replacement of the affected HPT disk. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Proposed AD Requirements in This NPRM

This proposed AD would require replacement of the affected HPT disk before reaching specified compliance times or at the next engine shop visit, whichever occurs first.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 21 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace HPT disk	20 work-hours × $85 per hour = $1,700	$550,000	$551,700	$11,585,700

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce Deutschland GmbH, formerly BMW Rolls-Royce GmbH): Docket No. FAA–2020–1174; Project Identifier MCAI–2019–00135–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by March 8, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG (RRD) (Type Certificate previously held by Rolls-Royce Deutschland GmbH, formerly BMW Rolls-Royce GmbH) BR700–710A1–10, BR700–710A2–20 and BR700–710C4–11 model turbofan engines with a high-pressure turbine (HPT) stage 1 disk having a part number and serial number listed in Planning Information, paragraph 1.A., of RRD Alert Non-Modification Service Bulletin (NMSB) SB–BR700–72–A900659, Revision 1, dated November 5, 2019, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by an investigation by RRD, which revealed a quality escape during the HPT stage 1 disk rim cooling air hole manufacturing process. The FAA is issuing this AD to prevent failure of the HPT stage 1 disk. The unsafe condition, if not addressed, could result in the release of high-energy debris, damage to the airplane, and reduced control of the airplane.

(f) Compliance

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

(g) Required Actions

Before the affected HPT stage 1 disk exceeds 2,840 flight cycles (FCs) since new, or within 60 days after the effective date of this AD, whichever occurs later, but not to exceed 8 years after the effective date of this AD if using FCs, remove the affected HPT stage 1 disk from service and replace with a part eligible for installation. Guidance on replacing the HPT stage 1 disk can be found in the Accomplishment Instructions, paragraph 3.B., of RRD Non-Modification Service Bulletin (NMSB) SB–BR700–72–A900659, Revision 1, dated November 5, 2019.

(h) Installation Prohibition

After the effective date of this AD, do not install any affected HPT stage 1 disk onto any engine.

(i) Definition

(1) For the purpose of this AD, a ''part eligible for installation'' is an HPT stage 1 disk that is not listed in paragraph 1.A. of RRD NMSB SB–BR700–72–A900659, Revision 1, dated November 5, 2019.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in Related Information. You may email your request to: *ANE-AD-AMOC@faa.gov.*

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

(k) Related Information

(1) For more information about this AD, contact Wego Wang, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7134; fax: (781) 238–7199; email: *wego.wang@faa.gov.*

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2019–0299, dated December 10, 2019, for more information. You may examine the EASA AD in the AD docket at *https://www.regulations.gov* by searching for and locating it in Docket No. FAA–2020–1174.

(3) For service information identified in this AD, contact Rolls-Royce Deutschland Ltd & Co KG, Eschenweg 11, Dahlewitz, 15827, Germany; phone: +49 0 33 7086 1200; email: *rrd.techhelp@rolls-royce.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

Issued on January 8, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–00672 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1140; Project Identifier AD–2020–01009–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2017–14–13, which applies to certain The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. AD 2017–14–13 requires a torque check of the screws in the cover assembly of the heel rest for both the captain's and the first officer's rudder pedals, and corrective action if necessary. Since the FAA issued AD 2017–14–13, operators have continued to find loose rudder pedal cover fasteners on previously inspected airplanes and airplanes outside the applicability of AD 2017–14–13. This proposed AD would require modifying the rudder pedal cover and shroud, and apply to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes and Model 737–8 and 737–9 airplanes. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by March 8, 2021.

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

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

p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1140.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1140; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Douglas Tsuji, Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3548; email: *douglas.tsuji@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–1140; Project Identifier AD–2020–01009–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person identified in the **FOR FURTHER INFORMATION CONTACT** section. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2017–14–13, Amendment 39–18957 (82 FR 33007, July 19, 2017) (''AD 2017–14–13''), for certain The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. AD 2017–14–13 requires a torque check of the screws in the cover assembly of the heel rest for both the captain's and the first officer's rudder pedals, and corrective action if necessary. AD 2017–14–13 resulted from a report of an aborted takeoff because the rudder pedals were not operating correctly. Investigation revealed a protruding screw in the rudder pedal heel rest adjacent to the pedals. The FAA issued AD 2017–14–13 to address a protruding screw in the cover assembly of the heel rest of a rudder pedal. A protruding screw could restrict rudder pedal motion and reduce differential braking control during takeoff or landing, which could cause a high-speed runway excursion.

Actions Since AD 2017–14–13 Was Issued

Since the FAA issued AD 2017–14–13, operators have continued to find loose rudder pedal cover fasteners on previously inspected airplanes and on airplanes outside the applicability of the AD. The FAA has determined that this design issue is an unsafe condition that affects all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes and Model 737–8 and 737–9 airplanes.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 737–27A1313 RB, Revision 1, dated June 24, 2020; and Boeing Alert Requirements Bulletin 737–27A1314 RB, Revision 1, dated June 24, 2020. The service information describes procedures for modifying the captain's and first officer's rudder pedal cover and shroud assemblies. These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would retain none of the requirements of AD 2017–14–13. This proposed AD would expand the applicability to include all The Boeing Company Model –600, –700, –700C, –800, –900, and –900ER series airplanes and Model 737–8 and 737–9 airplanes. This proposed AD would require accomplishment of the actions identified in Boeing Alert Requirements Bulletin 737–27A1313 RB, Revision 1, dated June 24, 2020; and Boeing Alert Requirements Bulletin 737–27A1314 RB, Revision 1, dated June 24, 2020; described previously, except as discussed under ''Differences Between this Proposed AD and the Service Information,'' and except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1140.

Differences Between This Proposed AD and the Service Information

The effectivity of Boeing Alert Requirements Bulletin 737–27A1313 RB, Revision 1, dated June 24, 2020, is limited to Model 737–8 and 737–9 airplanes with certain line numbers. The effectivity of Boeing Alert Requirements Bulletin 737–27A1314 RB, Revision 1, dated June 24, 2020, is limited to Model 737–600, 737–700, 737–700C, 737–800, 737–900, and 737–

900ER series airplanes with certain line numbers. However, the applicability of this proposed AD includes all Boeing Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes and Model 737–8 and 737–9 airplanes. Because the affected captain's and first officer's rudder pedal cover and shroud assemblies are rotable parts, the FAA has determined that these parts could later be installed on airplanes that were initially delivered with acceptable rudder pedal cover and shroud assemblies, thereby subjecting those airplanes to the unsafe condition. The agency has confirmed with Boeing that the Accomplishment Instructions in Boeing Alert Requirements Bulletin 737–27A1313 RB, Revision 1, dated June 24, 2020, and Boeing Alert Requirements Bulletin 737–27A1314 RB, Revision 1, dated June 24, 2020, are applicable to the expanded group of airplanes.

Costs of Compliance

The FAA estimates that this proposed AD affects 2,048 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modifying rudder pedal shroud assemblies.	Up to 13 work-hours × $85 per hour = Up to $1,105	$5,560	Up to $6,665	Up to $13,649,920.

The FAA has included all costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA has determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2017–14–13, Amendment 39–18957 (82 FR 33007, July 19, 2017), and

■ b. Adding the following new airworthiness directive:

The Boeing Company: Docket No. FAA–2020–1140; Project Identifier AD–2020–01009–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) action by March 8, 2021.

(b) Affected ADs

This AD replaces AD 2017–14–13, Amendment 39–18957 (82 FR 33007, July 19, 2017) (AD 2017–14–13).

(c) Applicability

This AD applies to all The Boeing Company airplanes specified in paragraphs (c)(1) and (2) of this AD, certificated in any category.

(1) Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes.

(2) Model 737–8 and 737–9 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Unsafe Condition

This AD was prompted by a report of an aborted takeoff because the rudder pedals were not operating correctly, and by additional reports of loose rudder pedal cover fasteners on previously inspected airplanes and on additional airplanes that were not included in the applicability of AD 2017–14–13. The FAA is issuing this AD to address incorrectly installed cover assembly fasteners from interfering with the operation of a rudder pedal. An incorrectly installed fastener could restrict rudder pedal motion and reduce differential braking control during takeoff or landing, which could cause a high-speed runway excursion.

(f) Compliance

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

(g) Determination of Modification Status

For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued before the effective date of this AD: Within 27 months after the date of issuance of the original airworthiness certificate or original export certificate of airworthiness, or within 27 months after the effective date of this AD, whichever occurs later, determine whether the captain's and first officer's rudder pedal cover and shroud assemblies have been modified as specified in Boeing Alert Requirements Bulletin 737–27A1313 RB, Revision 1, dated June 24, 2020, or 737–27A1314 RB, Revision 1, dated June 24, 2020, as applicable, or by production equivalent. A review of airplane maintenance records is acceptable for this requirement if the modification status can be conclusively determined from that review.

(h) Modification

For airplanes that have not been modified as determined by paragraph (g) of this AD: At

the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 737–27A1313 RB, Revision 1, dated June 24, 2020, or Boeing Alert Requirements Bulletin 737–27A1314 RB, Revision 1, dated June 24, 2020, as applicable, except as specified by paragraph (i) of this AD, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–27A1313 RB, Revision 1, dated June 24, 2020, or Boeing Alert Requirements Bulletin 737–27A1314 RB, Revision 1, dated June 24, 2020, as applicable.

Note 1 to paragraph (h): Guidance for accomplishing the actions required by paragraph (h) of this AD can be found in Boeing Alert Service Bulletin 737–27A1313, Revision 1, dated June 24, 2020, and Boeing Alert Service Bulletin 737–27A1314, Revision 1, dated June 24, 2020, which are referred to in Boeing Alert Requirements Bulletin 737–27A1313 RB, Revision 1, dated June 24, 2020, and Boeing Alert Requirements Bulletin 737–27A1314 RB, Revision 1, dated June 24, 2020, respectively.

(i) Exception to Service Information Specifications

Where Boeing Alert Requirements Bulletin 737–27A1313 RB, Revision 1, dated June 24, 2020, and Boeing Alert Requirements Bulletin 737–27A1314 RB, Revision 1, dated June 24, 2020, use the phrase ''the original issue date of'' each Requirements Bulletin for compliance, this AD requires using the effective date of this AD.

(j) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Requirements Bulletin 737–27A1313 RB, dated March 18, 2020, or Boeing Alert Requirements Bulletin 737–27A1314 RB, dated March 18, 2020.

(k) Parts Installation Limitation

(1) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after the effective date of this AD: As of the effective date of this AD, no person may install a captain's or first officer's rudder pedal cover or shroud assembly on any airplane, unless the cover or shroud assembly has been modified in accordance with the requirements of paragraph (h) of this AD.

(2) For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued prior to the effective date of this AD: After the modification required by paragraph (h) of this AD has been done, no person may install a captain's or first officer's rudder pedal cover or shroud assembly on any airplane, unless the cover or shroud assembly has been modified in accordance with the requirements of paragraph (h) of this AD. Reinstallation of a rudder pedal cover or shroud assembly that has not been modified in accordance with paragraph (h) of this AD but has been removed for other maintenance is allowed.

(l) Alternative Methods of Compliance (AMOCs)

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

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

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

(4) AMOCs approved previously for AD 2017–14–13 are not approved as AMOCs for the corresponding provisions of this AD.

(5) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (l)(5)(i) and (ii) of this AD apply.

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

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

(m) Related Information

(1) For more information about this AD, contact Douglas Tsuji, Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3548; email: *douglas.tsuji@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on December 17, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–01161 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0587; Product Identifier 2020–NM–086–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: The FAA is revising an earlier proposal for all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. This action revises the notice of proposed rulemaking (NPRM) by reducing the compliance time for certain airplanes. The FAA is proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since these actions would impose an additional burden over that in the NPRM, the FAA is reopening the comment period to allow the public the chance to comment on these changes.

DATES: The comment period for the NPRM published in the **Federal Register** on July 28, 2020 (85 FR 45355), is reopened.

The FAA must receive comments on this SNPRM by March 8, 2021.

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

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

For Boeing service information identified in this SNPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services

(C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.*

For Aviation Partners Boeing service information identified in this SNPRM, contact Aviation Partners Boeing, 2811 South 102nd St., Suite 200, Seattle, WA 98168; phone: 206–830–7699; fax: 206–767–0535; email: *leng@aviationpartners.com;* internet: *http://www.aviationpartnersboeing.com.*

You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020, is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0587.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0587; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this SNPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Wayne Ha, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5238; fax: 562–627–5210; email: *wayne.ha@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2020–0587; Product Identifier 2020–NM–086–AD'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this SNPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this SNPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this SNPRM. Submissions containing CBI should be sent to Wayne Ha, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5238; fax: 562–627–5210; email: *wayne.ha@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The FAA issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. The NPRM published in the **Federal Register** on July 28, 2020 (85 FR 45355). The NPRM was prompted by crack indications found in the lower aft wing skin bolt holes where the flap tracks attach to the track support fitting. The NPRM proposed to require repetitive inspections for cracking of the left and right wing, lower aft wing skin aft edge, at certain flap track locations, and applicable on-condition actions.

Actions Since the NPRM Was Issued

Since the FAA issued the NPRM, the FAA determined that the compliance time should be reduced for airplanes on which Aviation Partners Boeing (APB) blended winglets have been installed using supplemental type certificate (STC) ST01219SE.

Comments

The FAA gave the public the opportunity to comment on the NPRM. The following presents the comments received on the NPRM and the FAA's response to each comment.

Support for the NPRM

One commenter, Jesse Smith, agreed with the intent of the NPRM.

Request To Reduce Compliance Time for Certain Airplanes

APB asked that the FAA revise this AD to reduce the compliance times required for accomplishing the specified actions for airplanes that have incorporated STC ST01219SE. APB stated that it issued APB Alert Service Bulletin AP737C–57–003, dated July 28, 2020, (which contains the same actions as those specified in Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020, which is the source of service information for the actions specified in this proposed AD), with reduced compliance times for those airplanes, and, if approved by the FAA, could be added to paragraphs (g) and (h) of the proposed AD.

The FAA agrees with the commenter's request, and has reviewed Aviation Partners Boeing Alert Service Bulletin AP737C–57–003, dated July 28, 2020. The FAA revised paragraph (g) of this proposed AD, including adding paragraphs (g)(1) and (2) of this proposed AD. Paragraph (g)(2) of this proposed AD specifies, for airplanes on which winglets are installed using STC ST01219SE, doing the required actions in Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020, at the compliance times in Aviation Partners Boeing Alert Service Bulletin AP737C–57–003, dated July 28, 2020. The FAA has also added paragraphs (h)(4) and (5) of this proposed AD to provide exceptions to Aviation Partners Boeing Alert Service Bulletin AP737C–57–003, dated July 28, 2020.

Request To Clarify Discussion Section

Boeing asked that the Discussion section of the NPRM be clarified by removing ''This condition, if not addressed'' from the description of the unsafe condition, and instead starting the sentence with ''undetected cracking in the lower wing skin could result. . . .'' Boeing stated that the term ''this condition,'' is not clearly defined and may lead to confusion. Boeing added that Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020, describes inspections for cracking, and removing that language will more specifically indicate the unsafe condition being addressed in the

referenced service information. Boeing noted that the suggested language is also consistent with the language for the unsafe condition specified in paragraph (e) of the proposed AD.

The FAA acknowledges the commenter's request. However, the sentence in question is not carried over to this SNPRM. The FAA has not changed this AD regarding this issue.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020, and Aviation Partners Boeing Alert Service Bulletin AP737C–57–003, dated July 28, 2020. The service information describes procedures for repetitive high frequency eddy current (HFEC) inspections for cracking of the left and right wing, lower aft wing skin aft edge, at flap track numbers 1, 2, 3, 6, 7, and 8 attachment location and applicable on-condition actions. On-condition actions include repairing any cracking found. These documents are distinct since they apply to different airplane models in different configurations.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design. Certain changes described above expand the scope of the NPRM. As a result, the FAA has determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Proposed Requirements of This SNPRM

This SNPRM would require accomplishing the actions specified in the service information described previously. For information on the procedures and compliance times, see Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020, and Aviation Partners Boeing Alert Service Bulletin AP737C–57–003, dated July 28, 2020, at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0587.

Costs of Compliance

The FAA estimates that this proposed AD affects 141 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
HFEC inspections	7 work-hours × $85 per hour = $595 per inspection cycle.	$0	$595 per inspection cycle.	$83,895 per inspection cycle.

The FAA has received no definitive data that would enable the FAA to provide cost estimates for the on-condition actions specified in this proposed AD.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

The Boeing Company: Docket No. FAA–2020–0587; Product Identifier 2020–NM–086–AD.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by March 8, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 737–100, –200, 200C, –300, –400, and –500 series airplanes, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by crack indications found in the lower aft wing skin bolt holes where the flap tracks attach to the track support fitting. The FAA is issuing this AD to address undetected cracking in the lower wing skin, which could result in the inability of the structure to carry limit load, and adversely affect the structural integrity of the airplane.

(f) Compliance

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

(g) Required Actions

(1) For all airplanes except those identified in paragraph (g)(2) of this AD, except as specified in paragraph (h) of this AD, at the applicable times specified in the ''Compliance'' paragraph in Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020.

Note 1 to paragraphs (g)(1) and (2): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 737–57A1349, dated April 14, 2020, which is referred to in Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020.

(2) For airplanes on which Aviation Partners Boeing blended winglets are installed using supplemental type certificate (STC) ST01219SE: Except as specified in paragraph (h) of this AD, at the applicable time in the ''Compliance'' paragraph in Aviation Partners Boeing Alert Service Bulletin AP737C–57–003, dated July 28, 2020, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020.

(h) Exceptions to Service Information Specifications

(1) Where Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020, uses the phrase ''the original issue date of Requirements Bulletin 737–57A1349 RB,'' this AD requires using ''the effective date of this AD.''

(2) Where Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020, specifies contacting Boeing for repair instructions: This AD requires doing the repair and applicable on-condition actions before further flight using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(3) For airplanes identified as Group 1 in Boeing Alert Requirements Bulletin 737–57A1349 RB, dated April 14, 2020: Within 120 days after the effective date of this AD, do actions to correct the unsafe condition using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(4) Where Aviation Partners Boeing Alert Service Bulletin AP737C–57–003, dated July 28, 2020, uses the phrase ''the original issue date of this service bulletin,'' this AD requires using ''the effective date of this AD.''

(5) Where Aviation Partners Boeing Alert Service Bulletin AP737C–57–003, dated July 28, 2020, specifies contacting Boeing for repair instructions: This AD requires doing the repair and applicable on-condition actions before further flight using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

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

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact Wayne Ha, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5238; fax: 562–627–5210; email: *wayne.ha@faa.gov.*

(2) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.*

(3) For Aviation Partners Boeing service information identified in this AD, contact Aviation Partners Boeing, 2811 South 102nd St., Suite 200, Seattle, WA 98168; phone: 206–830–7699; fax: 206–767–0535; email: *leng@aviationpartners.com;* internet: *http://www.aviationpartnersboeing.com.*

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

Issued on December 30, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–01100 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–1193; Airspace Docket No. 20–AAL–28]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Hughes, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface at Hughes Airport, Hughes, AK, to accommodate new area navigation (RNAV) procedures. This action would ensure the safety and management of instrument flight rules (IFR) operations within the National Airspace System.

DATES: Comments must be received on or before March 8, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2020–1193; Airspace Docket No. 20–AAL–28, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fedreg.legal@nara.gov,* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S. 216th Street, Des Moines, WA 98198; telephone (206) 231–2245.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2020–1193; Airspace Docket No. 20–AAL–28''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by establishing Class E airspace extending upward from 700 feet above the surface at Hughes Airport, Hughes, AK.

The Class E airspace would be established within a 3.8-mile radius of the airport and within an area 2 miles each side of the 194° bearing extending from the airport 6.4 miles south. This area would protect aircraft on approach to runway 36 as they descend through 1,500 feet above ground level (AGL). In addition, an extension in the shape of a dogleg would be established 1.8 miles each side of the 14° bearing extending from the 3.8-mile radius to 6 miles north of the airport and then 1.8 miles each side of the 39° bearing from a point in space, Lat. 66°08′14″ N, long. 154°12′17″ W, forming an angle that extends from the 3.8-mile radius northeast 9.5 miles from the airport. This section would protect aircraft on approach to runway 18 descending through 1,500 feet AGL and those aircraft on departure until reaching 1,200 feet AGL.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR Part 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace.

* * * * *

AAL AK E5 Hughes, AK [New]

Hughes Airport, AK
(66°02′21″ N, 154°15′53″ W)

That airspace within a 3.8-mile radius of Hughes Airport, AK, and that airspace 2 miles each side of the 194° bearing extending from the 3.8-mile radius south 6.4 miles from the airport, and that airspace extending from the 3.8-mile radius beginning 1.8 miles west of the 14° bearing to Lat. 66°08′55″ N, long. 154°16′32″ W to Lat. 66°12′15″ N, long. 154°10′06″ W to Lat. 66°10′03″ N, long. 154°03′03″ W to Lat. 66°07′23″ N, long. 154°08′18″ W to the point on the 3.8-mile radius 1.8 miles east of the 14° bearing.

Issued in Seattle, Washington, on January 11, 2021.

Byron Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021–00835 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF VETERANS AFFAIRS

48 CFR Parts 852 and 873

RIN 2900–AQ78

VA Acquisition Regulation: Simplified Procedures for Health-Care Resources

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend and update its VA Acquisition Regulation (VAAR) in phased increments to revise or remove any policy superseded by changes in the Federal Acquisition Regulation (FAR), to remove any procedural guidance internal to VA into the VA Acquisition Manual (VAAM), and to incorporate any new agency specific regulations or policies. These changes seek to streamline and align the VAAR with the FAR and remove outdated and duplicative requirements and reduce burden on contractors. The VAAM incorporates portions of the removed VAAR as well as other internal agency acquisition policy. VA will rewrite certain parts of the VAAR and VAAM, and as VAAR parts are rewritten, will publish them in the **Federal Register**. VA will combine related topics, as appropriate. This rulemaking revises VAAR coverage concerning Simplified Procedures for Health-Care Resources as well as an affected part concerning Solicitation Provisions and Contract Clauses.

DATES: Comments must be received on or before March 22, 2021 to be considered in the formulation of the final rule.

ADDRESSES: Comments may be submitted through *www.Regulations.gov or mailed to* Mr. Rafael Taylor, (003A2A), Department of Veterans Affairs, Procurement Policy and Warrant Management Services, 425 I Street NW, Room 1064, Washington, DC 20001. Comments should indicate that they are submitted in response to ''RIN 2900–AQ78—VA Acquisition Regulation: Simplified Procedures for Health-Care Resources.'' Comments received will be available at *regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Mr. Rafael Taylor, Senior Procurement Analyst, Procurement Policy and Warrant Management Services, 003A2A, 425 I Street NW, Washington, DC 20001, (202) 382–2787. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Background

This rulemaking is issued under the authority of the Office of Federal Procurement Policy (OFPP) Act which provides the authority for an agency head to issue agency acquisition regulations that implement or supplement the FAR.

VA is proposing to revise the VAAR to add new policy or regulatory requirements and to remove any redundant guidance and guidance that is applicable only to VA's internal operating processes or procedures. Codified acquisition regulations may be amended and revised only through rulemaking. All amendments, revisions and removals have been reviewed and concurred with by VA's Integrated Product Team of agency stakeholders.

The VAAR uses the regulatory structure and arrangement of the FAR and headings and subject areas are consistent with FAR content. The VAAR is divided into subchapters, parts (each of which covers a separate aspect of acquisition), subparts, and sections.

The Office of Federal Procurement Policy Act, as codified in 41 U.S.C. 1707, provides the authority for the Federal Acquisition Regulation and for the issuance of agency acquisition regulations consistent with the FAR.

When Federal agencies acquire supplies and services using appropriated funds, the purchase is governed by the FAR, set forth at Title 48 Code of Federal Regulations (CFR), chapter 1, parts 1 through 53, and the agency regulations that implement and supplement the FAR. The VAAR is set forth at Title 48 CFR, chapter 8, parts 801 to 873.

Discussion and Analysis

VA proposes to make the following changes to the VAAR in this phase of its revision and streamlining initiative. For procedural guidance cited below that is proposed to be deleted from the VAAR, each section cited for removal has been considered for inclusion in VA's internal agency operating procedures in accordance with FAR 1.301(a)(2). Similarly, delegations of authority that are removed from the VAAR will be included in the VAAM as internal departmental guidance. The VAAM is being created in parallel with these revisions to the VAAR and is not subject to the rulemaking process as they are internal VA procedures and guidance. The VAAM will not be finalized until corresponding VAAR parts are finalized, and therefore the VAAM is not yet available online.

VAAR Part 852—Solicitation Provisions and Contract Clauses

We are proposing to revise the following provisions to make minor grammatical corrections and to capitalize all principal words in their titles: 852.273–70, Late Offers; 852.273–71, Alternative Negotiation Techniques; 852.273–72, Alternative Evaluation; 852.273–73, Evaluation—Health-Care Resources, and 852.273–74, Award Without Exchanges. The provisions 852.273–71, Alternative Negotiation Techniques, and 852.273–73, Evaluation—Health-Care Resources, are also amended to revise the citation in the first sentence to read ''873.110(d).''

VAAR Part 873—Simplified Procedures for Health-Care Resources

We propose to modify the title of part 873 by deleting the word ''Acquisition'' to reflect more accurately the meaning of the statute (38 U.S.C. 8153). The title would then be ''Simplified Procedures for Health-Care Resources.'' This change avoids any misunderstanding that these acquisitions would be subject to FAR Part 13, Simplified Acquisition Procedures, and the corresponding part 813 in the VAAR.

We also propose to revise the part 873 authorities to add 38 U.S.C. 8127–8128, VA's unique authority as implemented under the Veterans First Contracting Program.

We propose to replace the 38 U.S.C. 501 citation with 41 U.S.C. 1702 which addresses the acquisition planning and management responsibilities of Chief Acquisition Officers and Senior Procurement Executives, to include implementation of unique procurement

policies, regulations, and standards of the executive agency.

We propose to modify the citation 38 U.S.C. 8153 to 38 U.S.C. 8151–8153 to correctly cite the complete authority of the statute.

We propose to add the citation of 41 U.S.C. 1121(c)(3) which speaks to the authority of an executive agency under another law to prescribe policies, regulations, procedures, and forms for procurement that are subject to the authority conferred in the cited section, as well as other sections of Title 41 as shown therein.

We also propose to add 41 U.S.C 1303, an updated positive law codification to reflect additional authority of the VA as an executive agency to issue regulations that are essential to implement Governmentwide policies and procedures in the agency, as well as to issue additional policies and procedures required to satisfy the specific needs of the VA.

In 873.101, Policy, we propose to revise the single paragraph to explain more clearly the types of health-care resources that may be procured from VA-affiliated institutions under the authority of 38 U.S.C. 7302, and to explain when and how such resources that are commercial services may be procured from sources that are not affiliated with the Department under 38 U.S.C. 7302.

In 873.102, Definitions, we propose to revise the definition of ''Commercial service'' to remove the phrase ''except construction exceeding $2,000 and architect-engineer services'' since it is not a limitation contained in 38 U.S.C. 8153.

We propose to revise 873.103, Priority sources, by removing the unnecessary phrase ''Without regard to FAR 8.002(a)(2)'' in the first sentence. We also propose to add a statement regarding the applicability of 38 U.S.C. 8127(d) to this part by inserting a reference to revised policy regarding the priority of AbilityOne covered services as a mandatory source set forth at 808.002 (a)(2) (which implements Pub. L. 116–155, the Department of Veterans Affairs Contracting Preference Consistency Act of 2020). AbilityOne covered services remain a priority source under VAAR part 873 as set forth in 808.002(a)(2). We also propose to insert a reference to 873.107, Socioeconomic programs.

In VAAR section 873.104, Competition requirements, we propose to clarify that health-care resources may be acquired on a sole source basis from an institution affiliated with the Department under 38 U.S.C. 7302 if the resource is a commercial service, the use of medical equipment or space, or research. Such sole source contracts are not required to be publicized as required by FAR 5.101, nor do they require written justification under 41 U.S.C. 3304(e) or under FAR part 6. It would also clarify that when acquiring health-care resources from institutions or organizations not affiliated with the VA, then the Department shall permit all responsible sources, as appropriate, to submit a bid, proposal, or quotation for the resources to be procured and to provide for the consideration by the Department of bids, proposals, or quotations so submitted. Such actions shall also be publicized as otherwise required by VAAR section 873.108.

We propose to revise VAAR section 873.105, Acquisition planning, to delete the first paragraph as unnecessary; to redesignate the remaining paragraphs as (a), (b), and (c); to limit the need to assemble an acquisition team to those actions with non-affiliated sources described in VAAR section 873.104(b); and to comply with the requirements of the Veterans First preferences in VAAR subpart 819.70 and section 873.103 when performing market research.

We propose to revise the title of VAAR section 873.106 to read ''Exchanges with industry before receipt of proposals.'' We also propose to remove the reference to FAR part 10 as unnecessary, to add a sentence requiring that any exchange of information must be consistent with procurement integrity requirements in FAR 3.104, to replace the name ''Central Contractor Registration'' with that of the current system, ''System for Award Management,'' and to require research of the VA's Vendor Information Pages (VIP) database to help identify potential VIP-listed and verified Veteran-owned small business concerns.

In section 873.107, Socioeconomic programs, we propose to revise and clarify the policy set forth in this section to require implementation of the VA Rule of Two in accordance with VAAR subpart 819.70, and make necessary clarifications regarding priority sources and application of other small business programs. These clarifications and revisions are necessary to fully implement the requirements under various U.S. Federal court cases and new legislation, including the U.S. Supreme Court decision of June 16, 2016, in *Kingdomware Technologies, Inc.* v. *United States,* and the recently enacted Public Law 116–155, the Department of Veterans Affairs Contracting Preference Consistency Act of 2020, signed on August 8, 2020.

We propose to modify section 873.108, Publicizing contract actions, to require publication of only competitive acquisitions, to delete a reference to part 813 to avoid confusion, to remove repetitive language from section 873.104(a), and to make other minor edits.

In VAAR section 873.109, General requirements for acquisition of health-care resources, we propose to revise the section to conform to the requirement of the deviation ''Class deviation from VA Acquisition Regulation (VAAR) 815.303—Responsibilities,'' of December 15, 2016, designating the contracting officer to be the Source Selection Authority (SSA) unless the HCA has appointed another person to perform that role; to refer to both Performance Work Statements and Statements of Work when discussing ''specifications;'' and to correct a cross reference to read ''873.111(d)(1)(ii).''

We propose to revise section 873.110, Solicitation provisions, to capitalize all clauses and provisions referenced in the section; to revise paragraph (a) to clarify the basis for using provision 852.271–70, Late Offers, in solicitations; to correct the reference in (b) to ''Alternative Negotiation Techniques'' to cite ''873.111(d)(1),'' and the reference in (c) to ''873.111(d)(1)(ii);'' to revise paragraphs (d) and (e) to incorporate the appropriate capitalization of the provisions; and to remove from (f) the prescription of clause 852.207–70, Report of Employment Under Commercial Activities, as that clause is obsolete since the A–76 program is not currently effective.

In section 873.111, Acquisition strategies for health-care resources, we propose to make several minor edits to the text; to remove the opening phrase ''Without regard to FAR 13.003 or 13.500(a),'' as unnecessary; to insert the acronym ''RFQ'' and the word ''subparts'' paragraph (a)(1); to change the spelling of the word ''Part'' in (a)(2) to lower case; to delete existing paragraph (c) as unnecessary; and to redesignate the remaining paragraphs as (c) and (d).

We propose to revise section 873.113, Exchanges with offerors, to delete in paragraph (c) the repetitive use of the word ''perceived;'' and to correct the citation in paragraph (e) to 873.111(d)(1) regarding alternative negotiation techniques.

We propose to make two minor edits to the last sentence in paragraph (a) in 873.115, Proposal revisions, to insert the word ''all'' after the word ''safeguard'' to stress the need for protecting proposals and revisions, and to delete as unnecessary the word ''thereto.''

In section 873.116, Source selection decision, we propose to replace the term

''contracting officer'' in paragraphs (a) and (b) with ''Source Selection Authority'' or ''SSA'' to be consistent with the deviation ''Class deviation from VA Acquisition Regulation (VAAR) 815.303—Responsibilities,'' of December 15, 2016, and to remove from paragraph (c) the reference to section 815.308 since that section does not exist.

In section 873.118, Debriefings, we propose to revise the first sentence to read ''Offerors whose proposals are not accepted under a competitive request for proposals (RFP) may submit a written request for a debriefing to the contracting officer.'' The current language uses non-standard acquisition terms.

Executive Orders 12866, 13563 and 13771

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all 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). E.O. 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 not 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 proposed rule is not expected to be an E.O. 13771 regulatory action because this proposed rule is not significant under E.O. 12866.

Paperwork Reduction Act

This proposed 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 Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612).

This rulemaking does not change VA's policy regarding small businesses, does not have an economic impact to individual businesses, and there are no increased or decreased costs to small business entities. On this basis, the proposed rule would not have an economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

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 proposed rule will have no such effect on State, local, and tribal Governments or on the private sector.

List of Subjects

48 CFR Part 852

Government procurement, Reporting and recordkeeping requirements.

48 CFR Part 873

Government procurement.

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 July 17, 2020, for publication.

Consuela Benjamin,

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

For the reasons set out in the preamble, VA proposes to amend 48 CFR parts 852 and 873 as follows:

PART 852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authorities for part 852 continue to read as follows:

Authority: 38 U.S.C. 8127–8128, and 8151–8153; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1303; 41 U.S.C. 1702; and 48 CFR 1.301–1.304.

Subpart 852.2—Text of Provisions and Clauses

■ 2. Section 852.273–70 is revised to read as follows:

852.273–70 Late Offers.

As prescribed in 873.110(a), insert the following provision:

LATE OFFERS (DATE)

This provision replaces paragraph (f) of FAR provision 52.212–1, Instructions to Offerors—Commercial Items. Offers or modifications of offers received after the time set forth in a request for quotations or request for proposals may be considered, at the discretion of the Contracting Officer, if determined to be in the best interest of the Government. Late bids submitted in response to an invitation for bid (IFB) will not be considered.

(End of provision)

■ 3. Section 852.273–71 is revised to read as follows:

852.273–71 Alternative Negotiation Techniques.

As prescribed in 873.110(b), insert the following provision:

ALTERNATIVE NEGOTIATION TECHNIQUES (DATE)

The Contracting Officer may elect to use the alternative negotiation techniques described in 873.111(d) in conducting this procurement. If used, Offerors may respond by maintaining offers as originally submitted, revising offers, or submitting an alternative offer. The Government may consider initial offers unless revised or withdrawn, revised offers, and alternative offers in making the award. Revising an offer does not guarantee an offeror an award.

(End of provision)

■ 4. Section 852.273–72 is revised to read as follows:

852.273–72 Alternative Evaluation.

As prescribed in 873.110(c), insert the following provision:

ALTERNATIVE EVALUATION (DATE)

(a) The Government will award a contract resulting from this solicitation to the responsible Offeror submitting the lowest priced offer that conforms to the solicitation. During the specified period for receipt of offers, the amount of the lowest offer will be posted and may be viewed by [*Contracting Officer insert description of how the information may be viewed electronically or*

otherwise]. Offerors may revise offers anytime during the specified period. At the end of the specified time period for receipt of offers, the responsible Offeror submitting the lowest priced offer will be in line for award.

(b) Except when it is determined not to be in the Government's best interest, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are materially unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

(End of provision)

■ 5. Section 852.273–73 is revised to read as follows:

852.273–73 Evaluation—Health-Care Resources.

As prescribed in 873.110(d), in lieu of FAR provision 52.212–2, the Contracting Officer may insert a provision substantially as follows:

EVALUATION—HEALTH–CARE RESOURCES (DATE)

(a) The Government will award a contract resulting from this solicitation to the responsible Offeror whose proposal, conforming to the solicitation, will be most advantageous to the Government, price and other factors considered. The following information or factors shall be used to evaluate offers: [*Contracting Officer insert evaluation information or factors, such as technical capability to meet the Government's requirements, past performance, or such other evaluation information or factors as the Contracting Officer deems necessary to evaluate offers. Price must be evaluated in every acquisition. The Contracting Officer may include the evaluation information or factors in their relative order of importance, such as in descending order of importance. The relative importance of any evaluation information must be stated in the solicitation.*]

(b) Except when it is determined not to be in the Government's best interest, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are materially unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s). The Government may reject any or all proposals if such action is in the Government's interest. Additionally, the Government may waive informalities and minor irregularities in proposals received.

(c) If this solicitation is a request for proposals (RFP), a written notice of award or acceptance of a proposal, mailed or otherwise furnished to the successful Offeror within the time for acceptance specified in the solicitation, shall result in a binding contract without further action by either party. Before the proposal's specified expiration time, the Government may accept a proposal (or part of a proposal), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received by the Contracting Officer before award.

(End of provision)

■ 6. Section 852.273–74 is revised to read as follows:

852.273–74 Award Without Exchanges.

As prescribed in 873.110(e), insert the following provision:

AWARD WITHOUT EXCHANGES (DATE)

The Government intends to evaluate proposals and award a contract without exchanges with Offerors. Therefore, each initial proposal should contain the Offeror's best terms from a cost or price and technical standpoint. However, the Government reserves the right to conduct exchanges if later determined by the Contracting Officer to be necessary.

■ 7. Part 873 is revised to read as follows:

PART 873—SIMPLIFIED PROCEDURES FOR HEALTH-CARE RESOURCES

Sec.

873.101 Policy.
873.102 Definitions.
873.103 Priority sources.
873.104 Competition requirements.
873.105 Acquisition planning.
873.106 Exchanges with industry before receipt of proposals.
873.107 Socioeconomic programs.
873.108 Publicizing contract actions.
873.109 General requirements for acquisition of health-care resources.
873.110 Solicitation provisions.
873.111 Acquisition strategies for health-care resources.
873.112 Evaluation information.
873.113 Exchanges with offerors.
873.114 Best value pool.
873.115 Proposal revisions.
873.116 Source selection decision.
873.117 Award to successful offeror.
873.118 Debriefings.

Authority: 38 U.S.C. 8127–8128; 38 U.S.C. 8151–8153; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1303; 41 U.S.C. 1702; and 48 CFR 1.301–1.304.

873.101 Policy.

(a) *General.* In accordance with 38 U.S.C. 8153, to secure health-care resources which otherwise might not be feasibly available, or to effectively utilize certain other health-care resources, the Department of Veterans Affairs (VA) may make arrangements by contract for the mutual use, or exchange of use, of health-care resources between VA health-care facilities and any health-care provider, or other entity or individual. This part prescribes simplified procedures for contracts with entities not affiliated with VA under 38 U.S.C. 7302 to secure health-care resources that are a commercial service, or the use of medical equipment or space. VA may enter into such a contract if such resources are not, or would not be, used to their maximum effective capacity. (38 U.S.C. 8153)

(b) *Precedence.* These procedures shall be used in conjunction with the Federal Acquisition Regulation (FAR) and other parts of the VAAR. However, when a policy or procedure in the FAR or another part of the VAAR is inconsistent with the procedures contained in this part, this part shall take precedence. (38 U.S.C. 8153)

873.102 Definitions.

Commercial service means a service that is offered and sold competitively in the commercial marketplace, is performed under standard commercial terms and conditions, and is procured using firm-fixed price contracts. (38 U.S.C. 8153)

Health-care providers include health-care plans and insurers and any organizations, institutions, or other entities or individuals who furnish health-care resources. (38 U.S.C. 8153)

Health-care resource includes hospital care and medical services (as those terms are defined in 38 U.S.C. 1701 and services under sections 1782 and 1783 of this title) any other health-care service, and any health-care support or administrative resource. (38 U.S.C. 8152)

873.103 Priority sources.

Except for the acquisition of covered services available from the Committee for Purchase From People Who Are Blind or Severely Disabled and the AbilityOne Program (see FAR subpart 8.7), there are no priority sources for the acquisition of health-care resources consisting of commercial services or the use of medical equipment or space in accordance with 808.002(a)(2) and 873.107. (38 U.S.C. 8153)

873.104 Competition requirements.

(a) *Affiliated institutions.* (1) A health-care resource may be acquired on a sole source basis if a commercial service, the use of medical equipment or space, or research, and is to be acquired from an institution affiliated with the VA in accordance with 38 U.S.C. 7302, including medical practice groups and other entities associated with affiliated institutions, blood banks, organ banks, or research centers. (38 U.S.C. 8153(a)(3)(A))

(2) Acquisitions of health-care resources identified in paragraph (a)(1) of this section are not required to be publicized as otherwise required by 873.108 or FAR 5.101.

(b) *Non-affiliated entities.* (1) If the health-care resource required is a

commercial service or the use of medical equipment or space, and is to be acquired from an entity not described in paragraph (a)(1) of this section, contracting officers shall permit all responsible sources, as appropriate, to submit a bid, proposal, or quotation for the resource to be procured, and provide for the consideration by VA of bids, proposals, or quotations so submitted. (38 U.S.C. 8153(a)(3)(B))

(2) Acquisition of health-care resources identified in paragraph (b)(1) of this section shall be publicized as otherwise required by 873.108. Moreover, for any such acquisition described in paragraph (b)(1) of this section to be conducted on a sole source basis, the contracting officer must prepare a justification that includes the information and is approved at the levels prescribed in FAR part 6.303. (38 U.S.C. 8153(a)(3)(D))

873.105 Acquisition planning.

(a) For the acquisition of health-care resources consisting of commercial services or the use of medical equipment or space from non-affiliated institutions as described in 873.104(b), where the acquisition is expected to exceed the simplified acquisition threshold (SAT), an acquisition team must be assembled. The team shall be tailored by the contracting officer for each particular acquisition expected to exceed the SAT. The team should consist of a mix of staff, appropriate to the complexity of the acquisition, and may include fiscal, legal, administrative, and technical personnel, and such other expertise as necessary to assure a comprehensive acquisition plan. The team should include the small business advocate representing the contracting activity or a higher-level designee. At a minimum, the team must include the contracting officer and a representative of the Office of General Counsel and the requesting service. (38 U.S.C. 8153)

(b) The contracting officer or the acquisition team, as appropriate, must conduct market research, including satisfying the requirements of VAAR 808.002(a)(2) and 873.107, Socioeconomic programs, and a VA Rule of Two determination. It is the responsibility of the contracting officer to ensure the requirement is appropriately publicized and information about the procurement opportunity is adequately disseminated as set forth in 873.107. (38 U.S.C. 8153)

(c) In lieu of the requirements of FAR part 7 addressing documentation of the acquisition plan, the contracting officer may conduct an acquisition strategy meeting with cognizant offices to seek approval for the proposed acquisition approach. If a meeting is conducted, briefing materials shall be presented to address the acquisition plan topics and structure in FAR 7.105. Formal written minutes—summarizing decisions, actions, and conclusions—shall be prepared and included in the contract file, along with a copy of the briefing materials. (38 U.S.C. 8153)

873.106 Exchanges with industry before receipt of proposals.

(a) Exchange of information among all interested parties involved in an acquisition described in 873.104(b), from the earliest identification of a requirement through release of the solicitation, is encouraged. Any exchange of information must be consistent with procurement integrity requirements in FAR 3.104. The nature and extent of exchanges between the Government and industry shall be a matter of the contracting officer's discretion (for acquisitions not exceeding the simplified acquisition threshold) or the acquisition team's discretion, as coordinated by the contracting officer. (38 U.S.C. 8153)

(b) Techniques to promote early exchange of information include—

(1) Industry or small business conferences;

(2) Public hearings;

(3) Market research in accordance with FAR 10.002(b), which shall be followed to the extent that the provisions therein would provide relevant information;

(4) One-on-one meetings with potential offerors;

(5) Presolicitation notices;

(6) Draft requests for proposals (RFPs);

(7) Requests for information (RFIs);

(8) Presolicitation or preproposal conferences;

(9) Site visits;

(10) Electronic notices (*e.g.,* internet); and

(11) Use of the System for Award Management (SAM) (*see http://www.sam.gov/.*

(12) Researching VA's Vendor Information Pages (VIP) database at *https://www.vip.vetbiz.va.gov/.*

873.107 Socioeconomic programs.

(a) The Veterans First Contracting Program in VAAR subpart 819.70 takes precedence over other small business programs. (38 U.S.C. 8127–8128)

(b)(1) Except for contract actions subject to 808.002(a)(2), competitive contract actions not otherwise excluded under this part shall be set-aside for VIP-listed service-disabled veteran-owned small business (SDVOSB) concerns or veteran-owned small business (VOSB) concerns if the contracting officer has a reasonable expectation that two or more eligible small business concerns owned and controlled by Veterans will submit offers and that the award can be made at a fair and reasonable price that offers best value to the United States. (38 U.S.C. 8127–8128)

(2) The contracting officer shall proceed with the acquisition under the simplified procedures of this part considering priority sources (see 808.008(a)(2) and 873.103) and preferences for other small businesses in accordance with 819.203–70 and 819.7004. (38 U.S.C. 8153)

(c) Without regard to FAR 13.003(b)(1), 19.203, 19.502, the head of the contracting activity (HCA) may approve a waiver from the requirement for any set-aside for small business participation when a waiver is determined to be in the best interest of the Government. (38 U.S.C. 8153)

(d) The contracting officer shall ensure priorities for veteran-owned small businesses are implemented within the VA hierarchy of small business program preferences, established by 38 U.S.C. 8127 and 8128, as implemented in VAAR subpart 819.70, the Veterans First Contracting Program. Specifically, the contracting officer shall consider preferences for verified service-disabled veteran-owned small businesses (SDVOSBs) first, then preferences for verified veteran-owned small businesses (VOSBs). These priorities will be followed by preferences for other small business concerns in accordance with FAR 19.203, 819.203–70 and 819.7004. (38 U.S.C. 8153)

873.108 Publicizing contract actions.

(a) All competitive acquisitions under this part, except as provided in paragraph (b) of this section, for dollar amounts in excess of the SAT, shall be publicly announced utilizing a medium designed to permit all responsible sources, as appropriate under the provisions of this part, to submit a bid, proposal, or quotation (as appropriate).

(1) The publication medium may include the internet, including the Governmentwide point of entry (GPE), and local, regional or national publications or journals, as appropriate, at the discretion of the contracting officer, depending on the complexity of the acquisition.

(2) Notice shall be published for a reasonable time prior to issuance of a solicitation, depending on the complexity or urgency of the acquisition, in order to afford potential offerors a reasonable opportunity to respond. If the notice includes a

complete copy of the RFQ or solicitation, a prior notice is not required, and the RFQ or solicitation shall be considered to be announced and issued at the same time.

(3) The notice may include contractor qualification parameters, such as time for delivery of service, credentialing or medical certification requirements, small business or other socio-economic preferences, the appropriate small business size standard, and such other qualifications as the contracting officer deems necessary to meet the needs of the Government. (38 U.S.C. 8153)

(b) The requirement for public announcement does not apply to sole source acquisitions described in 873.104(a). However, as required by 38 U.S.C. 8153(a)(3)(D), acquisitions from an institution not affiliated with the Department in accordance with 38 U.S.C. 7302, if conducted on a sole source basis, must still be justified and publicized (see 873.104(b)(2)). (38 U.S.C. 8153)

(c) For acquisitions below the SAT, a public announcement is optional. (38 U.S.C. 8153)

(d) Each solicitation issued under these procedures must prominently identify that the requirement is being solicited under the authority of 38 U.S.C. 8153 and part 873. (38 U.S.C. 8153)

873.109 General requirements for acquisition of health-care resources.

(a) *Source selection authority.* Unless the head of the contracting activity (HCA) appoints another individual to serve as the Source Selection Authority (SSA), the contracting officer shall be the SSA for acquisitions of health-care resources, consisting of commercial services, or the use of medical equipment or space, utilizing the guidance contained in this part 873. (38 U.S.C. 8153)

(b) *Performance Work Statement/ Statement of Work.* The performance work statement (PWS) or statement of work (SOW) must define the requirement and should, in most instances, include qualifications or limitations such as time limits for delivery of service, medical certification or credentialing restrictions, and small business or other socio-economic preferences. The contracting officer may include any other such terms as the contracting officer deems appropriate for each specific acquisition. (38 U.S.C. 8153)

(c) *Documentation.* Without regard to FAR 13.106–3(b), 13.501(b), or 15.406–3, the contract file must include—

(1) A brief written description of the procedures used in awarding the contract;

(2) A written determination that the health-care resources being procured are not otherwise feasibly available or that utilization of such health-care resources is necessary to meet mission requirements;

(3) Documentation of market research and the results of such research;

(4) The number of offers received; and

(5) An explanation, tailored to the size and complexity of the acquisition, of the basis for the contract award decision. (38 U.S.C. 8153)

(d) *Time for receipt of quotations or offers.* (1) Without regard to FAR 5.203, contracting officers shall set a reasonable time for receipt of quotations or proposals in the solicitations.

(2) Without regard to FAR 15.208 or 52.212–1(f), quotations or proposals received after the time set forth in an RFQ or request for proposals (RFP) may be considered at the discretion of the contracting officer if determined to be in the best interest of the Government. Contracting officers must document the rationale for accepting quotations or proposals received after the time specified in the RFQ or RFP. This paragraph (d)(2) shall not apply to RFQs or RFPs if alternative evaluation techniques described in 873.111(d)(1)(ii) are used. This paragraph (d)(2) does not apply to invitations for bid (IFBs). (38 U.S.C. 8153)

(e) *Cancellation of procurements.* Any acquisition may be canceled by the contracting officer at any time during the acquisition process if cancellation is determined to be in the best interest of the Government and a memorandum for the record in included in the solicitation file explaining the reasons for the cancellation. (38 U.S.C. 8153)

873.110 Solicitation provisions.

(a) As required in 873.109(d), contracting officers shall set a reasonable time for receipt of quotations or proposals and shall insert the provision at 852.273–70, Late Offers, in all RFQs and RFPs exceeding the micro-purchase threshold. However, this provision shall not be used if the provision 852.273–71, Alternative Negotiation Techniques, is to be used. (38 U.S.C. 8153)

(b) The contracting officer shall insert a provision in RFQs and solicitations, substantially the same as the provision at 852.273–71, Alternative Negotiation Techniques, when either of the alternative negotiation techniques described in 873.111(d)(1) will be used. (38 U.S.C. 8153)

(c) The contracting officer shall insert the provision at 852.273–72, Alternative Evaluation, in lieu of the provision at 52.212–2, Evaluation—Commercial Items, when the alternative negotiation technique described in 873.111(d)(1)(ii) will be used. (38 U.S.C. 8153)

(d) When evaluation information, as described in 873.112, is to be used to select a contractor under a RFQ or RFP for health-care resources consisting of commercial services or the use of medical equipment or space, the contracting officer may insert the provision at 852.273–73, Evaluation—Health-Care Resources, in the RFQ or RFP in lieu of FAR provision 52.212–2. (38 U.S.C. 8153)

(e) As provided at 873.113(f), if award may be made without exchange with offerors, the contracting officer shall include the provision at 852.273–74, Award Without Exchanges, in the RFQ or RFP. (38 U.S.C. 8153)

(f) The contracting officer shall insert the FAR clause at 52.207–3, Right of First Refusal of Employment, in all RFQs, solicitations, and contracts issued under the authority of 38 U.S.C. 8151–8153 which may result in a conversion, from in-house performance to contract performance, of work currently being performed by Department of Veterans Affairs employees. (38 U.S.C. 8153)

873.111 Acquisition strategies for health-care resources.

The following acquisition processes and techniques may be used, singly or in combination with others, as appropriate, to design acquisition strategies suitable for the complexity of the requirement and the amount of resources available to conduct the acquisition. These strategies should be considered during acquisition planning. The contracting officer shall select the process most appropriate to the particular acquisition. There is no preference for sealed bid acquisitions. (38 U.S.C. 8153)

(a) *Request for quotations (RFQ).* (1) Without regard to FAR subparts 6.1 or 6.2, contracting officers must solicit a sufficient number of sources to promote competition to the maximum extent practicable and to ensure that the purchase is advantageous to the Government, based, as appropriate, on either price alone or price and other factors (*e.g.,* past performance and quality). RFQs must notify vendors of the basis upon which the award is to be made. (*see* FAR 13.004)

(2) For acquisitions in excess of the SAT, the procedures set forth in FAR part 13 concerning RFQs may be utilized without regard to the dollar

thresholds contained therein. (38 U.S.C. 8153)

(b) *Sealed bidding.* FAR part 14 provides procedures for sealed bidding.

(c) *Multiphase acquisition technique.* (1) *General.* Without regard to FAR 15.202, multiphase acquisitions may be appropriate when the submission of full proposals at the beginning of an acquisition would be burdensome for offerors to prepare and for Government personnel to evaluate. Using multiphase techniques, the Government may seek limited information initially, make one or more down-selects, and request a full proposal from an individual offeror or limited number of offerors. Provided that the notice notifies offerors, the contracting officer may limit the number of proposals during any phase to the number that will permit an efficient competition among proposals offering the greatest likelihood of award. The contracting officer may indicate in the notice an estimate of the greatest number of proposals that will be included in the down-select phase. The contracting officer may down-select to a single offeror. (38 U.S.C. 8153)

(2) *First phase notice.* In the first phase, the Government shall publish a notice (see 873.108) that solicits responses and that may provide, as appropriate, a general description of the scope or purpose of the acquisition and the criteria that will be used to make the initial down-select decision. The notice may also inform offerors of the evaluation criteria or process that will be used in subsequent down-select decisions. The notice must contain sufficient information to allow potential offerors to make an informed decision about whether to participate in the acquisition. The notice must advise offerors that failure to participate in the first phase will make them ineligible to participate in subsequent phases. The notice may be in the form of a synopsis in the Governmentwide point of entry (GPE) or a narrative letter or other appropriate method that contains the information required by this paragraph. (38 U.S.C. 8153)

(3) *First phase responses.* Offerors shall submit the information requested in the notice described in paragraph (d)(2) of this section. Information sought in the first phase may be limited to a statement of qualifications and other appropriate information (*e.g.,* proposed technical concept, past performance information, limited pricing information). (38 U.S.C. 8153)

(4) *First phase evaluation and down-select.* The Government shall evaluate all offerors' submissions in accordance with the notice and make a down-select decision. (38 U.S.C. 8153)

(5) *Subsequent phases.* Additional information shall be sought in the second phase so that a down-select can be performed or an award made without exchanges, if necessary. The contracting officer may conduct exchanges with remaining offeror(s), request proposal revisions, or request best and final offers, as determined necessary by the contracting officer, in order to make an award decision. (38 U.S.C. 8153)

(6) *Debriefing.* Without regard to FAR 15.505, contracting officers must debrief offerors whose proposals are not accepted under a competitive request for proposals (RFP) as required by 873.118. (38 U.S.C. 8153)

(d) *Alternative negotiation techniques.* (1) Contracting officers may utilize alternative negotiation techniques for the acquisition of health-care resources. Alternative negotiation techniques may be used when award will be based on either price or price and other factors. Alternative negotiation techniques include but are not limited to:

(i) Indicating to offerors a price, contract term or condition, commercially available feature, and/or requirement (beyond any requirement or target specified in the solicitation) that offerors will have to improve upon or meet, as appropriate, in order to remain competitive.

(ii) Posting offered prices electronically or otherwise (without disclosing the identity of the offerors) and permitting revisions of offers based on this information.

(2) Except as otherwise permitted by law, contracting officers shall not conduct acquisitions under this section in a manner that reveals the identities of offerors, releases proprietary information, or otherwise gives any offeror a competitive advantage (*see* FAR 3.104). (38 U.S.C. 8153)

873.112 Evaluation information.

(a) Without regard to FAR 15.304—Evaluation factors and significant subfactors (except for 15.304(c)(1) and (c)(3), which do apply to acquisitions under this authority), the criteria, factors, or other evaluation information that apply to an acquisition, and their relative importance, are within the broad discretion of agency acquisition officials as long as the evaluation information is determined to be in the best interest of the Government. (38 U.S.C. 8153)

(b) Price or cost to the Government must be evaluated in every source selection. Past performance shall be evaluated in source selections for competitive acquisitions exceeding the SAT unless the contracting officer documents that past performance is not an appropriate evaluation factor for the acquisition. (38 U.S.C. 8153)

(c) The quality of the product or service may be addressed in source selection through consideration of information such as past compliance with solicitation requirements, technical excellence, management capability, personnel qualifications, and prior experience. The information required from quoters, bidders, or offerors shall be included in notices or solicitations, as appropriate. (38 U.S.C. 8153)

(d) The relative importance of any evaluation information included in a solicitation must be set forth therein. (38 U.S.C. 8153)

873.113 Exchanges with offerors.

(a) Without regard to FAR 15.201 or 15.306, acquisitions generally involve exchanges between the Government and competing offerors. Open exchanges support the goal of efficiency in Government by providing the Government with relevant information (in addition to that submitted in the offeror's initial proposal) needed to understand and evaluate the offeror's proposal. The nature and extent of exchanges between the Government and offerors is a matter of contracting officer judgment. Clarifications, communications, and discussions are not applicable to acquisitions under this part 873. (38 U.S.C. 8153)

(b) Exchanges with potential offerors may take place throughout the source selection process. Exchanges may start in the planning stages and continue through contract award. Exchanges should occur most often with offerors determined to be in the best value pool (see 873.114). The purpose of exchanges is to ensure there is mutual understanding between the Government and the offerors on all aspects of the acquisition, including offerors' submittals/proposals. Information disclosed as a result of oral or written exchanges with an offeror may be considered in the evaluation of an offeror's proposal. (38 U.S.C. 8153)

(c) Exchanges may be conducted, in part, to obtain information that explains or resolves ambiguities or other concerns (*e.g.,* perceived errors, omissions, or deficiencies) in an Offeror's proposal. (38 U.S.C. 8153)

(d) Exchanges shall only be initiated if authorized by the contracting officer and need not be conducted with all offerors. (38 U.S.C. 8153)

(e) Except for acquisitions based on alternative negotiation techniques contained in 873.111(d)(1), the contracting officer and other Government personnel involved in the acquisition shall not disclose

information regarding one offeror's proposal to other offerors without consent of the offeror in accordance with FAR parts 3 and 24. (38 U.S.C. 8153)

(f) Award may be made on initial proposals without exchanges if the solicitation states that the Government intends to evaluate proposals and make award without exchanges, unless the contracting officer determines that exchanges are considered necessary. (38 U.S.C. 8153)

873.114 Best value pool.

(a) Without regard to FAR 15.306(c), the contracting officer may determine the most highly rated proposals having the greatest likelihood of award based on the information or factors and subfactors in the solicitation. These vendors constitute the best value pool. This determination is within the sole discretion of the contracting officer. Competitive range determinations are not applicable to acquisitions under this part 873. (38 U.S.C. 8153)

(b) In planning an acquisition, the contracting officer may determine that the number of proposals that would otherwise be included in the best value pool is expected to exceed the number at which an efficient, timely, and economical competition can be conducted. In reaching such a conclusion, the contracting officer may consider such factors as the results of market research, historical data from previous acquisitions for similar services, and the resources available to conduct the source selection. Provided the solicitation notifies offerors that the best value pool can be limited for purposes of making an efficient, timely, and economical award, the contracting officer may limit the number of proposals in the best value pool to the greatest number that will permit an efficient competition among the proposals offering the greatest likelihood of award. The contracting officer may indicate in the solicitation the estimate of the greatest number of proposals that will be included in the best value pool. The contracting officer may limit the best value pool to a single offeror. (38 U.S.C. 8153)

(c) If the contracting officer determines that an offeror's proposal is no longer in the best value pool, the proposal shall no longer be considered for award. Written notice of this decision must be provided to unsuccessful offerors at the earliest practicable time. (38 U.S.C. 8153)

873.115 Proposal revisions.

(a) The contracting officer may request proposal revisions as often as needed during the proposal evaluation process at any time prior to award from vendors remaining in the best value pool. Proposal revisions shall be submitted in writing. The contracting officer may establish a common cutoff date for receipt of proposal revisions. Contracting officers may request best and final offers n. In any case, contracting officers and acquisition team members must safeguard all proposals and revisions to avoid unfair dissemination of an offeror's proposal. (38 U.S.C. 8153)

(b) If an offeror initially included in the best value pool is no longer considered to be among those most likely to receive award after submission of proposal revisions and subsequent evaluation thereof, the offeror may be eliminated from the best value pool without being afforded an opportunity to submit further proposal revisions. (38 U.S.C. 8153)

(c) Requesting and/or receiving proposal revisions does not necessarily conclude exchanges. However, requests for proposal revisions should advise offerors that the Government may make award without obtaining further revisions. (38 U.S.C. 8153)

873.116 Source selection decision.

(a) An integrated comparative assessment of proposals should be performed before source selection is made. The SSA shall independently determine which proposal(s) represents the best value, consistent with the evaluation information or factors and subfactors in the solicitation, and that the prices are fair and reasonable. The SSA may determine that all proposals should be rejected if it is in the best interest of the Government. (38 U.S.C. 8153)

(b) The source selection team, or advisory boards or panels, may conduct comparative analysis(es) of proposals and make award recommendations, if the SSA requests such assistance. (38 U.S.C. 8153)

(c) The source selection decision must be documented in accordance with FAR 15.308. (38 U.S.C. 8153)

873.117 Award to successful offeror.

(a) The contracting officer shall award a contract to the successful offeror by furnishing the contract or other notice of the award to that offeror. (38 U.S.C. 8153)

(b) If a request for proposal (RFP) process was used for the solicitation and if award is to be made without exchanges, the contracting officer may award a contract without obtaining the offeror's signature a second time. The offeror's signature on the offer constitutes the offeror's agreement to be bound by the offer. If a request for quotation (RFQ) process was used for the solicitation, and if the contracting officer determines there is a need to establish a binding contract prior to commencement of work, the contracting officer should obtain the offeror's acceptance signature on the contract to ensure formation of a binding contract. (38 U.S.C. 8153)

(c) If the award document includes information that is different than the latest signed offer, both the offeror and the contracting officer must sign the contract award. (38 U.S.C. 8153)

(d) When an award is made to an offeror for less than all of the items that may be awarded and additional items are being withheld for subsequent award, each notice shall state that the Government may make subsequent awards on those additional items within the offer acceptance period. (38 U.S.C. 8153)

873.118 Debriefings.

Offerors whose proposals are not accepted under a competitive request for proposals (RFP) may submit a written request for a debriefing to the contracting officer. Without regard to FAR 15.505, preaward debriefings may be conducted by the contracting officer when determined to be in the best interest of the Government. Post-award debriefings shall be conducted in accordance with FAR 15.506. (38 U.S.C. 8153)

[FR Doc. 2020–29196 Filed 1–19–21; 8:45 am]

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Notices

Federal Register

Vol. 86, No. 12

Thursday, January 21, 2021

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–2020–0035]

Notice of Availability of an Environmental Assessment for Release of Bikasha collaris and Gadirtha fusca for Biological Control of Chinese Tallow

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment relative to permitting the release of the insects *Bikasha collaris* and *Gadirtha fusca* for biological control of Chinese tallow tree (*Triadica sebifera*) in the contiguous United States. Based on the environmental assessment and other relevant data, we have reached a preliminary determination that the release of this control agent will not have a significant impact on the quality of the human environment. We are making the environmental assessment available to the public for review and comment.

DATES: We will consider all comments that we receive on or before February 22, 2021.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0035.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0035, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0035* 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) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Colin D. Stewart, Assistant Director, Pests, Pathogens, and Biocontrol Permits, Permitting and Compliance Coordination, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 851–2327; email: *Colin.Stewart@usda.gov.*

SUPPLEMENTARY INFORMATION: Chinese tallow, native to China, is one of the most aggressive and widespread invasive weeds in the Southeastern United States; it grows as a large shrub, or a medium-height but large diameter tree, up to 60 feet tall and 3 feet in diameter with dark green bark and hairless leaves. Since its introduction, the weed has been reported primarily in 10 States including North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, Arkansas, Texas, and California. Tallow invasions alter species composition, community structure, and ecosystem processes in many native habitats.

Bikasha collaris is a small beetle. Adults are about 2 millimeters long and feed on tallow leaves, young stems, and even woody stems. In nature, females lay eggs on the soil surface at the base of plants. Larvae hatch and tunnel into the ground and feed on the roots of tallow plants. *Gadirtha fusca* is a small moth with adults about 2 centimeters long. Eggs are usually laid individually on leaves, and early and late instar larvae feed externally on leaves.

The Animal and Plant Health Inspection Service's (APHIS') review and analysis of the potential environmental impacts associated with the proposed release are documented in detail in an environmental assessment (EA) entitled ''Field Release of the Insects *Bikasha collaris* (Coleoptera: Chrysomelidae) and *Gadirtha fusca* (Lepidoptera: Nolidae) for Classical Biological Control of Chinese Tallow Tree in the Contiguous United States'' (April 2020). We are making the EA available to the public for review and comment. We will consider all comments that we receive on or before the date listed under the heading **DATES** at the beginning of this notice.

The EA may be viewed on the *Regulations.gov* website or in our reading room (see **ADDRESSES** above for a link to *Regulations.gov* and information on the location and hours of the reading room). You may also request paper copies of the EA by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the EA when requesting copies.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Done in Washington, DC, this 13th day of January 2021.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–01124 Filed 1–19–21; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0122]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Importation of Gypsy Moth Host Materials From Canada

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations to prevent the introduction of gypsy moth

from Canada into noninfested areas of the United States.

DATES: We will consider all comments that we receive on or before March 22, 2021.

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

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0112.*

• *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0112, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0112* 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) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the importation of gypsy moth host material from Canada, contact Mr. Marc Phillips, Senior Regulatory Policy Specialist, PPQ, APHIS, USDA, 4700 River Road, Unit 133, Riverdale, MD 20737; (301) 851–2114. For copies of more detailed information on the information collection, contact Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851–2533.

SUPPLEMENTARY INFORMATION:

Title: Importation of Gypsy Moth Host Materials From Canada.

OMB Control Number: 0579–0142.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to prohibit or restrict the importation, entry, exportation, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. This authority has been delegated to the Animal and Plant Health Inspection Service (APHIS), which administers regulations to implement the PPA. Regulations governing the importation of gypsy moth host material into the United States from Canada are contained in 7 CFR 319.77–1 through 319.77–5.

The regulations are intended to prevent the introduction of gypsy moth into noninfested areas of the United States by placing certain inspection and documentation requirements on gypsy moth host material (*i.e.,* regulated articles) imported from Canada. Under the regulations, depending on the place of origin of the regulated articles and their destination in the United States, certain information collection activities are required such as a phytosanitary certificate, certificate of origin, written statement, compliance agreement, and emergency action notification.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the 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 on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.375 hours per response.

Respondents: Canadian plant health authorities; growers, exporters, or shippers of Christmas trees, shrubs, logs, pulpwood, and other articles from gypsy moth-infested provinces in Canada; and private individuals entering the United States with mobile homes or outdoor household articles.

Estimated annual number of respondents: 3,201.

Estimated annual number of responses per respondent: 4.

Estimated annual number of responses: 11,612.

Estimated total annual burden on respondents: 4,358 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 13th day of January 2021.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–01141 Filed 1–19–21; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0076]

Environmental Impact Statement for Predator Damage Management in Oregon

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent for public scoping.

SUMMARY: The Animal and Plant Health Inspection Service is preparing an environmental impact statement analyzing alternatives for predator damage management in Oregon. This notice proposes issues and alternatives for consideration in the environmental impact statement and requests public comments to further delineate the scope of the alternatives, the environmental issues, and other issues of public concern to be considered. This notice also serves to inform the public that the U.S. Forest Service and the U.S. Department of the Interior's Bureau of Land Management have joined as cooperating agencies in the environmental impact statement process.

DATES: We will consider all comments that we receive on or before February 22, 2021.

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

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0076.*

• *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2019–0076, State Director—Oregon Predator Damage Management EIS, USDA APHIS-Wildlife Services, 6035 NE 78th CT. Suite 100, Portland, OR 97216.

Supporting documents and any comments received on this topic may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0076* 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) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. Kevin Christensen, Assistant State Director, Wildlife Services, APHIS, USDA, 6035 NE 78th CT. Suite 100, Portland, OR 97216; (503) 820–2751.

SUPPLEMENTARY INFORMATION:

Background

On November 14, 2019, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** (84 FR 61868, Docket No. APHIS–2019–0076) a notice [1] informing the public of APHIS' intent to prepare an environmental impact statement (EIS) analyzing alternatives for predator damage management (PDM) in Oregon. We will continue to prepare the EIS under the Council on Environmental Quality's regulations in effect on the date of the notice of intent's publication (November 14, 2019) and APHIS' National Environmental Policy Act Implementing Procedures (7 CFR part 372).

Predators provide many positive ecological, cultural, and aesthetic benefits. They may also be involved in conflicts with humans, including preying upon or harassing livestock; damaging other agricultural resources and property; and threatening human health and safety. In limited instances, predation may impede wildlife management agency efforts to enhance populations of prey species, such as threatened or endangered species or ungulate populations. APHIS' Wildlife Services (APHIS–WS) program evaluates and responds to requests for assistance with PDM from the public, private entities, other agencies, and Native American Tribes within the State of Oregon. APHIS–WS only becomes involved in PDM if it has received a request for assistance and has established appropriate agreements and authorizations with the landowners/managers, applicable agency, or Tribal authorities. Over fiscal years 2015–2019, APHIS–WS responded to more than 6,700 requests per year for information or assistance in reducing conflicts with predators in Oregon.

APHIS–WS in Oregon currently uses an integrated approach to PDM. The approach involves access to the full range of legally available nonlethal and lethal PDM methods to reduce conflicts with coyote, black bear, striped skunk, raccoon, cougar (mountain lion), red fox, bobcat, badger, Virginia opossum, gray fox, feral/free-ranging/hybrid dog, feral and free-ranging domestic cat, spotted skunk, weasel, and gray wolf. APHIS–WS assistance may be in the form of advice, depredation investigations, information on sources of PDM materials, training, and loan of equipment (technical assistance) or hands-on assistance with implementing PDM methods (operational assistance). APHIS–WS applies methods in accordance with applicable Federal, State, Tribal, and local regulations. APHIS–WS develops and annually renews work plans with land management agencies to address specific activities and restrictions required to safely conduct PDM on public lands in a manner consistent with applicable land management agency policies and resource management plans.

APHIS–WS gives preference to practical and effective nonlethal methods. In some cases, concurrent use of nonlethal and lethal methods or immediate use of lethal methods may be the most appropriate solution (*e.g.,* threats to human safety). APHIS–WS may use or recommend the following methods to reduce damage: Changes to agricultural practices, capture and relocation, livestock guarding animals, habitat modification, exclusion, frightening devices, carcass disposal, human behavior modification (*e.g.,* trash management and not feeding wildlife), shooting from the ground or from aircraft, gas cartridges, snares, traps, and trained decoy and tracking dogs. APHIS–WS is not proposing to use M–44s or Compound-1080 in Oregon.

APHIS–WS conducts its activities pursuant to the Acts of March 2, 1931 (7 U.S.C. 8351–8352), as amended, and December 22, 1987 (7 U.S.C. 8353), which established APHIS–WS' authority to provide its services. APHIS–WS also coordinates its PDM activities in Oregon pursuant to memoranda of understanding with the U.S. Forest Service and the U.S. Department of the Interior's Bureau of Land Management (BLM). APHIS–WS also conducts its activities in accordance with applicable Federal and State laws and regulations.

Proposed Action

APHIS–WS is preparing an EIS to evaluate alternatives for agency involvement in managing damage and conflicts associated with predators in Oregon. APHIS–WS will serve as the lead Federal agency for purposes of the National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 *et seq.*). The U.S. Forest Service and BLM are cooperating agencies on the EIS. Once completed, the EIS will replace APHIS–WS' existing environmental assessments on predator damage management and the separate environmental assessment on wolf damage management in Oregon.[2]

BLM intends to adopt the EIS and analysis to streamline and facilitate future site-specific NEPA analysis and implementation actions on BLM-administered lands for all BLM Oregon districts. The BLM in Oregon may authorize APHIS–WS in Oregon to perform certain wildlife damage control activities on BLM-administered lands in accordance with a separately issued BLM Record of Decision.

Scoping

We encourage comments that will assist in further delineating the scope of alternatives, environmental impacts, and other issues of public concern. Please also submit any scientific data, research, or studies that you believe are relevant to the analysis. Comments, information, and analyses provided should be as specific as possible to explain why the information is important to the analysis.

Alternatives

The EIS will consider a range of reasonable alternatives. The EIS will include a ''no action'' alternative, which is defined as a continuation of the ongoing predator damage management practices described above, in accordance with the Council on Environmental Quality's regulations for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508). We are considering the following alternatives for comparative analysis in the EIS:

- APHIS–WS in Oregon continues the current PDM activities as previously analyzed under NEPA;
- APHIS–WS in Oregon continues the current PDM activities and includes additional wolf damage management activities aligned with U.S. Fish and Wildlife Service management authorities and with State rules and statutes identified in the 2019 Oregon Wolf Conservation and Management Plan;
- APHIS–WS in Oregon conducts only non-lethal PDM activities;
- APHIS–WS in Oregon conducts only non-lethal PDM activities, except

[1] To view the notice, go to *https://www.regulations.gov/docket?D=APHIS-2019-0076.*

[2] Environmental Assessments replaced by the EIS will include Management of Black Bear Damage to Timber in Western Oregon (2003), Implementation of the Oregon Cougar Management Plan (2007), Wildlife Damage Management in Roseburg (1997), Wildlife Damage Management in Northwest District (1997), Wildlife Damage Management of the John Day ADC District in Eastern Oregon (1996), and Gray Wolf Damage Management in Oregon (2014).

in cases involving the protection of human/pet health and safety or protection of federally threatened or endangered species; or

• APHIS–WS in Oregon conducts no PDM activities in Oregon.

We welcome additional recommendations for management alternatives.

Issues for Detailed Consideration in the Analysis

In considering reasonable alternatives, the EIS will analyze the effects of APHIS–WS' PDM activities in Oregon on important environmental issues and other issues of public concern. APHIS–WS and the cooperating agencies have identified the following issues for consideration in the EIS:

• Impacts of intentional take on State and regional predator populations;

• Effects on nontarget animal populations, including species federally listed under the Endangered Species Act (61 U.S.C. 1531 *et seq.*);

• Impacts of the alternatives on predator-prey relationships and ecosystem processes (*e.g.,* trophic cascades);

• Humaneness and ethical perspectives regarding PDM activities;

• Risks and benefits to human and pet safety from PDM activities;

• Impacts on Special Management Areas, including Wilderness and Wilderness Study Areas; and

• Sociocultural impacts, including impacts on values, hunting, non-consumptive uses, aesthetic impacts, Native American cultural uses, and economic effects.

We encourage the public to submit comments identifying additional issues.

After the comment period closes, APHIS–WS will review and consider all comments timely received and any other relevant information in the development of the EIS. All comments received will be available for public review as required and allowed by law. Upon completion of the draft EIS, APHIS–WS will publish a notice announcing its availability and an opportunity to comment in the **Federal Register** and via the *GovDelivery.com* email registry. To receive notices regarding this project or other Wildlife Services NEPA projects, please register at *https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new.*

The EIS will be prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508) in effect at the time of the publication of our notice of intent (November 14, 2019); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Done in Washington, DC, this 13th day of January 2021

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–01148 Filed 1–19–21; 8:45 am]

BILLING CODE 3410–34–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meetings of the South Dakota Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of public meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that the South Dakota State Advisory Committee to the Commission will hold virtual meetings on Wednesday, January 20, 2021; Wednesday, February 17, 2021; and Wednesday, March 17, 2021 from 3:00 p.m.–4:00 p.m. (CT). The purpose of the meetings is to discuss testimony heard related to the Committee's topic on maternal health disparities of Native American women in South Dakota.

DATES: These meetings will be held from 3:00 p.m. to 4:00 p.m. (CT) on 1/20/21, 2/17/21, and 3/17/21. The access information for all three meetings is the same:

• To join by web conference: *https://tinyurl.com/y7heztq9*

• To join by phone only, dial 1–800–360–9505; Access code: 199 118 9479

FOR FURTHER INFORMATION CONTACT: Mallory Trachtenberg at *mtrachtenberg@usccr.gov* or by phone at (202) 809–9618.

SUPPLEMENTARY INFORMATION: These meetings are available to the public through the Webex links above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing. may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the call-in number found through registering at the web link provided for each meeting.

Members of the public are entitled to make comments during the open period at the end of each meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the respective meeting. Written comments may be emailed to Mallory Trachtenberg at *mtrachtenberg@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (202) 809–9618. Records and documents discussed during the meeting will be available for public viewing as they become available at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda: Wednesday, January 20, 2021; Wednesday, February 17, 2021; and Wednesday, March 17, 2021 from 3:00 p.m.–4:00 p.m. (CT)

I. Welcome and Roll Call

II. Announcements and Updates

III. Approval of Minutes

IV. Discussion: Maternal Health Disparities of Native American Women

V. Public Comment

VI. Next Steps

VII. Adjournment

Dated: January 14, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–01210 Filed 1–19–21; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Hawai'i Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a teleconference meeting of the Hawai'i Advisory Committee (Committee) to the Commission will be held from 10:00 a.m. to 11:00 a.m. on Wednesday, January 27, 2021 (Hawaiian Time). The purpose of the meeting is to review outline of report focused on COVID–19 and Pacific Islander communities.

DATES: The meeting will be held on Wednesday, January 27, 2021 from 10:00 a.m.–11:00 a.m. HST.

Public Call Information: Dial: 800–367–2403. Conference ID: 2900555.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes, Designated Federal Officer (DFO) at *afortes@usccr.gov* or by phone at (202) 681–0857.

SUPPLEMENTARY INFORMATION: For copies of meeting documents, email *afortes@usccr.gov.* This meeting is available to the public through the following toll-free call-in number: 800–367–2403, conference ID number: 2900555. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012 or email Ana Victoria Fortes at *afortes@usccr.gov.* Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl0AAA.*

Please click on ''Committee Meetings'' tab. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Discuss Outline
III. Discuss Report Writing Process
IV. Public Comment
V. Discuss Next Steps
a. Tentative next meeting: March 10, 2021; 10:00 a.m.–12:00 p.m. (2 hour meeting)
VI. Adjournment

Dated: January 14, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–01209 Filed 1–19–21; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Hawai'i Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a teleconference meeting of the Hawai'i Advisory Committee (Committee) to the Commission will be held from 10:00 a.m. to 12:00 p.m. on Wednesday, March 10, 2021 (Hawaiian Time). The purpose of the meeting will be to review first draft of report on COVID–19 and Pacific Islander communities.

DATES: The meeting will be held on Wednesday, March 10, 2021 from 10:00 a.m.–12:00 p.m. HST.

Public Call Information:
Dial: 800–353–6461.
Conference ID: 5120066.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes, Designated Federal Officer (DFO) at *afortes@usccr.gov* or by phone at (202) 681–0857.

SUPPLEMENTARY INFORMATION: For copies of meeting documents, email *afortes@usccr.gov.* This meeting is available to the public through the following toll-free call-in number: 800–353–6461, conference ID number: 5120066. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012 or email Ana Victoria Fortes at *afortes@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl0AAA.*

Please click on ''Committee Meetings'' tab. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Review Report
III. Public Comment
IV. Discuss Next Steps
V. Adjournment

Dated: January 14, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–01208 Filed 1–19–21; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Rhode Island Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of public meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that the Rhode Island State Advisory Committee to the Commission will convene meetings on February 10, 2021 and March 10, 2021 at 12:00 p.m. (ET). The purpose of the meetings is to discuss the Committee's report on licensing for formerly incarcerated individuals in Rhode Island, and potentially consider new topics if time allows.

DATES: Wednesday, February 10, 2021 and Wednesday, March 10, 2021 at 12:00 p.m. (ET).

Public Web Conference Link (video and audio): Link: *https://tinyurl.com/yclg2fd9;* Password: USCCR.

Phone Only: Dial 1–800–360–9505; Access code: 199 344 3090.

FOR FURTHER INFORMATION CONTACT: Mallory Trachtenberg at *mtrachtenberg@usccr.gov* or by phone at (202) 809–9618.

SUPPLEMENTARY INFORMATION: The meeting is available to the public through the web link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing. Individuals may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with conference details found through registering at the web link above. To request additional accommodations, please email *mtrachtenberg@usccr.gov* at least 7 days prior to the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Mallory Trachtenberg at *mtrachtenberg@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (202) 809–9618. Records and documents discussed during the meeting will be available for public viewing as they become available at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda

Wednesday, February 10, 2021 and March 10, 2021 From 12:00–1:00 p.m. (ET)

I. Welcome and Roll Call
II. Announcements and Updates
III. Approval of Minutes
IV. Draft Report Discussion
V. Potential Topic Discussion, as time allows
VI. Public Comment
VII. Next Steps
VIII. Adjournment

Dated: January 13, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–01151 Filed 1–19–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

U.S. Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Current Population Survey (CPS) Basic Demographic Items

AGENCY: Census Bureau, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed reinstatement without change of the Current Population Survey Basic Demographics as required by the Paperwork Reduction Act of 1995, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before March 22, 2021.

ADDRESSES: Interested persons are invited to submit written comments by email to Kyra Linse, Acting Survey Director, Current Population Surveys via the internet at *dsd.cps@census.gov.* Please reference Current Population Survey (CPS) Basic Demographic Itemsn in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2020–0031, to the Federal e-Rulemaking Portal: *http://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Taylor Smith, Survey Statistician, 301–763–7131, *taylor.a.smith@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau plans to request clearance from the Office of Management and Budget (OMB) for the collection of basic demographic information on the Current Population Survey (CPS) beginning in November 2021. The current clearance expires October 31, 2021.

The CPS has been the source of official government statistics on employment and unemployment for over 70 years. The Bureau of Labor Statistics (BLS) and the Census Bureau jointly sponsor the basic monthly survey. The Census Bureau also prepares and conducts all the field work. At the OMB's request, the Census Bureau and the BLS divide the clearance request in order to reflect the joint sponsorship and funding of the CPS program. BLS submits a separate clearance request for the portion of the CPS that collects labor force information for the civilian noninstitutional population. Some of the information within that portion includes employment status, number of hours worked, job search activities, earnings, duration of unemployment, and the industry and occupation classification of the job held the previous week. The justification that follows is in support of the demographic data.

The demographic information collected in the CPS provides a unique set of data on selected characteristics for the civilian noninstitutional population. Some of the demographic information we collect are age, marital status, sex, Armed Forces status, education, race, origin, and family income. We use these data in conjunction with other data, particularly the monthly labor force data, as well as periodic supplement data. We also use these data independently for internal analytic research and for evaluation of other surveys. In addition, we use these data as a control to produce accurate estimates of other personal characteristics.

II. Method of Collection

The CPS basic demographic information is collected from individual

households by both personal visit and telephone interviews each month. All interviews are conducted using computer-assisted interviewing. Households in the CPS are in sample for four consecutive months, and for the same four months the following year. This is called a 4–8–4 rotation pattern; households are in sample for four months, in a resting period for eight months, and then in sample again for four months.

III. Data

OMB Control Number: 0607–0049.

Form Number(s): There are no forms. All interviews are conducted on computers.

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

Affected Public: Households.

Estimated Number of Respondents: 59,000 per month.

Estimated Time per Response: 1.5 minutes.

Estimated Total Annual Burden Hours: 17,700.

Estimated Total Annual Cost to Public: There is no cost to the respondents other than their time (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Sections 8(b), 141, and 182.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–01235 Filed 1–19–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

U.S. Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Survey of Residential Building or Zoning Permit Systems (C–411)

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 November 9, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau.

Title: Survey of Residential Building or Zoning Permit Systems (C–411).

OMB Control Number: 0607–0350.

Form Number(s): C–411(v), C–411(m), C–411(c).

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

Number of Respondents: 820 annual average.

Average Hours per Response: 15 minutes.

Burden Hours: 205.

Needs and Uses: The U.S. Census Bureau is requesting an extension of a currently approved collection for Form C–411, ''Survey of Residential Building or Zoning Permit Systems.''

The Census Bureau produces statistics used to monitor activity in the large and dynamic construction industry. These statistics help state and local governments and the federal government, as well as private industry, to analyze this important sector of the economy. The accuracy of the Census Bureau statistics regarding the amount of construction authorized depends on data supplied by building and zoning officials throughout the country. The Census Bureau uses Form C–411 to obtain information from state and local building permit officials needed for updating the universe of permit-issuing places which serves as the sampling frame for the Report of Privately-Owned Residential Building or Zoning Permits Issued (OMB number 0607–0094), also known as the Building Permits Survey (BPS), and the Survey of Housing Starts, Sales, and Completions (OMB number 0607–0110), also known as Survey of Construction (SOC). These two sample surveys provide widely used measures of construction activity, including the principal economic indicators, New Residential Construction and New Home Sales. Data from the BPS and SOC are also used by the Bureau of Economic Analysis (BEA) in the calculation of estimates of the Residential Fixed Investment portion of the Nation's Gross Domestic Product (GDP). In addition, data from the BPS are used by the Census Bureau in the calculation of annual population estimates; these estimates are widely used by government agencies to allocate funding and other resources to local governments.

The questions on Form C–411 pertain to the legal requirements for issuing building or zoning permits in the local jurisdictions. Information is obtained on such items as geographic coverage and types of construction for which permits are issued.

The appropriate form is sent to a jurisdiction when the Census Bureau has reason to believe that a new permit system has been established or an existing one has changed. This is based on information from a variety of sources including survey respondents, regional councils and the Census Bureau's Geography Division, which keeps abreast of changes in corporate status. We anticipate approximately a 50% response rate to the mailed C–411 forms, which is supplemented with existing known information from the C–404 monthly and annual collection, individual follow-ups with jurisdictions by email or phone, and publicly available information to maintain

coverage for the universe of permit issuing places. We anticipate having accurate and up to date coverage for the universe for over 85% of jurisdictions as a result of these combined operations.

We use the information to verify the existence of new permit systems or changes to existing systems. Based on the information, the Census Bureau adds new permit-issuing places to the universe, deletes places no longer issuing permits, and makes changes to the universe to reflect those places that have merged.

Failure to maintain the universe of permit-issuing places would result in deficient samples and inaccurate statistics. This in turn jeopardizes the accuracy of the above-mentioned economic indicators. These indicators are closely monitored by the Board of Governors of the Federal Reserve System and other economic policy makers because of the sensitivity of the housing industry to changes in interest rates.

Affected Public: State, Local, or Tribal government.

Frequency: Every five years with annual follow-up, as needed.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Sections 131 and 182.

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

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–0350.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–01186 Filed 1–19–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of the Census

2020 Census Tribal Consultation; Virtual Public Meeting

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of virtual public meeting and request for comments.

SUMMARY: The Bureau of the Census (Census Bureau) will conduct its first calendar year 2021 tribal consultation meeting on February 18 via national webinar. The tribal consultation meeting reflects the Census Bureau's commitment to strengthen government-to-government relationships with federally recognized tribes. The Census Bureau will provide updates and seek input on the 2020 Census Disclosure Avoidance System (DAS). In preparation for the webinar, the Census Bureau request comments on various questions related to tribes' use of decennial census data.

DATES: The Census Bureau will conduct the tribal consultation webinar on Thursday, February 18, 2021, from 3:00 p.m. to 4:30 p.m. EST. Any questions or topics to be considered in the tribal consultation meetings must be received in writing via email or fax by Thursday, February 18.

ADDRESSES: The Census Bureau tribal consultation webinar meeting will be held via the WebEx platform at the following presentation link: *https://uscensus.webex.com/uscensus/onstage/g.php?MTID=e83f743e02f061c59b12ef423aee8a8b6.*

If the webinar requires a password, type Census#1. For audio, please call the following number: 1–877–717–2157. When prompted, please use the following Participant Code: 5229469.

Please direct all written comments via email or fax to Dee Alexander, Tribal Affairs Coordinator, Office of Congressional and Intergovernmental Affairs, Intergovernmental Affairs Office, U.S. Census Bureau Washington, DC 20233; fax (301) 763–3780; or by email at *Dee.A.Alexander@census.gov* or *ocia.tao@census.gov.*

FOR FURTHER INFORMATION CONTACT: Dee Alexander, Tribal Affairs Coordinator, Office of Congressional and Intergovernmental Affairs, Intergovernmental Affairs Office, U.S. Census Bureau, Washington, DC 20233; telephone (301) 763–9335; fax (301) 763–3780; or by email at *Dee.A.Alexander@census.gov* or *ocia.tao@census.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Census Bureau's procedures for outreach, notice, and consultation ensure involvement of tribes, to the extent practicable and permitted by law, before making decisions or implementing policies, rules, or programs that affect federally recognized tribal governments. These meetings are open to citizens of federally recognized tribes by invitation.

The Census Bureau's Decennial Directorate and the Intergovernmental Affairs Office have been responsible for the development and implementation of outreach and promotion activities to assist in obtaining a complete and accurate census count in 2020 among all residents, including the American Indian and Alaska Native populations. This program is one part of the overall outreach and promotion efforts directed at building awareness about the importance of the Census Bureau's commitment to produce quality 2020 Census American Indian and Alaska Native data for all tribal communities and organizations.

In accordance with Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, issued November 6, 2000, the Census Bureau has adhered to its tribal consultation policy by seeking the input of tribal governments in the planning and implementation of the 2020 Census with the goal of ensuring the most accurate counts and data for the American Indian and Alaska Native population. The Census Bureau conducted one national tribal consultation webinar in September 2019 and two formal tribal consultation meetings in October 2019 and February 2020 specific to the 2020 Census Disclosure Avoidance System. The February 18 national webinar will provide a forum for tribes to receive an update and to provide input on the 2020 Census Disclosure Avoidance System regarding work done specifically for the American Indian and Alaska Native tribal areas.

For more information, please see the following URL link: *https://www.census.gov/programs-surveys/decennial-census/2020-census/planning-management/2020-census-data-products/2020-das-updates.html.*

In preparation for the February 18 webinar, we are seeking comments in response to the specific questions on the 2020 Census Disclosure Avoidance System and the American Indian and Alaska Native Geography Hierarchy.

Request for Comments

Question 1

How does your tribe use data from the redistricting (Pub. L. 94–171) data product? Please be specific as to the use, variable(s), and level(s) of geography.

Example: Our tribal government uses total population counts at the Census tract level, as a percentage of the total state population, to apply for state administered social assistance grants.

Question 2

How does your tribe use data from the Demographic Profiles and Demographic and Housing Characteristics data products? Please be specific as to the use, variable(s), and level(s) of geography.

Example: Our native village uses average household size and race/ethnicity composition at the block group level to apply for state administered housing grants, which accounted for 27% of our annual housing assistance budget in 2019.

Question 3

With the understanding that protecting the privacy of Census respondents requires that some uncertainty/noise be added to the data (as it has been in prior Censuses), which of the use cases that you identified in question #1 are most important to your tribe?

Question 4

With the understanding that protecting the privacy of Census respondents requires that some uncertainty/noise be added to the data (as it has been in prior Censuses), at what level of statistical uncertainty would the tabulations included in the redistricting (Pub. L. 94–171), Demographic Profiles, or Demographic and Housing Characteristics files no longer be usable for the use cases that you identified in question #1.

Example: If total population at the Census tract level differed from the enumerated count by more than ±3%, our tribe would be obligated to rely on other data sources as evidence to support our grant applications.'' Or ''If the AIAN Alone or in Combination population of our county differed from the enumerated count by more than 10 persons, we would be unable to rely upon the data for our tribe's demographic projections because they would be less accurate than the data we collect ourselves.

Steven D. Dillingham, Director, Bureau of the Census, approved the publication of this Notice in the **Federal Register**.

Dated: January 14, 2021.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–01240 Filed 1–19–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Request for Investigation Under Section 232 of the Trade Expansion Act

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of Information Collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before March 22, 2021.

ADDRESSES: Interested persons are invited to submit comments by email to Mark Crace, IC Liaison, Bureau of Industry and Security, at *mark.crace@bis.doc.gov* or to *PRAcomments@doc.gov*). Please reference OMB Control Number 0694–0120 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Mark Crace, IC Liaison, Bureau of Industry and Security, phone 202–482–8093 or by email at *mark.crace@bis.doc.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

Upon request, BIS will initiate an investigation to determine the effects of imports of specific commodities on the national security and will make the findings known to the President for possible adjustments to imports through tariffs. The findings are made publicly available and are reported to Congress. The purpose of this collection is to account for the public burden associated with the surveys distributed to determine the impact on national security.

These surveys are designed to gather information so that BIS can evaluate the impact of foreign imports of strategic commodities on the national security of the United States. Each Section 232 study is for a specific commodity or technology that is required for national security reasons (*e.g.,* precision bearings, microprocessors, machine tools, etc). These surveys attempt to determine the size of the domestic U.S. industry, how the domestic U.S. industry has been effected by foreign imports, demand for the commodity during peacetime, demand during wartime, the ability of the U.S. domestic industry to meet a surge in demand during wartime, and the potential impact on U.S. national security if wartime demand cannot be met by domestic U.S. suppliers.

II. Method of Collection

BIS custom-designs unique instruments for each Section 232 survey. The method of collection could be via paper or electronic.

III. Data

OMB Control Number: 0694–0120.
Form Number(s): None.
Type of Review: Regular submission.
Affected Public: Business or other for-profit organizations.
Estimated Number of Respondents: 800.
Estimated Time per Response: 15 hours.
Estimated Total Annual Burden Hours: 12,000.
Estimated Total Annual Cost to Public: 0.
Respondent's Obligation: Mandatory.
Legal Authority: Section 232 of the Trade Expansion Act.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request

to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–01163 Filed 1–19–21; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–051]

Certain Hardwood Plywood From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that 24 exporters of certain hardwood plywood products (hardwood plywood) from the People's Republic of China (China) under review had no shipments of subject merchandise during the period of review (POR) January 1, 2019 through December 31, 2019. Commerce also preliminarily determines that the 34 remaining companies subject to this review, including Lianyungang Yuantai International Trade Co., Ltd. (Yuantai), are part of the China-wide entity because they did not demonstrate eligibility for separate rates.

DATES: Applicable January 21, 2021.

FOR FURTHER INFORMATION CONTACT: Kabir Archuletta, Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2593.

SUPPLEMENTARY INFORMATION:

Background

On March 10, 2020, Commerce published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty (AD) order [1] on hardwood plywood from China with respect to 58 producers/exporters.[2] Subsequently, we released U.S. Customs and Border Protection (CBP) data to interested parties for comment.[3] We received comments from the petitioner [4] but no other interested party commented on the CBP data.

In April 2020, we received timely no-shipment certifications from 24 companies,[5] and we also received a separate rate certification (SRC) from Yuantai.[6] We did not receive a no-shipment statement, separate rate application (SRA), or SRC from any other company subject to this review. Also, in April 2020, Commerce exercised its discretion to toll administrative review deadlines by 50 days.[7] As a result, all deadlines in this proceeding were extended by 50 days.

In April and May 2020, we requested additional information from Yuantai related to its SRC,[8] and although Yuantai timely provided some information,[9] it later informed Commerce that it was unable to respond further because the company had ceased operations.[10]

In July 2020, Commerce exercised its discretion to toll administrative review deadlines by an additional 60 days.[11] The revised deadline for the preliminary results of this review is now January 21, 2021.[12]

For a complete description of the events that followed the initiation of this administrative review, *see* the Preliminary Decision Memorandum.[13] A list of topics included in the Preliminary Decision Memorandum is included as Appendix III to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The product covered by this order is hardwood plywood from China. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.[14]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213.

[1] *See Certain Hardwood Plywood Products from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 83 FR 504 (January 4, 2018) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 13860 (March 10, 2020).

[3] *See* Memorandum, ''U.S. Customs Data for Respondent Selection,'' dated March 20, 2020.

[4] The petitioner is the Coalition for Fair Trade in Hardwood Plywood. *See* Petitioner's Letter, ''The Petitioner's Comments on CBP Data and Respondent Selection,'' dated March 27, 2020.

[5] We received timely no shipment certifications from the following companies: (1) Anhui Hoda Wood Co., Ltd.; (2) Celtic Co., Ltd.; (3) Cosco Star International Co., Ltd.; (4) Happy Wood Industrial Group Co., Ltd.; (5) Jiaxing Hengtong Wood Co., Ltd.; (6) Linyi Chengen Import and Export Co., Ltd.; (7) Linyi Evergreen Wood Co., Ltd.; (8) Linyi Glary Plywood Co., Ltd.; (9) Linyi Huasheng Yongbin Wood Co., Ltd.; (10) Linyi Jiahe Wood Industry Co., Ltd.; (11) Linyi Sanfortune Wood Co., Ltd.; (12) Qingdao Top P&Q International Corp.; (13) Shandong Qishan International Trading Co., Ltd.; (14) Shanghai Brightwood Trading Co., Ltd.; (15) Shanghai Futuwood Trading Co., Ltd.; (16) Shanghai Luli Trading Co., Ltd.; (17) Suining Pengxiang Wood Co., Ltd.; (18) Suqian Hopeway International Trade Co., Ltd.; (19) Suzhou Oriental Dragon Import and Export Co., Ltd.; (20) Vietnam Finewood Company Limited; (21) Xuzhou Jiangheng Wood Products Co., Ltd.; (22) Xuzhou Jiangyang Wood Industries Co., Ltd.; (23) Xuzhou Timber International Trade Co., Ltd.; and (24) Zhejiang Dehua TB Import & Export Co., Ltd.

[6] *See* Yuantai's Letter, ''Hardwood Plywood Products from the People's Republic of China: Separate Rate Certification,'' dated April 9, 2020.

[7] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated April 24, 2020.

[8] *See* Commerce's Letters, ''Administrative Review of the Antidumping Duty Order of Certain Hardwood Plywood Products from the People's Republic of China: Separate Rate Certification,'' dated April 15, 2020; and ''Administrative Review of the Antidumping Duty Order of Certain Hardwood Plywood Products from the People's Republic of China: Separate Rate Certification Supplemental Questionnaire,'' dated May 18, 2020.

[9] *See* Yuantai's Letter, ''Hardwood Plywood Products from the People's Republic of China: Separate Rate Certification,'' dated April 20, 2020.

[10] *See* Yuantai's Letter, ''Hardwood Plywood Products from the People's Republic of China: Letter in Lieu of 2nd Supplemental Separate Rate Certification Questionnaire Response,'' dated May 26, 2020.

[11] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020. All deadlines in this proceeding have been extended by 60 days.

[12] The preliminary results deadline falls on January 20, 2021, which is a federal holiday. Commerce's practice dictates that where a deadline falls on a weekend or federal holiday, the appropriate deadline is the next business day. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

[13] *See* Memorandum, ''Decision Memorandum for the Preliminary Results for the 2019 Antidumping Duty Administrative Review: Certain Hardwood Plywood from the People's Republic of China,'' dated concurrently with, and herby adopted by, this notice (Preliminary Decision Memorandum).

[14] *Id.*

Preliminary Determination of No Shipments

Based upon the no-shipment certifications received by Commerce, and our review of CBP data, we preliminarily find that 24 companies had no shipments during the POR. For additional information regarding this determination, *see* the Preliminary Decision Memorandum. Consistent with our assessment practice in non-market economy administrative reviews,[15] Commerce is not rescinding this review for these 24 companies.[16] Commerce intends to complete the review and issue appropriate instructions to CBP based on the final results of this review.

Separate Rates

Commerce preliminarily finds that Yuantai has not established its eligibility for a separate rate. Additionally, because 33 other companies under review did not submit a no-shipment certification, SRA, or SRC, Commerce preliminarily determines that these companies have not demonstrated their eligibility for separate rates.[17] For additional information, *see* the Preliminary Decision Memorandum.

China-Wide Entity

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.[18] Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the China-wide entity.[19] Because no party requested a review of the China-wide entity in this review, the China-wide entity is not under review and the China-wide entity's rate (*i.e.,* 183.36 percent) is not subject to change.[20] For additional information, *see* the Preliminary Decision Memorandum.

Public Comment

In accordance with 19 CFR 351.309(c), case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of these preliminary results, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.[21] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[22]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Oral presentations at the hearing will be limited to those issues raised in the briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[23]

Assessment Rates

Upon issuance of the final results of this review, Commerce will determine, and CBP shall assess, AD duties on all appropriate entries of subject merchandise covered by this review.[24] We have not calculated any assessment rates in this administrative review. Based on record evidence, we have determined that 24 companies had no shipments of subject merchandise and, therefore, pursuant to Commerce's assessment practice, any suspended entries that entered under their case numbers, where available, will be liquidated at the China-wide entity rate.[25] For all remaining companies subject to this review, which are part of the China-wide entity, we will instruct CBP to liquidate their entries at the current rate for the China-wide entity (*i.e.,* 183.36 percent). Commerce intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review in the **Federal Register**.[26]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rates for the 24 companies that had no shipments during the POR will remain unchanged from the rates assigned to them in the most recently completed segment for each company; (2) for previously investigated or reviewed Chinese and non-Chinese exporters that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity (*i.e.,* 183.36 percent); and (4) for all non-Chinese exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also 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 POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These preliminary results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(l) of the Act, and 19 CFR 351.213(h)(1).

[15] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011); *see also the* ''Assessment Rate'' section, below.

[16] *See* Appendix II.

[17] *See* Appendix I.

[18] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[19] *Id.*

[20] *See Order,* 83 FR at 512.

[21] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[22] *See Temporary Rule Modifying AD/CVD Service Requirements Due to Covid-19, Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[23] *See* 19 CFR 351.310(d).

[24] *See* 19 CFR 351.212(b)(1).

[25] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

[26] *Id.*

Dated: January 12, 2021.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Companies Not Eligible for a Separate Rate

1. Feixian Longteng Wood Co., Ltd.
2. Golder International Trade Co., Ltd.
3. Highland Industries-Hanlin
4. Huainan Mengping Import and Export Co., Ltd.
5. Jiangsu High Hope Arser Co., Ltd.[27]
6. Jiangsu Sunwell Cabinetry Co., Ltd.
7. Jiangsu Top Point International Co., Ltd.
8. Jiaxing Gsun Imp. & Exp. Co., Ltd.
9. Lianyungang Yuantai International Trade Co., Ltd.
10. Linyi Bomei Furniture Co., Ltd.
11. Linyi City Dongfang Jinxin Economic and Trade Co., Ltd. (a/k/a Linyi City Dongfang Jinxjin Economic and Trade Co., Ltd.)
12. Linyi Dahua Wood Co., Ltd.
13. Linyi Hengsheng Wood Industry Co., Ltd.
14. Linyi Linhai Wood Co., Ltd.
15. Linyi Mingzhu Wood Co., Ltd.
16. Pingyi Jinniu Wood Co., Ltd.
17. Qingdao Good Faith Import and Export Co., Ltd.
18. SAICG International Trading Co., Ltd.
19. Shandong Dongfang Bayley Wood Co., Ltd.
20. Shandong Jinhua International Trading Co., Ltd.
21. Shandong Jinluda International Trade Co., Ltd.
22. Shandong Senmanqi Import & Export Co., Ltd.
23. Shandong Shengdi International Trading Co., Ltd.
24. Sumec International Technology Co., Ltd.
25. Suzhou Fengshuwan Import and Export Trade Co., Ltd. a/k/a Suzhou Fengshuwan I&E Trade Co., Ltd.
26. Win Faith Trading Limited
27. Xuzhou Amish Import & Export Co., Ltd.
28. Xuzhou Andefu Wood Co., Ltd.
29. Xuzhou Constant Forest Industry Co., Ltd.
30. Xuzhou DNT Commercial Co., Ltd.
31. Xuzhou Longyuan Wood Industry Co., Ltd.
32. XuZhou PinLin International Trade Co., Ltd.
33. Xuzhou Shengping Imp and Exp Co., Ltd.
34. Yishui Zelin Wood Made Co., Ltd.

Appendix II

Companies Preliminarily Found to Have No Shipments

1. Anhui Hoda Wood Co., Ltd.
2. Celtic Co., Ltd.
3. Cosco Star International Co., Ltd.
4. Happy Wood Industrial Group Co., Ltd.
5. Jiaxing Hengtong Wood Co., Ltd.
6. Linyi Chengen Import and Export Co., Ltd.
7. Linyi Evergreen Wood Co., Ltd.
8. Linyi Glary Plywood Co., Ltd.
9. Linyi Huasheng Yongbin Wood Co., Ltd.
10. Linyi Jiahe Wood Industry Co., Ltd.
11. Linyi Sanfortune Wood Co., Ltd.
12. Qingdao Top P&Q International Corp.
13. Shandong Qishan International Trading Co., Ltd.
14. Shanghai Brightwood Trading Co., Ltd.
15. Shanghai Futuwood Trading Co., Ltd.
16. Shanghai Luli Trading Co., Ltd.
17. Suining Pengxiang Wood Co., Ltd.
18. Suqian Hopeway International Trade Co., Ltd.
19. Suzhou Oriental Dragon Import and Export Co., Ltd.
20. Xuzhou Jiangheng Wood Products Co., Ltd.
21. Xuzhou Jiangyang Wood Industries Co., Ltd.
22. Xuzhou Timber International Trade Co., Ltd.
23. Vietnam Finewood Company Limited
24. Zhejiang Dehua TB Import & Export Co., Ltd.

Appendix III

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Methodology
V. Recommendation

[FR Doc. 2021–01165 Filed 1–19–21; 8:45 am]

BILLING CODE 3510–DS–P

[27] Previously had a separate rate but did not file a no shipment certification or request a separate rate.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–954]

Certain Magnesia Carbon Bricks From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) continues to determine that Fedmet Resources Corporation (Fedmet) had no shipments of certain magnesia carbon bricks (magnesia carbon bricks) from the People's Republic of China (China) to the United States during the period of review (POR) September 1, 2018 through August 31, 2019. We also continue to find that the 16 remaining companies subject to this review are part of the China-wide entity because they did not file no shipment statements, separate rate applications (SRAs), or separate rate certifications (SRCs).

DATES: Applicable January 21, 2021.

FOR FURTHER INFORMATION CONTACT: Nathan James, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5305.

SUPPLEMENTARY INFORMATION:

Background

On July 28, 2020, Commerce published the preliminary results of this administrative review.[1] We invited parties to comment on the *Preliminary Results.* No party submitted comments. Accordingly, the final results remain unchanged from the *Preliminary Results.*

Scope of the Order

The scope of the order covers magnesia carbon bricks from China. For a complete description of the scope of the order, *see* the Preliminary Decision Memorandum.

Final Determination of No Shipments

Commerce preliminarily found that Fedmet had no shipments of subject merchandise to the United States during the POR. As noted in Preliminary Decision Memorandum, we received a no shipment statement from Fedmet, and the statement was consistent with the information we received from U.S. Customs and Border Protection (CBP).[2]

No party commented on our preliminary no-shipment finding with respect to Fedmet. Therefore, for these final results, we continue to find that Fedmet had no shipments of subject merchandise to the United States during the POR.

China-Wide Entity

With the exception of Fedmet, we find all other companies for which a review was requested to be part of the China-wide entity because they failed to file no-shipment statements, SRAs, or SRCs. Accordingly, the following companies are part of the China-wide entity: (1) Dandong Xinxing Carbon Co., Ltd.; (2) Fengchi Imp. and Exp. Co.; (3) Fengchi Imp. and Exp. Co., Ltd. of Haicheng City; (4) Fengchi Mining Co., Ltd. of Haicheng City; (5) Fengchi Refractories Co., of Haicheng City; (6) Haicheng Donghe Taidi Refractory Co., Ltd.; (7) Henan Xintuo Refractory Co., Ltd.; (8) Liaoning Fucheng Refractories; (9) Liaoning Zhongmei High Temperature Material Co., Ltd.; (10) Liaoning Zhongmei Holding Co., Ltd.;

[1] *See Certain Magnesia Carbon Bricks From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2018–2019, 85 FR 45375* (July 28, 2020) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See Preliminary Results* PDM at 2.

(11) RHI Refractories Liaoning Co., Ltd.; (12) Shenglong Refractories Co., Ltd.; (13) Tangshan Strong Refractories Co., Ltd.; (14) The Economic Trading Group of Haicheng Houying Corp. Ltd.; (15) Yingkou Heping Samwha Minerals, Co., Ltd.; and (16) Yingkou Heping Sanhua Materials Co., Ltd.

Because no party requested a review of the China-wide entity, and Commerce no longer considers the China-wide entity as an exporter conditionally subject to administrative reviews, we did not conduct a review of the China-wide entity. The rate previously established for the China-wide entity is 236.00 percent and is not subject to change as a result of this review.

Assessment Rates

We have not calculated any assessment rates in this administrative review. Based on record evidence, we have determined that Fedmet had no shipments of subject merchandise, and therefore, pursuant to Commerce's assessment practice, any suspended entries that entered under its case number will be liquidated at the China-wide entity rate.[3]

For all remaining companies subject to this review, which are part of the China-wide entity, we will instruct CBP to liquidate their entries at the current rate for the China-wide entity (*i.e.,* 236.00 percent). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the publication date of the final results of this administrative review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice, as provided by section 751(a)(2)(C) of the Tariff Act of 1930, as amended (the Act): (1) For previously investigated or reviewed Chinese and non-Chinese exporters that received a separate rate in a prior segment of this proceeding, and which were not assigned the China-wide rate in this review, the cash deposit rate will continue to be the existing exporter-specific rate published for the most recently completed period; (2) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the China-wide rate of 236.00 percent; and (3) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this 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 double antidumping duties.

Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h).

Dated: January 12, 2021.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–01166 Filed 1–19–21; 8:45 am]

BILLING CODE 3510–DS–P

[3] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

Meeting of the United States Travel and Tourism Advisory Board

AGENCY: United States Travel and Tourism Advisory Board, International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an Open Meeting.

SUMMARY: The United States Travel and Tourism Advisory Board (Board or TTAB) will hold a meeting on Wednesday, February 10, 2021. The Board advises the Secretary of Commerce (Secretary) on matters relating to the U.S. travel and tourism industry. The purpose of the meeting is for Board members to discuss and potentially adopt a letter to the Secretary recommending priorities in travel and tourism that should be addressed to support the recovery and growth of the sector and restore foreign travel to the United States. The final agenda will be posted on the Department of Commerce website for the Board at *https://www.trade.gov/ttab-meetings* at least one week in advance of the meeting.

DATES: Wednesday, February 10, 2021, 3:00 p.m.–4:00 p.m. EST. The deadline for members of the public to register, including requests to make comments during the meeting and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EST on Wednesday, February 3, 2021.

ADDRESSES: The meeting will be held virtually. The access information will be provided by email to registrants.

Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted by email to *TTAB@trade.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Aguinaga, the United States Travel and Tourism Advisory Board, National Travel and Tourism Office, U.S. Department of Commerce; telephone: 202–482–2404; email: *TTAB@trade.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry.

Public Participation: The meeting will be open to the public and will be accessible to people with disabilities. Any member of the public requesting to join the meeting is asked to register in advance by the deadline identified under the **DATES** caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted but may not be possible to fill. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public comments may be limited to three (3) minutes per person. Members of the public wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting to make

statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EST on Wednesday, February 3, 2021, for inclusion in the meeting records and for circulation to the members of the Board.

In addition, any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Jennifer Aguinaga at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EST on Wednesday, February 3, 2021, to ensure transmission to the Board prior to the meeting. Comments received after that date and time will be distributed to the members but may not be considered during the meeting. Copies of Board meeting minutes will be available within 90 days of the meeting.

Jennifer Aguinaga,

Designated Federal Officer, United States Travel and Tourism Advisory Board.

[FR Doc. 2021–01112 Filed 1–19–21; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–008]

Certain Circular Welded Carbon Steel Pipes and Tubes From Taiwan: Final Results of Antidumping Duty Administrative Review, 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that Shin Yang Steel Co., Ltd. (Shin Yang), a producer/exporter of merchandise subject to this administrative review, made sales of subject merchandise at less than normal value during the period of review (POR) May 1, 2018 through April 30, 2019.

DATES: Applicable January 21, 2021.

FOR FURTHER INFORMATION CONTACT: Nicolas Mayora, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230; telephone: (202) 482–3053.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty (AD) order on certain circular welded carbon steel pipes and tubes from Taiwan, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[1] On July 24, 2020, Commerce published in the **Federal Register** the *Preliminary Results* of this administrative review.[2] We invited interested parties to comment on the *Preliminary Results.* A complete summary of events that occurred since Commerce published the *Preliminary Results* can be found in the Issues and Decision Memorandum.[3]

Scope of the Order

The merchandise subject to this order is certain circular welded carbon steel pipes and tubes from Taiwan. The products are currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 7306.30.5025, 7306.30.5032, 7306.30.5040, and 7306.30.5055. Although the HTSUS subheadings are provided for convenience and customs purposes, the written product description of the scope of the order remains dispositive. For a full description of the scope, *see* the Issues and Decision Memorandum.[4]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as an Appendix. The Issues and Decision memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of comments received from parties, and for the reasons explained in the Issues and Decision Memorandum, Commerce made certain changes to the *Preliminary Results.* Specifically, we revised our treatment of Shin Yang's purchases of hot-rolled coil from its affiliate.[5] In addition, we used the updated U.S. sales database provided by Shin Yang on March 3, 2020.[6] However, these revisions did not result in a change to the weighted-average dumping margin calculated for Shin Yang in these final results of review.

Final Results of the Review

Commerce determines that the following weighted-average dumping margin exists for Shin Yang for the POR from May 1, 2018 through April 30, 2019:

Producer/exporter	Dumping margin (percent)
Shin Yang Steel Co., Ltd	1.71

Disclosure

We intend to disclose the calculations performed for these final results to interested parties in this proceeding within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, AD duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

For Shin Yang, because its weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent), Commerce has calculated importer-specific (or customer-specific) antidumping duty assessment rates for merchandise subject to this review.[7] We calculated importer-specific antidumping duty assessment rates by aggregating the total amount of dumping calculated for the examined sales of

[1] *See Certain Circular Welded Carbon Steel Pipes and Tubes from Taiwan: Antidumping Duty Order,* 49 FR 19369 (May 7, 1984) (*Order*).

[2] *See Certain Circular Welded Carbon Steel Pipes and Tubes from Taiwan: Preliminary Results of Administrative Review of the Antidumping Duty Order; 2018–2019,* 85 FR 44852 (July 24, 2020) (*Preliminary Results*).

[3] *See* Memorandum, ''Issues and Decision Memorandum for Final Results of the Antidumping Duty Administrative Review of Certain Circular Welded Carbon Steel Pipes and Tubes from Taiwan; 2018–2019,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] For a full description of the scope, *see* the Issues and Decision Memorandum.

[5] *See* Memorandum, ''Cost of Production and Constructed Value Calculation Adjustments for the Final Results—Shin Yang Steel Co., Ltd.,'' dated concurrently with, and hereby adopted by, this notice.

[6] *See* Shin Yang's March 3, 2020 Section B–C Supplemental Questionnaire Response at Exhibit 9.

[7] *See Antidumping Proceedings: Calculation of the Weighted Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

each importer and dividing each of these amounts by the total sales quantity associated with those sales.

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Shin Yang for which the company did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate if there is no rate for the intermediate company involved in the transaction. Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of this review in the **Federal Register**.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of the final results of this administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Shin Yang will be equal to the rate established in the final results of this administrative review; (2) for merchandise exported by producers and/or exporters not covered in this review, but covered in a prior segment of this proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment in which the company was reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 9.70 percent, the all-others rate established in the LTFV investigation.[8] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this 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 double antidumping duties.

Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213(h).

Dated: January 12, 2021.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Changes Since the Preliminary Results
V. Discussion of the Issues
  Comment 1. Whether to Adjust Shin Yang's Reported Costs for Affiliated Purchases in Accordance with the Major Input Rule
  Comment 2. Whether to Adjust Shin Yang's Reported General and Administrative Expense Ratio
  Comment 3. Whether to Deduct Section 232 Duties from Shin Yang's U.S. Sales Price
VI. Recommendation

[FR Doc. 2021–01219 Filed 1–19–21; 8:45 am]

BILLING CODE 3510–DS–P

[8] *See Certain Circular Welded Carbon Steel Pipes and Tubes from Taiwan: Antidumping Duty Order,* 49 FR 19369 (May 7, 1984).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Hydrographic Services Review Panel Meeting for March 3–4, 2021

AGENCY: National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Announcement for open public meeting and notice of request for public comments.

SUMMARY: This serves as notice of a virtual public meeting for the NOAA Hydrographic Services Review Panel (HSRP) on March 3, 2021, 12:45–5:30 p.m. EST, and March 4, 2021, 1–5 p.m. EST via webinar. The HSRP agenda will be posted in advance on the website. Individuals or groups who want to comment on NOAA navigation services topics are encouraged to submit advance public comments and letters via email or via the question function in the webinar.

DATES:

NOAA HSRP public virtual meeting will meet via webinar as follows:

1. March 3, 2021, 12:45–5:30 p.m., EST.
2. March 4, 2021, 1–5 p.m. EST.

ADDRESSES: You may submit public comments identified by ''March 2021 HSRP meeting public comments'' in the subject line of the message in advance of the meeting or request to be added to the meeting announcements list by sending an email request to: *Virginia.Dentler@noaa.gov, and hydroservices.panel@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Lynne Mersfelder-Lewis, HSRP program manager, Office of Coast Survey, NOS, NOAA, email: *hydroservices.panel@noaa.gov, Lynne.Mersfelder@noaa.gov,* and phone 240–533–0064.

SUPPLEMENTARY INFORMATION:

Advance registration is required for the webinar at: *https://register.gotowebinar.com/register/6060715212000442635.* The agenda, speakers and time are subject to change, please refer to the website for the most updated information. The HSRP meeting agenda, draft meeting documents, presentations, and background materials are posted and updated online and can be downloaded prior to the meeting at: *https://www.nauticalcharts.noaa.gov/hsrp/hsrp.html* and *https://www.nauticalcharts.noaa.gov/hsrp/meetings.html.*

Past HSRP recommendation letters, issue and position papers are located online at: *https://www.nauticalcharts.noaa.gov/hsrp/recommendations.html.*

Public comments are encouraged and requested on the navigation services portfolio for CO–OPS, NGS and OCS. Advance written statements will be shared with the HSRP members and will be included in the meeting public record. Due to the condensed nature of the meeting, each individual or group

providing written public comments will be limited to one comment per public comment period with no repetition of previous comments. Comments can also be submitted in writing during the public comment period through the webinar. Comments will be read into the record, transcribed, and become part of the meeting record. Due to time meeting constraints, all comments may not be addressed during the meeting.

The Hydrographic Services Review Panel (HSRP) is a Federal Advisory Committee established to advise the Under Secretary of Commerce for Oceans and Atmosphere, the NOAA Administrator, on matters related to the responsibilities and authorities set forth in section 303 of the Hydrographic Services Improvement Act of 1998, as amended, and such other appropriate matters that the Under Secretary refers to the Panel for review and advice.

Matters To Be Considered

The panel is convening on issues relevant to NOAA's navigation services, including stakeholder use of navigation services data, products and services, and other topics related to hydrographic surveys, nautical charting, the ongoing National Spatial Reference System (NSRS) modernization including changes to flood plain management, navigation services contributions to resilience and coastal data and information systems, coastal and ocean modeling, PORTS® (Physical Oceanographic Real-Time System) sensor enhancements and expansion, the projects of the NOAA-University of New Hampshire Joint Hydrographic Center Cooperative Agreement, the new NOAA five-year cooperative agreement with the University of Southern Florida to launch the Center for Ocean Mapping and Innovative Technologies (COMIT), updates on legislative and budget priorities, and other topics. Navigation services include the data, products, and services provided by the NOAA programs and activities that undertake geodetic observations, gravity modeling, coastal and shoreline mapping, bathymetric mapping and modeling, hydrographic surveying, nautical charting, tide and water level observations, current observations, flooding, resilience, inundation and sea level rise, marine and coastal modeling, geospatial and LIDAR data, and related topics. This suite of NOAA products and services support safe and efficient navigation, resilient coasts and communities, and the nationwide positioning information infrastructure to support America's climate needs and commerce. The Panel will hear about the missions and uses of NOAA's navigation services, the value these services bring, and what improvements could be made. Other matters may be considered.

Special Accommodations

This meeting is physically accessible to people with disabilities and there will be sign language interpretation and captioning services. Please direct requests for other auxiliary aids to *Melanie.Colantuno@noaa.gov* at least 10 business days in advance of the meeting.

Kathryn Ries,

Deputy Director, Office of Coast Survey, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2021–01193 Filed 1–19–21; 8:45 am]

BILLING CODE 3510–JE–P

COMMODITY FUTURES TRADING COMMISSION

Fees for Reviews of the Rule Enforcement Programs of Designated Contract Markets and Registered Futures Associations

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of 2020 schedule of fees.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') charges fees to designated contract markets and registered futures associations to recover the costs incurred by the Commission in the operation of its program of oversight of self-regulatory organization rule enforcement programs, specifically National Futures Association (''NFA''), a registered futures association, and the designated contract markets. Fees collected from each self-regulatory organization are deposited in the Treasury of the United States as miscellaneous receipts. The calculation of the fee amounts charged for 2020 by this notice is based upon an average of actual program costs incurred during fiscal year (''FY'') 2017, FY 2018, and FY 2019.

DATES: Each self-regulatory organization is required to remit electronically the applicable fee on or before March 22, 2021.

FOR FURTHER INFORMATION CONTACT: Anthony C. Thompson, Executive Director and Chief Administrative Officer, Commodity Futures Trading Commission; (202) 418–5697; Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. For information on electronic payment, contact Jennifer Fleming; (202) 418–5034; Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background Information

A. General

This notice relates to fees for the Commission's review of the rule enforcement programs at the registered futures associations [1] and designated contract markets (''DCM''), each of which is a self-regulatory organization (''SRO'') regulated by the Commission. The Commission recalculates the fees charged each year to cover the costs of operating this Commission program.[2] The fees are set each year based on direct program costs, plus an overhead factor. The Commission calculates actual costs, then calculates an alternate fee taking volume into account, and then charges the lower of the two.[3]

B. Overhead Rate

The fees charged by the Commission to the SROs are designed to recover program costs, including direct labor costs and overhead. The overhead rate is calculated by dividing total Commission-wide overhead direct program labor costs into the total amount of the Commission-wide overhead pool. For this purpose, direct program labor costs are the salary costs of personnel working in all Commission programs. Overhead costs generally consist of the following Commission-wide costs: Indirect personnel costs (leave and benefits), rent, communications, contract services, utilities, equipment, and supplies. This formula has resulted in the following overhead rates for the most recent three years (rounded to the nearest whole percent): 169 percent for FY 2017, 182 percent for FY 2018, and 174 percent for FY 2019.

C. Conduct of SRO Rule Enforcement Reviews

Under the formula adopted by the Commission in 1993, the Commission calculates the fee to recover the costs of its rule enforcement reviews and examinations, based on the three-year average of the actual cost of performing such reviews and examinations at each SRO. The cost of operation of the Commission's SRO oversight program varies from SRO to SRO, according to the size and complexity of each SRO's

[1] National Futures Association is the only registered futures association.

[2] *See* Section 237 of the Futures Trading Act of 1982, 7 U.S.C. 16a, and 31 U.S.C. 9701. For a broader discussion of the history of Commission fees, see 52 FR 46070, Dec. 4, 1987.

[3] 58 FR 42643, Aug. 11, 1993, and 17 CFR part 1, app. B.

program. The three-year averaging computation method is intended to smooth out year-to-year variations in cost. Timing of the Commission's reviews and examinations may affect costs—a review or examination may span two fiscal years and reviews and examinations are not conducted at each SRO each year.

As noted above, adjustments to actual costs may be made to relieve the burden on an SRO with a disproportionately large share of program costs. The Commission's formula provides for a reduction in the assessed fee if an SRO has a smaller percentage of United States industry contract volume than its percentage of overall Commission oversight program costs. This adjustment reduces the costs so that, as a percentage of total Commission SRO oversight program costs, they are in line with the pro rata percentage for that SRO of United States industry-wide contract volume.

The calculation is made as follows: The fee required to be paid to the Commission by each DCM is equal to the lesser of actual costs based on the three-year historical average of costs for that DCM or one-half of average costs incurred by the Commission for each DCM for the most recent three years, plus a pro rata share (based on average trading volume for the most recent three years) of the aggregate of average annual costs of all DCMs for the most recent three years.

The formula for calculating the second factor is: 0.5a + 0.5 vt = current fee. In this formula, ''a'' equals the average annual costs, ''v'' equals the percentage of total volume across DCMs over the last three years, and ''t'' equals the average annual costs for all DCMs. NFA has no contracts traded; hence, its fee is based simply on costs for the most recent three fiscal years. This table summarizes the data used in the calculations of the resulting fee for each entity:

TABLE 1—SUMMARY OF DATA USED IN FEE CALCULATIONS

	Actual total costs			3-Year average actual costs	3-Year total volume %	Adjusted volume costs	2020 Assessed fee
	FY 2017	FY 2018	FY 2019				
Cantor Futures Exchange, L.P.	$60,045	$56,551		$38,866	0.02	$19,527	$19,527
CBOE Futures Exchange, LLC	31,026	16,033	40,517	29,192	1.40	21,600	21,600
Chicago Board of Trade	96,442	2,296	22,835	40,525	32.69	183,313	40,525
Chicago Mercantile Exchange, Inc.	472,157	235,127	383,995	363,760	42.23	392,507	363,760
Eris Exchange, LLC	53,010	33,170		28,727	0.01	14,397	14,397
ICE Futures U.S., Inc.	199,090	50,096	73,464	107,550	6.86	87,993	87,993
Minneapolis Grain Exchange, Inc.	42,226	438	39,525	27,396	0.05	13,944	13,944
Nasdaq OMX Futures Exchange, Inc.	251,200	109,413	1,741	120,785	0.59	63,311	63,311
New York Mercantile Exchange, Inc.	212,798	3,397	45,425	87,206	12.77	107,290	87,206
Nodal Exchange, LLC	100,600	33,162	2,312	45,358	0.06	22,996	22,996
North American Derivatives Exchange, Inc.	84,666	6,986	135,159	75,604	0.22	38,891	38,891
OneChicago, LLC	36,444	61,276		32,573	0.20	17,276	17,276
Subtotal	1,639,704	607,946	744,973	997,541	100.00	997,541	791,427
National Futures Association	660,710	507,673	540,821	569,735			569,735
Total	2,300,414	1,115,619	1,285,794	1,567,276	100.00	997,541	1,361,161

An example of how the fee is calculated for one exchange, the Chicago Board of Trade, is set forth here:

a. Actual three-year average costs = $40,525

b. The alternative computation is: [(.5) ($40,525)] + (.5) [(.3269048) ($997,541)] = $183,313

c. The fee is the lesser of a or b; in this case $40,525

As noted above, the alternative calculation based on contracts traded is not applicable to NFA because it is not a DCM and has no contracts traded. The Commission's average annual cost for conducting oversight review of the NFA rule enforcement program during fiscal years 2017 through 2019 was $569,735. The fee to be paid by the NFA for the current fiscal year is $569,735.

II. Schedule of Fees

Fees for the Commission's review of the rule enforcement programs at the registered futures associations and DCMs regulated by the Commission are as follows:

TABLE 2—SCHEDULE OF FEES

	3-Year average actual costs	3-Year total volume %	Adjusted volume costs	2020 Assessed fee
Cantor Futures Exchange, L.P.	$38,866	0.02	$19,527	$19,527
CBOE Futures Exchange, LLC	29,192	1.40	21,600	21,600
Chicago Board of Trade	40,525	32.69	183,313	40,525
Chicago Mercantile Exchange, Inc.	363,760	42.23	392,507	363,760
Eris Exchange, LLC	28,727	0.01	14,397	14,397
ICE Futures U.S., Inc.	107,550	6.86	87,993	87,993
Minneapolis Grain Exchange, Inc.	27,396	0.05	13,944	13,944
Nasdaq OMX Futures Exchange, Inc.	120,785	0.59	63,311	63,311
New York Mercantile Exchange, Inc.	87,206	12.77	107,290	87,206
Nodal Exchange, LLC	45,358	0.06	22,996	22,996
North American Derivatives Exchange, Inc.	75,604	0.22	38,891	38,891
OneChicago, LLC	32,573	0.20	17,276	17,276
Subtotal	997,541	100.00	997,541	791,427

TABLE 2—SCHEDULE OF FEES—Continued

	3-Year average actual costs	3-Year total volume %	Adjusted volume costs	2020 Assessed fee
National Futures Association	569,735			569,735
Total	1,567,276	100.00	997,541	1,361,161

III. Payment Method

The Debt Collection Improvement Act (DCIA) requires deposits of fees owed to the government by electronic transfer of funds. *See* 31 U.S.C. 3720. For information about electronic payments, please contact Jennifer Fleming at (202) 418–5034 or *jfleming@cftc.gov,* or see the CFTC website at *https://www.cftc.gov,* specifically, *https://www.cftc.gov/cftc/cftcelectronicpayments.htm.*

Fees collected from each self-regulatory organization shall be deposited in the Treasury of the United States as miscellaneous receipts. *See* 7 U.S.C 16a.

Issued in Washington, DC, on this 13th day of January, 2021, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2021–01145 Filed 1–19–21; 8:45 am]

BILLING CODE 6351–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Statement Regarding the Provision of Financial Products and Services to Consumers With Limited English Proficiency

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is issuing this Statement Regarding the Provision of Financial Products and Services to Consumers with Limited English Proficiency (Statement) to encourage financial institutions to better serve consumers with limited English proficiency (LEP) and to provide principles and guidelines to assist financial institutions in complying with the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), the Equal Credit Opportunity Act (ECOA), and other applicable laws.

DATES: The Bureau released this Statement on its website on January 13, 2021.

FOR FURTHER INFORMATION CONTACT: Ena P. Koukourinis, Senior Counsel, Office of Fair Lending and Equal Opportunity, at *CFPB_FairLending@cfpb.gov* or 202–435–7000. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov*.

SUPPLEMENTARY INFORMATION:

I. Statement Regarding the Provision of Financial Products and Services to Consumers With Limited English Proficiency

A. Background

The Bureau works to ensure a fair, transparent, and competitive consumer financial marketplace. To that end, the Bureau seeks to promote access to financial products and services for all consumers, including LEP consumers.[1] Despite having considerable credit needs and representing a large segment of the U.S. population, LEP consumers often encounter significant barriers to participating in the consumer financial marketplace.[2] Many of these challenges stem from language access issues—financial disclosures and written documents are generally not available in languages other than English and some financial institutions do not have bilingual employees or access to interpretation services.[3]

Recognizing the compliance risks and uncertainty that many financial institutions raise as challenges to better serving LEP consumers in non-English languages, the Bureau is issuing this Statement to outline compliance principles and guidelines that encourage financial institutions to expand access to products and services for LEP consumers. In doing so, the Bureau seeks to: (1) Promote access to financial products for all consumers; (2) facilitate compliance by providing clear rules of the road; and (3) educate and empower consumers to make better informed financial decisions.[4] Financial institutions play an important role in building a more inclusive financial system and presenting opportunities for LEP consumers to build their financial capabilities.[5] The effective and responsible integration of LEP consumers into the financial marketplace has the potential to create positive benefits for consumers and the financial services industry alike.[6]

The Dodd-Frank Act emphasizes the Bureau's role in ensuring ''fair, equitable, and nondiscriminatory access to credit.'' [7] Consistent with that purpose, the Bureau encourages financial institutions to promote access to financial products and services for all consumers by better serving LEP consumers. In providing such assistance and serving LEP consumers, financial institutions must also comply with Dodd-Frank Act prohibitions against engaging in any unfair, deceptive, or abusive act or practice (UDAAP) [8] and the ECOA.[9] This Statement provides guidance on how financial institutions can provide access to credit in languages other than English in a manner that is beneficial to consumers, while taking steps to ensure financial institutions' actions are compliant with the ECOA, the prohibitions against UDAAPs, and other applicable laws.

Approximately 22 percent of the U.S. population over the age of 5 (in all, 67.8 million people) speak a language other than English at home and, of these, 37.6 percent are LEP.[10] LEP consumers face

[1] In this document, a consumer with ''limited English proficiency'' or a ''limited English proficient'' (LEP) consumer means a person who has a limited ability to read, write, speak, or understand English.

[2] *See* Consumer Financial Protection Bureau, Spotlight on serving limited English proficient consumers: Language access in the consumer financial marketplace, 6–7 (Nov. 2017), *https://files.consumerfinance.gov/f/documents/cfpb_spotlight-serving-lep-consumers_112017.pdf.*

[3] *Id.* at 12.

[4] *See* Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203 (2010), sec. 1021 (Dodd-Frank Act); *see also* CFPB Director Kathleen Kraninger, *Kraninger Marks Second Year as Director of the Consumer Financial Protection Bureau* (Dec. 11, 2020), *https://www.consumerfinance.gov/about-us/newsroom/kraninger-marks-second-year-director-consumer-financial-protection-bureau/.*

[5] *Supra* note 2.

[6] Consumer Financial Protection Bureau, Spotlight on serving limited English proficient consumers: Language access in the consumer financial marketplace, 6–7 (Nov. 2017), *https://files.consumerfinance.gov/f/documents/cfpb_spotlight-serving-lep-consumers_112017.pdf.*

[7] Dodd-Frank Act, sec. 1013(c)(2)(A), 124 Stat. 1376 (2010) (codified as 12 U.S.C. 5493(c)(2)(A)).

[8] *Id.* at sec. 1036 (codified as 12 U.S.C. 5536).

[9] 15 U.S.C 1691 *et seq.*

[10] U.S. Census Bureau, 2019 American Community Survey 1-Year Estimates, Table S1601:

unique challenges in learning about and accessing financial products and services.[11] For instance, limited English proficiency can hinder consumers' financial literacy and make it difficult to conduct everyday financial affairs, including understanding and completing key financial documents, managing bank accounts, resolving problems with financial products and institutions, and accessing financial education and money management tools.[12] Attempts to address these challenges have led to myriad Federal and State statutes and regulations.[13]

Over the past several years, to gain insights to inform policy decisions, the Bureau has engaged with stakeholders on fair lending compliance topics and access to credit issues. The Bureau participated in robust information-gathering activities, including meetings with consumer and civil rights advocacy organizations, other Federal agencies, policymakers, representatives from financial institutions of various sizes, and trade associations to obtain feedback on the provision of financial products and services to LEP consumers. Bureau leadership and staff presented on LEP-related topics and gathered feedback from stakeholders at conferences and other external and internal events. In addition, the Bureau conducted research on complaints submitted to the Bureau reflecting LEP consumers' experience with financial institutions. These efforts resulted in the Bureau's November 2017 publication, *Spotlight on serving limited English proficient consumers.*[14] In addition, the Bureau's 2016 Fall edition of *Supervisory Highlights* provides supervisory observations regarding financial institutions' provision of non-English language services to LEP consumers.[15]

Since that time, the Bureau has continued its work on LEP-related issues. In the Bureau's 2019 Fair Lending Report to Congress, the Director identified that ''[o]ne particular fair lending issue ripe for innovative solutions is making financial products and services more accessible to consumers who are unbanked and underbanked, including those who are Limited English Proficient.'' [16]

In July 2020, the Director held an LEP Consumer and Industry Roundtable that convened representatives from consumer and civil rights advocacy organizations, policymakers, industry, and trade associations. The Bureau has also received input through numerous stakeholder meetings, comments to rulemakings, and various Requests for Information (RFIs) regarding access to credit for LEP consumers.[17] Many of these responsive comments and submissions urged the Bureau to provide additional guidance to institutions seeking to expand their offering of products and services to LEP consumers while maintaining compliance with applicable laws.[18]

Most recently, on August 3, 2020, the Bureau issued an RFI ''to identify opportunities to prevent credit discrimination, encourage responsible innovation, promote fair, equitable, and nondiscriminatory access to credit, address potential regulatory uncertainty, and develop viable solutions to regulatory compliance challenges under the ECOA and Regulation B.'' [19] Among the requests, the Bureau sought information that would enable it ''to understand the challenges specific to serving LEP consumers and to find ways to encourage creditors to increase

Language Spoken at Home (2019), *https://data.census.gov/cedsci/table?q=speak%20language%20other%20than%20english&tid=ACSST1Y2019.S1601&hidePreview=false.*

[11] *Supra* note 6; *see also* New York City Dept. of Consumer Aff., Lost in Translation (2019), *https://www1.nyc.gov/assets/dca/downloads/pdf/partners/LEPDebtCollection_Report.pdf* (documenting greater challenges faced by LEP consumers in navigating the consumer debt collection system); Americans for Financial Reform, Barriers to Language Access in the Housing Market: Stories from the Field (May 2016), *https://ourfinancialsecurity.org/wp-content/uploads/2016/05/AFR_LEP_Narratives_05.26.2016.pdf*; Edward Golding, Laurie Goodman, and Sarah Strochak, Urban Institute, Is Limited English Proficiency a Barrier to Homeownership? (2018), *https://www.urban.org/research/publication/limited-english-proficiency-barrier-homeownership.*

[12] CFPB, Spotlight on serving limited English proficient consumers: Language access in the consumer financial marketplace (Nov. 2017), *https://www.consumerfinance.gov/data-research/research-reports/spotlight-serving-limited-english-proficient-consumers/*; *see also* FDIC, 2013 FDIC National Survey of Unbanked and Underbanked Households, 16–17 (Oct. 2014), *https://www.fdic.gov/householdsurvey/2013report.pdf* (finding that 34.9 percent of households where Spanish is the only language spoken are ''unbanked,'' compared to just 7.1 percent of households where Spanish is not the only language spoken); U.S. Government Accountability Office, Factors Affecting the Financial Literacy of Individuals with Limited English Proficiency at Highlights, GAO–10–518 (May 2010), *http://www.gao.gov/assets/310/304561.pdf.*

[13] *See, e.g.,* 12 CFR 1005.31(g)(1)(i) (requiring disclosures in languages other than English in certain circumstances involving remittance transfers); 12 CFR 1026.24(i)(7) (addressing obligations relating to advertising and disclosures in languages other than English for closed-end credit); 12 CFR 1002.4(e) (providing that disclosures made in languages other than English must be available in English upon request); 12 CFR 1005.18(b)(9) (requiring financial institutions to provide pre-acquisition disclosures in a foreign language if the financial institution uses that same foreign language in connection with the acquisition of a prepaid account in certain circumstances); Cal. Civ. Code sec. 1632(b) (as amended Sept. 25, 2020) (requiring that certain agreements ''primarily'' negotiated in Spanish, Chinese, Tagalog, Vietnamese, or Korean must be translated to the language of the negotiation under certain circumstances); Or. Rev. Stat. sec. 86A.198 (requiring a mortgage banker, broker, or originator to provide translations of certain notices related to the mortgage transaction if the banker, broker, or originator advertises and negotiates in a language other than English under certain circumstances); Tex. Fin. Code Ann. sec. 341.502(a–1) (providing that for certain loan contracts negotiated in Spanish, a summary of the loan terms must be made available to the debtor in Spanish in a form identical to required TILA disclosures for closed-end credit); 6 RCNY sections 5–77 (imposing certain language-related requirements on debt collection entities).

[14] CFPB, Spotlight on serving limited English proficient consumers: Language access in the consumer financial marketplace (Nov. 2017), *https://www.consumerfinance.gov/data-research/research-reports/spotlight-serving-limited-english-proficient-consumers/.*

[15] *See* CFPB, Supervisory Highlights: Fall 2016, 21–26 (Oct. 2016), *https://files.consumerfinance.gov/f/documents/Supervisory_Highlights_Issue_13__Final_10.31.16.pdf*; *see also* CFPB, ECOA Baseline Review Module 4, 13–14, 21–22 (Apr. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_supervision-and-examination-manual_ecoa-baseline-exam-procedures_2019-04.pdf* (These modules are used by CFPB examination teams to conduct ECOA Baseline Reviews to evaluate how an institution's CMS identifies and manages fair lending risk under ECOA. The observations described in the referenced LEP section of *Supervisory Highlights* resulted from, at least in part, Bureau examiners' review of financial institutions' fair lending risks and controls related to servicing options for LEP consumers).

[16] CFPB, Fair Lending Report of the Bureau of Consumer Financial Protection (April 2020), 1, *https://files.consumerfinance.gov/f/documents/cfpb_2019-fair-lending_report.pdf.*

[17] *See, e.g.,* CFPB, Request for Information on the Equal Credit Opportunity Act and Regulation B, 85 FR 46600–46603 (Aug. 3, 2020); CFPB, Request for Information to Assist the Taskforce on Federal Consumer Financial Law, 85 FR 18214–18217 (Apr. 1, 2020); CFPB, Request for Information Regarding the Bureau's Adopted Regulations and New Rulemaking Authorities, 83 FR 12286–12289 (Mar. 21, 2018).

[18] *See, e.g.,* U.S. Chamber of Com. Center for Capital Markets Competitiveness, Comment Letter on Request for Information Regarding the Bureau's Inherited Regulations and Inherited Rulemaking Authorities, Docket No. CFPB–2018–0012, 5–6 (June 25, 2018); Mortgage Bankers Association, Comment Letter on Request for Information Regarding the Bureau's Adopted Regulations and New Rulemaking Authorities, Docket No. CFPB–2018–0011, 27–28 (June 19, 2018); Americans for Financial Reform *et al.,* Comment to CFPB's Proposed Debt Collection Rule (Sept. 18, 2019), *https://www.consumeradvocates.org/sites/default/files/2019.9.18%20Debt%20Collection%20-%20Language%20Access%20Comment%20Letter_0.pdf* (comment of 43 consumer, civil and human rights, labor, community, housing, and legal services organizations recommending certain protections for LEP consumers in the Bureau's proposed debt collection rule).

[19] CFPB, Request for Information on the Equal Credit Opportunity Act and Regulation B, 85 FR 46600–46603 (Aug. 3, 2020), *https://www.federalregister.gov/documents/2020/08/25/2020-18557/request-for-information-on-the-equal-credit-opportunity-act-and-regulation-b-extension-of-comment*; CFPB, Request for Information on the Equal Credit Opportunity Act and Regulation B; Extension of Comment Period, 85 FR 165 (Aug. 25, 2020), *https://beta.regulations.gov/document/CFPB-2020-0026-0032.*

assistance to LEP consumers.'' [20] Specifically, the RFI asked:

> Should the Bureau provide additional clarity under ECOA and/or Regulation B to further encourage creditors to provide assistance, products, and services in languages other than English to consumers with limited English proficiency? If so, in what way(s)? [21]

The Bureau received a wide variety of responses to this question from several stakeholder groups, including consumer and civil rights advocacy organizations, financial institutions, industry trade associations, other financial regulators, and individuals.[22] Almost all commenters recognize the importance of providing products and services to LEP consumers. Some consumer advocacy organizations request that changes to LEP-related legal requirements take place via notice-and-comment rulemaking. They also suggest that the Bureau require institutions to develop a Language Access Plan, similar to guidance by other Federal agencies.[23] Consumer advocacy organizations, financial institutions, and industry trade associations alike encourage the Bureau to provide more translated documents and notices.

Financial institutions and industry trade association commenters advocate for flexibility in serving LEP consumers, including allowing risk-based approaches to decision making related to the scope and support for non-English languages. These commenters explained that, because there are over 350 languages spoken in the United States, it would be unrealistic and cost-prohibitive for any financial institution to fulfill all the credit needs of all customers in all languages. In addition, industry representatives express uncertainty regarding how to prioritize one language over others and what factors may be considered when institutions seek to provide services in one or more languages.[24] Some industry groups also request clarity regarding marketing in non-English languages, including whether a disclosure describing the extent of services in that language is sufficient on its own to dispel risks that the practice would be considered an unfair, deceptive, or abusive practice.[25]

A few trade associations also underscore the technical, operational, and compliance challenges specific to providing translated documents to LEP consumers. For example, the commenters point to the operational complexity of translating and disseminating documents and data through technology platforms designed to rely on standard English characters.[26] Moreover, if financial institutions do opt to translate documents, they cite uncertainty regarding which documents to translate, how to determine the accuracy of those translations, and how to defend the rationale for selecting particular forms or disclosures for translation.[27] As a result, some of these industry groups assert that providing verbal interpretation via telephone is a more effective short-term solution to improving services for LEP consumers.

In considering whether and how to offer services to LEP consumers in languages other than English, industry stakeholders express a willingness and desire to serve LEP consumers, but cite challenges related to balancing legal requirements and practical considerations, including resource and operational constraints. Specifically, these challenges arise in making:

(1) Language selection(s): Determining in which non-English language(s) to provide products and services; and

(2) Product and lifecycle selections: Deciding (a) which products and services to offer in non-English language(s), and (b) where in the product lifecycle to provide services in non-English language(s).

Industry and trade association stakeholders are particularly concerned about potential fair lending risks under ECOA regarding making and implementing decisions about language selection for non-English language services. These stakeholders are also concerned about potential UDAAP risks in determining how and in which languages to offer products and services, particularly where not all products and services are provided in languages other than English. Some of these groups request Bureau clarification that: (1) An inability to offer support in languages other than English, unless specifically required by law, does not violate ECOA or Regulation B, and/or (2) offering support in a specific non-English language and not in other non-English languages is not considered an unfair, deceptive, abusive, or discriminatory practice. These groups also encourage the Bureau to clarify that collecting consumers' language preference information does not violate the ECOA or Regulation B.[28]

These legal issues create some uncertainty and can impose costs, which may inhibit some financial institutions from serving LEP consumers.[29] As a result, LEP

[20] *Id.* at 46601.

[21] *Id.* at 46601–02.

[22] *See, e.g.,* Americans for Financial Reform Education Fund Language Access Task Force, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0145; National Community Reinvestment Coalition, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0128; East Bay Community Law Center, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0131; Housing Policy Council, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0103; Consumer Bankers Association, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0147; National Association of Federal Credit Unions, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0135; Anonymous, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0067; National Fair Housing Alliance, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–133; American Financial Services Association, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0140; American Bankers Association, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0143; Center for Capital Markets, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0136; City of Houston City Controller, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0120.

[23] *See, e.g.,* U.S. Dept. of Justice, Language Access Plan (2012), *https://www.justice.gov/civil/file/997661/download* (noting that its LEP Access Plan is ''not intended to create new services or obligations, but to eliminate or reduce limited English proficiency as a barrier or impediment to accessing the core programs and activities of the Civil Division'').

[24] *See, e.g.,* Housing Policy Council, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0094, 2 (Dec. 1, 2020).

[25] *See, e.g.,* Mortgage Bankers Association, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0115, 4 (Dec. 1, 2020) (noting that some institutions forego providing marketing in non-English languages as a result of the regulatory uncertainty).

[26] *See, e.g.,* Housing Policy Council, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0094, 2 (Dec. 1, 2020).

[27] *See e.g., id.* at 3.

[28] *See, e.g.,* U.S. Bank, Comment Letter on Request for Information: Equal Credit Opportunity Act and Regulation B, Document No. CFPB–2020–0026–0110, 3 (Dec. 1, 2020).

[29] The Bureau has a variety of tools that financial institutions can use to reduce legal uncertainty, including the No-Action Letter Policy, Compliance Assistance Sandbox Policy, and Policy to Encourage Trial Disclosure Programs. *See* CFPB, Innovation at the Bureau, *https://www.consumerfinance.gov/rules-policy/innovation/* (last accessed 12/14/20). Similarly, the Bureau's Advisory Opinion program provides written guidance to assist financial institutions in understanding their legal and regulatory obligations through advisory opinions; *see also* CFPB, Advisory Opinion program, *https://www.consumerfinance.gov/compliance/advisory-opinion-program/* (last accessed 12/14/20)

consumers may not be able to easily access generally available credit, lower-priced credit, or creditor assistance (whether before or after credit is extended). The Bureau is issuing this Statement to assist financial institutions seeking to increase access to fair and nondiscriminatory credit for LEP consumers.

B. Statement

This Statement provides principles and guidelines to inform and assist financial institutions in their decision making related to serving LEP consumers. Section B.1 provides general principles for financial institutions to consider in serving LEP consumers in languages other than English. Section B.2 provides guidelines institutions can use to help implement those principles and develop compliance solutions, including key considerations to inform those decisions and specific information about common components of a compliance management system (CMS).

1. Guiding Principles for Serving LEP Consumers

The Bureau encourages financial institutions to better serve LEP consumers while ensuring compliance with relevant Federal, State, and other legal requirements.[30] Industry stakeholders note that potential legal uncertainty discourages some financial institutions from serving LEP consumers in languages other than English. The Bureau has also spoken to many financial institutions that nevertheless choose to serve LEP consumers in myriad ways and to varying degrees.[31] The Bureau encourages institutions to better serve LEP consumers by applying the principles and guidelines in this Statement. The Bureau anticipates that if financial institutions do so, there will continue to be variations among financial institutions in the manner, and the extent to which, they provide products and services to LEP consumers.

Financial institutions that wish to implement pilot programs or other phased approaches for rolling out LEP-consumer-focused products and services may consider doing so in a manner consistent with the guidelines in section B.2 of this Statement. Phased approaches may allow financial institutions to serve LEP consumers incrementally while managing risks and taking steps to ensure compliance with appliable laws.

Financial institutions may consider developing a variety of compliance approaches related to the provision of products and services to LEP consumers consistent with the guidelines in section B.2 of this Statement. Factors relevant in the compliance context may vary depending on the size, complexity, and risk profile of an institution.[32] Therefore, differences in financial institutions and the ways they choose to serve LEP consumers will likely require different compliance solutions.

Financial institutions may mitigate certain compliance risks by providing LEP consumers with clear and timely disclosures in non-English languages describing the extent and limits of any language services provided throughout the product lifecycle.[33] In those disclosures, financial institutions may provide information about the level of non-English language support as well as communication channels through which LEP consumers can obtain additional information and ask questions.

Financial institutions may wish to consider extending credit pursuant to a legally compliant special purpose credit program (SPCP) to increase access to credit for certain underserved LEP consumers. Regulation B, which implements the ECOA, sets forth standards and general rules for SPCPs.[34] By permitting the consideration of a prohibited basis such as race or national origin in connection with an SPCP, ECOA and Regulation B provide creditors with a tool to help meet the credit needs of underserved communities. The Bureau recently issued an advisory opinion to provide stakeholders with guidance concerning how to develop and implement an SPCP.[35] While SPCPs are a useful tool to further that goal, financial institutions may responsibly serve LEP consumers without the use of SPCPs.

2. Guidelines for Developing Compliance Solutions When Serving LEP Consumers

Financial institutions may use the following key considerations and CMS guidelines to mitigate ECOA, UDAAP, and other legal risks when making threshold determinations and other decisions related to serving LEP consumers in languages other than English.[36]

a. Key Considerations

i. Language Selection

In determining whether to provide non-English language services to LEP consumers and in which language(s), financial institutions may consider documented and verifiable information (*e.g.,* the stated language preferences of its current customers[37] or U.S. Census

(published in the **Federal Register** at 85 FR 77987 (Dec. 3, 2020)).

[30] *See, e.g., supra* note 13.

[31] *See, e.g.,* CFPB, Spotlight on serving limited English proficient consumers: Language access in the consumer financial marketplace, 8–10 (Nov. 2017), *https://www.consumerfinance.gov/data-research/research-reports/spotlight-serving-limited-english-proficient-consumers/* (providing insights from financial institutions about serving LEP consumers, including assessment of language needs, centralized point of contact for technical assistance, translation and interpretation systems, training and support for staff and contractors, and interactions with consumers).

[32] CFPB, Supervisory Highlights: Fall 2016, 25 (Oct. 2016), *https://files.consumerfinance.gov/f/documents/Supervisory_Highlights_Issue_13__Final_10.31.16.pdf*; *see also* CFPB, ECOA Baseline Review Module 2, 6 (Apr. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_supervision-and-examination-manual_ecoa-baseline-exam-procedures_2019-04.pdf* (providing instructions to Bureau examiners on evaluating a financial institution's fair lending CMS, including its approach to managing the fair lending risks posed by its service providers).

[33] *See* CFPB, Supervisory Highlights: Fall 2016, 23 (Oct. 2016), *https://files.consumerfinance.gov/f/documents/Supervisory_Highlights_Issue_13__Final_10.31.16.pdf* (referencing supervisory observations of fair lending risks related to marketing only some available credit card products to Spanish-speaking consumers, while marketing several additional credit card products to English-speaking consumers. To mitigate any compliance risks related to these practices, one or more financial institutions revised their marketing materials to notify consumers in Spanish of the availability of other credit card products and included clear and timely disclosures to prospective consumers describing the extent and limits of any language services provided throughout the product lifecycle).

[34] 12 CFR 1002.8.

[35] CFPB, Advisory Opinion: Equal Credit Opportunity Act (Regulation B) Special Purpose Credit Programs (Dec. 2020), *https://files.consumerfinance.gov/f/documents/cfpb_advisory-opinion_special-purpose-credit-program_2020-12.pdf.*

[36] Although in a different context, other agencies have provided similar guidance in an attempt to increase access to services for LEP individuals. *See, e.g.,* U.S. Dept. of Housing and Urban Dev., Office of General Counsel Guidance on Fair Housing Act Protections for Persons with Limited English Proficiency (2016), *https://www.hud.gov/sites/documents/LEPMEMO091516.PDF* ("This guidance discusses how the Fair Housing Act applies to a housing provider's consideration of a person's limited ability to read, write, speak or understand English. Specifically, this guidance addresses how the disparate treatment and discriminatory effects methods of proof apply in Fair Housing Act cases in which a housing provider bases an adverse housing action–such as a refusal to rent or renew a lease—on an individual's limited ability to read, write, speak or understand English."); U.S. Dept. of Justice, Language Access Plan (2012), *https://www.justice.gov/civil/file/997661/download* ("This policy and the LEP Access Plan are not intended to create new services or obligations, but to eliminate or reduce limited English proficiency as a barrier or impediment to accessing the core programs and activities of the Civil Division."); U.S. Dept. of Justice, Common Language Access Questions, Technical Assistance, and Guidance for Federally Conducted and Federally Assisted Programs (Aug. 2011), *https://www.lep.gov/sites/lep/files/resources/081511_Language_Access_CAQ_TA_Guidance.pdf.*

[37] *See infra* section B.2.a.iii for additional information on language preference collection and tracking.

Bureau demographic or language data [38]). For example, the Bureau has previously noted that some nationwide institutions largely focus on serving Spanish-speaking consumers, while regional institutions typically align any language services with local demographics.[39]

ii. Product and Service Selection

In determining which products and services to offer in languages other than English, financial institutions may consider a variety of factors, including the extent to which LEP consumers use particular products and the availability of non-English language services.[40]

In determining when during the product lifecycle financial institutions can offer services in non-English languages and the extent of those services, financial institutions may consider activities and communications—whether verbal or written—that most significantly impact consumers. To determine whether a verbal or written communication is one that significantly impacts consumers, financial institutions may consider whether the communication conveys essential information about credit terms and conditions (*e.g.,* loan pricing), or about borrower obligations and rights, including those related to delinquency and default servicing, loss mitigation, and debt collection. Financial institutions may also consider existing customer data on what services LEP consumers use most frequently.[41]

In making product and service selections, financial institutions should review relevant policies, procedures, and practices for features that may pose heightened risk of unlawful discrimination, including distinctions in product offerings or terms related to prohibited bases (*e.g.,* national origin, age) or proxies for prohibited bases (*e.g.,* geography).[42]

iii. Language Preference Collection and Tracking

Financial institutions may collect and track customer language information in a variety of ways to facilitate communication with LEP consumers in non-English languages.[43] For example, in 2017, the Bureau issued an official approval of the final redesigned Uniform Residential Loan Application (URLA) that was to include a question to collect mortgage applicants' language preference.[44] Although the Federal Housing Finance Agency (FHFA) later opted to remove the language preference question from the URLA, the Bureau has not rescinded the approval, which confirms that financial institutions' use of the URLA containing the question identifying a mortgage applicant's language preference does not violate Regulation B sections 1002.5(b)—(d) or the ECOA.[45] The Bureau specifically reviewed the language preference question with respect to Regulation B, section 1002.5(b) concerning requests for information about national origin and determined it to be compliant. Financial institutions can use similar questions to collect customer language preference information outside of the mortgage context. Financial institutions do not violate the ECOA or Regulation B when they collect the language preference of an applicant or borrower in a credit transaction.

However, financial institutions should ensure that information collected about a consumer's language preference is not used in a way that violates applicable laws. For example, the Bureau has brought enforcement actions against institutions for violations that resulted, at least in part, from the exclusion of consumers with non-English language preferences from offers provided to similarly situated consumers without those language preferences.[46] Financial institutions choosing to collect and track customer language preferences should consider closely monitoring how that information is used within the institution to ensure compliance with applicable laws.[47]

iv. Translated Documents

Financial institutions must adhere to Federal and State laws requiring that they provide consumers with translated documents under certain circumstances.[48] Nothing in this Statement alters the applicability of those requirements.

If the translation of documents is not legally mandated, financial institutions may assess whether and to what extent to provide translated documents to consumers. Financial institutions may conduct these assessments and document the related decisions consistent with the guidelines provided in section B.2.b.i. Financial institutions that choose to provide translated documents to LEP consumers, must ensure the accuracy of those

[38] *See* Supervisory Highlights: Fall 2016, 21–22 (Oct. 2016), *https://files.consumerfinance.gov/f/documents/Supervisory_Highlights_Issue_13__Final_10.31.16.pdf.*

[39] CFPB, Spotlight on serving limited English proficient consumers: Language access in the consumer financial marketplace, 8 (Nov. 2017), *https://files.consumerfinance.gov/f/documents/cfpb_spotlight-serving-lep-consumers_112017.pdf.*

[40] *See infra* section B.2.a.iii for additional information on language preference collection and tracking.

[41] *Id.*

[42] *See* 12 CFR 1002.4(a); *see also* CFPB, ECOA Baseline Review Module 2, 8 (Apr. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_supervision-and-examination-manual_ecoa-baseline-exam-procedures_2019-04.pdf* (instructing examiners to review aspects of institutions' policies and procedures that may pose heightened fair lending risk); *In re American Express Centurion Bank,* No. 2017–CFPB–0016 (Aug. 23, 2017), *https://files.consumerfinance.gov/f/documents/201708_cfpb_american-express_content-order.pdf* (taking action against two American Express banking subsidiaries for discriminating against certain consumers with Spanish-language preferences, and consumers in Puerto Rico, the U.S. Virgin Islands, and other U.S. territories by charging them higher interest rates, imposing stricter credit cutoffs, and providing less debt forgiveness compared to consumers without Spanish-language preferences or addresses in Puerto Rico and the U.S. territories).

[43] CFPB, Supervisory Highlights: Fall 2016, 21 (Oct. 2016), *https://files.consumerfinance.gov/f/documents/Supervisory_Highlights_Issue_13__Final_10.31.16.pdf.*

[44] The URLA question stated:

Language Preference—Your loan transaction is likely to be conducted in English. This question requests information to see if communications are available to assist you in your preferred language. Please be aware that communications may NOT be available in your preferred language.

Optional—Mark the language you would prefer, if available:

O English O Chinese O Korean O Spanish O Tagalog O Vietnamese O Other: ____ O I do not wish to respond

Your answer will NOT negatively affect your mortgage application. Your answer does not mean the Lender or Other Loan Participants agree to communicate or provide documents in your preferred language. However, it may let them assist you or direct you to persons who can assist you.

Language assistance and resources may be available through housing counseling agencies approved by the U.S. Department of Housing and Urban Development. To find a housing counseling agency, contact one of the following Federal government agencies:

- U.S. Department of Housing and Urban Development (HUD) at (800) 569–4287 or *www.hud.gov/counseling.*
- Consumer Financial Protection Bureau (CFPB) at (855) 411–2372 or *www.consumerfinance.gov/find-a-housing-counselor.*

[45] 82 FR 55810 (Nov. 20, 2017).

[46] *See, e.g., In re Synchrony Bank,* No. 2014–CFPB–0007 (June 19, 2014), *http://files.consumerfinance.gov/f/201406_cfpb_consent-order_synchrony-bank.pdf* (citing violations of ECOA resulting from the exclusion of consumers from offers that would otherwise have been provided but for the Bank's language preference flag and/or the fact that the consumers had addresses in Puerto Rico or the U.S. territories); *In re American Express Centurion Bank,* No. 2017–CFPB–0016 (Aug. 23, 2017), *https://files.consumerfinance.gov/f/documents/201708_cfpb_american-express_content-order.pdf* (taking action against two American Express banking subsidiaries for discriminating against certain consumers with Spanish-language preferences, and consumers in Puerto Rico, the U.S. Virgin Islands, and other U.S. territories by charging them higher interest rates, imposing stricter credit cutoffs, and providing less debt forgiveness compared to consumers without Spanish-language preferences or addresses in Puerto Rico and the U.S. territories).

[47] *See infra* section B.2.b.ii on CMS-related monitoring.

[48] *See, e.g., supra* note 13.

translations [49] and should seek to prioritize communications and activities that most significantly impact consumers.[50]

In addition, financial institutions may wish to use translated documents provided by the Bureau and other government agencies.[51] Links to the Bureau's LEP-related resources, including glossaries of financial terms, can be found on its website.[52] The Bureau is committed to continuing to provide more translated documents in the future.

b. Generally Applicable CMS Guidelines

Financial institutions can mitigate fair lending and other risks associated with providing services in languages other than English by implementing a strong compliance management system that affirmatively considers how to serve LEP consumers in a compliant manner. Financial institutions serving LEP consumers may: (1) Develop an LEP-specific CMS, or (2) integrate an LEP focus into the financial institution's broader fair lending, UDAAP, and/or consumer compliance CMS. To be most effective, the CMS coverage should be comprehensive and commensurate with the financial institution's size, complexity, and risk profile.[53]

Common features of a well-developed CMS include: A compliance program (*i.e.,* policies and procedures, training, monitoring and/or audit, and consumer complaint response) and third-party service provider oversight.[54] In the fair lending context, financial institutions should consider an in-depth review of policies and procedures for products containing features that may pose heightened risk of unlawful discrimination.[55] The following subsections provide specific detail about components that can be included (or refined if existing) in a financial institution's CMS to mitigate fair lending and other risks associated with providing products and services in non-English languages.

i. Documentation of Decisions

A well-developed CMS will sufficiently document applicable policies, procedures, and decision making.[56] The Bureau strongly encourages financial institutions providing products and services in non-English languages to document decisions related to the selection of: (1) Language(s), (2) product(s), and (3) service(s).[57] Documentation may include anything that a financial institution considers in making the language(s), product(s), or service(s) decision, including infrastructure, systems, or other operational limitations; cost estimates; or any other information that allows a regulator to understand the decision-making process.

For example, that documentation may include any information that the financial institution considered in selecting a particular language or languages in which to serve LEP consumers (*e.g.,* the stated language preferences of its current customers [58] or U.S. Census Bureau demographic or language data [59]). In addition, the documentation may include the reasons for selecting particular products and services, including the extent of non-English language communications and other customer support resources. The documentation may also include the financial institution's plan to phase-in additional languages, products, or services over time.

Financial institutions seeking to expand language, product, and/or service offerings, may document the existing offerings and decisions related to expanded offerings. In determining whether to expand or discontinue particular products or services, financial institutions may consider documenting the extent of consumer use (or lack thereof) of those product and service offerings.

ii. Monitoring

Common features of a well-developed CMS include quality assurance testing and monitoring of business transactions and processes.[60] The Bureau encourages financial institutions providing services in languages other than English to regularly monitor those services, including changes in those services, for fair lending and UDAAP risks.[61] For

[49] Several Federal financial regulatory agencies have published translated forms, disclosures, and glossaries for use by financial institutions in ensuring the accuracy and consistency in translated terms. *See, e.g.,* CFPB, Glossary of English-Spanish Financial Terms (Oct. 2018), *https://files.consumerfinance.gov/f/documents/cfpb_adult-fin-ed_spanish-style-guide-glossary.pdf*; CFPB, Glossary of English-Chinese Financial Terms (Feb. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_adult-fin-ed_chinese-style-guide-glossary.pdf*; FHFA, Mortgage Translations Home, *https://www.fhfa.gov/MortgageTranslations* (includes Mortgage Translations clearinghouse, an easy-to-use collection of translated documents and tools to assist lenders, servicers, housing counselors, and others in helping LEP mortgage borrowers).

[50] *See supra* section B.2.a.ii on product and service selection, providing considerations for assessing whether written or verbal communications significantly impact consumers; *see, e.g.,* U.S. Dept. of Housing and Urban Development, Final Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 2736 (Jan. 2007), *https://www.federalregister.gov/documents/2007/01/22/07-217/final-guidance-to-federal-financial-assistance-recipients-regarding-title-vi-prohibition-against* (highlighting that ''[t]he decision as to what program-related documents should be translated into languages other than English is a complex one'' and describing factors that recipients of Federal financial assistance can consider in ''deciding: (1) [w]hat documents should be translated; (2) what target languages other than English are appropriate; and (3) whether more effective alternatives exist'').

[51] *See, e.g.,* CFPB, Loan estimate and closing disclosure forms and samples, *https://www.consumerfinance.gov/policy-compliance/guidance/mortgage-resources/tila-respa-integrated-disclosures/forms-samples/* (linking to various Spanish versions of TRID model and sample forms); FHFA, Mortgage Translations Home, *https://www.fhfa.gov/MortgageTranslations*.

[52] CFPB, Helping newcomers and multilingual communities, *https://www.consumerfinance.gov/language/*.

[53] *Supra,* note 32.

[54] *See* CFPB, Supervisory Highlights: Summer 2013, (Aug. 2013), *https://files.consumerfinance.gov/f/201308_cfpb_supervisory-highlights_august.pdf* (discussing the pillars of a well-functioning CMS); *see also* CFPB, ECOA Baseline Review Module 2, 6 (Apr. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_supervision-and-examination-manual_ecoa-baseline-exam-procedures_2019-04.pdf* (providing instructions to Bureau examiners on evaluating a financial institution's fair lending CMS, including its approach to managing the fair lending risks posed by its service providers).

[55] *See* 12 CFR 1002.4(a); *see also* CFPB, ECOA Baseline Review Module 2, 8 (Apr. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_supervision-and-examination-manual_ecoa-baseline-exam-procedures_2019-04.pdf* (instructing examiners to review aspects of institutions' policies and procedures that may pose heightened fair lending risk, including (1) particular incentives created by employee compensation or performance goal structures (both compensation and non-compensation based); (2) discretion over underwriting, pricing, or product selection (*e.g.,* steering risk); or (3) distinctions related to geography or prohibited bases).

[56] Supervisory Highlights: Fall 2016, 24 (Oct. 2016), *https://files.consumerfinance.gov/f/documents/Supervisory_Highlights_Issue_13__Final_10.31.16.pdf*.

[57] *See id.* at 23 (underscoring that the lack of documentation describing how one or more institutions decided to exclude certain products from Spanish language marketing raised questions about the adequacy of the institution's fair lending-related CMS).

[58] *See supra* section B.2.a.iii for additional information on language preference collection and tracking.

[59] *See* Supervisory Highlights: Fall 2016, 21–22 (Oct. 2016), *https://files.consumerfinance.gov/f/documents/Supervisory_Highlights_Issue_13__Final_10.31.16.pdf*.

[60] *Id.* at 24.

[61] *See id.* at 24–25; *see also In re Synchrony Bank,* No. 2014–CFPB–0007 (June 19, 2014), *http://files.consumerfinance.gov/f/201406_cfpb_consent-order_synchrony-bank.pdf* (citing violations of ECOA resulting from the exclusion of consumers from offers that would otherwise have been provided but for the Bank's language preference flag and/or the fact that the consumers had addresses in Puerto Rico or the U.S. territories); *In re American Express Centurion Bank,* No. 2013–CFPB–0011 (Dec. 24, 2013), *http://files.consumerfinance.gov/f/201312_cfpb_consent_amex_centurion_011.pdf* (citing the institution for, among other things, deceptive acts or practices in telemarketing of a

Continued

example, financial institutions should consider assessing the quality of customer assistance provided in non-English languages, including by assessing whether personnel receive the same training, convey the same information, and have the same authority as other customer service personnel.[62]

In addition, financial institutions should consider monitoring or conducting regular fair lending and UDAAP-related assessments of their advertising, including promotional materials and marketing scripts for new products.[63] If institutions market products to particular populations, including LEP consumers, they should consider the nature and extent of that marketing and whether any particular populations are missing or excluded.[64] Furthermore, institutions should consider reviewing new products, as well as changes in the terms and conditions of existing products, for potential UDAAP concerns to determine whether their internal controls are adequate.

Financial institutions should also ensure that marketing, disclosures, and other materials are appropriately designed to ensure accurate understanding by LEP consumers.[65] In 2013, the Bureau brought an enforcement action against a financial institution for illegal credit card practices, including deceptive marketing with respect to credit card ''add-on products'' (*i.e.,* payment protection and credit monitoring).[66] While sales calls to enroll the vast majority of Puerto Rico consumers in this product were conducted in Spanish, the institution did not provide uniform Spanish-language scripts for these enrollment calls, and all written materials provided to consumers were in English.[67]

iii. Fair Lending Testing

Common features of a well-developed CMS include regular statistical analysis of loan-level data for potential disparities on a prohibited basis (*e.g.,* national origin) in underwriting, pricing, or other aspects of the credit transaction, including in mortgage and non-mortgage products (*e.g.,* credit cards, auto lending, small business lending, and student lending).[68]

iv. Third-Party Vendor Oversight

If a financial institution contracts with service providers to offer any products or services to LEP consumers on behalf of the financial institution, it should ensure that the products and services provided to LEP consumers do not violate applicable laws or pose fair lending or UDAAP risks to LEP consumers.[69] Those financial institutions should implement a service provider oversight program that incorporates a review of fair lending, UDAAP, and other applicable laws.[70] While third-parties may offer a host of essential products and services to LEP consumers, some of which are provided in languages other than English,[71] financial institutions' service provider oversight programs should consider focusing particular attention on third parties who participate in underwriting or pricing decisions.[72]

3. Conclusion

Recognizing the compliance risks and uncertainty that many financial institutions raise as challenges to better serving LEP consumers in non-English languages, the Bureau is issuing this Statement to outline compliance principles and guidelines that encourage financial institutions to expand access to products and services for LEP consumers.

Nothing in this Statement should be interpreted to relieve institutions from their obligation to comply with laws applicable to providing financial products and services to LEP consumers. Nor does this Statement

credit card add-on product to Spanish-speaking customers in Puerto Rico because the institution did not adequately alert consumers enrolling via Spanish-language telemarketing calls about the steps necessary to receive and access the full product benefits).

[62] CFPB, ECOA Baseline Review Module 4, 13–14, 21–22 (Apr. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_supervision-and-examination-manual_ecoa-baseline-exam-procedures_2019-04.pdf* (instructing examiners to evaluate institutions' fair lending risk related to servicing options for LEP consumers).

[63] *See* CFPB, Supervisory Highlights: Fall 2016, 25 (Oct. 2016), *https://files.consumerfinance.gov/f/documents/Supervisory_Highlights_Issue_13__Final_10.31.16.pdf*; see also CFPB, Unfair, Deceptive, or Abusive Acts or Practices Examination Procedures, Management and Policy-Related Examination Procedures, 13–16 (Oct. 2012), *https://files.consumerfinance.gov/f/documents/102012_cfpb_unfair-deceptive-abusive-acts-practices-udaaps_procedures.pdf* (The Bureau's examiners use UDAAP Examination Procedures to assess the quality of the financial institution's CMS, including internal controls and policies and procedures, for avoiding unfair, deceptive, or abusive acts or practices. The Management and Policy-Related Examination Procedures, specifically, describe UDAAP-related transaction testing of (1) Marketing and disclosures, (2) availability of terms and services as advertised, and (3) availability of actual credit to the consumer.).

[64] *See In re Synchrony Bank, No. 2014–CFPB–0007* (June 19, 2014), *http://files.consumerfinance.gov/f/201406_cfpb_consent-order_synchrony-bank.pdf* (citing violations of ECOA resulting from the exclusion of consumers from offers that would otherwise have been provided but for the Bank's language preference flag and/or the fact that the consumers had addresses in Puerto Rico or the U.S. territories).

[65] *See In re American Express Centurion Bank,* No. 2013–CFPB–0011 (Dec. 24, 2013), *http://files.consumerfinance.gov/f/201312_cfpb_consent_amex_centurion_011.pdf* (citing the institution for, among other things, deceptive acts or practices in telemarketing of a credit card add-on product to Spanish-speaking customers in Puerto Rico because the institution did not adequately alert consumers enrolling via Spanish-language telemarketing calls about the steps necessary to receive and access the full product benefits); *see also Federal Trade Commission* v. *Mortgages para Hispanos.com,* (Case No. 4:06–cv–00019 (E.D.Tex. 2006) (bringing an action against a company targeting Hispanic homeowners for a home refinance which was negotiated in Spanish but presented English-language closing documents with different, less favorable terms). Several Federal and State financial regulatory agencies have published translated forms, disclosures, and glossaries for use by financial institutions in ensuring the accuracy and consistency in translated terms. *See, e.g.,* CFPB, Glossary of English-Spanish Financial Terms (Oct. 2018), *https://files.consumerfinance.gov/f/documents/cfpb_adult-fin-ed_spanish-style-guide-glossary.pdf*; CFPB, Glossary of English-Chinese Financial Terms (Feb. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_adult-fin-ed_chinese-style-guide-glossary.pdf*; FHFA, Mortgage Translations Home, *https://www.fhfa.gov/MortgageTranslations* (includes FHFA's Mortgage Translations Clearinghouse, an easy-to-use collection of translated documents and tools to assist lenders, servicers, housing counselors, and others in helping LEP mortgage borrowers).

[66] *See In re American Express Centurion Bank,* No. 2013–CFPB–0011 (Dec. 24, 2013), *http://files.consumerfinance.gov/f/201312_cfpb_consent_amex_centurion_011.pdf.*

[67] *Id.*

[68] CFPB, Supervisory Highlights: Fall 2016, 24–25 (Oct. 2016), *https://files.consumerfinance.gov/f/documents/Supervisory_Highlights_Issue_13__Final_10.31.16.pdf.*

[69] *See, e.g., In re American Express Centurion Bank,* No. 2013–CFPB–0011 (Dec. 24, 2013), *http://files.consumerfinance.gov/f/201312_cfpb_consent_amex_centurion_011.pdf* (referring to marketing practices that involved three of the institution's subsidiaries and their vendors and telemarketers, who engaged in misleading and deceptive tactics to sell some of the company's credit card add-on products. Pursuant to the Consent Order, American Express was required to continue to strengthen its management of third-party vendors who provided the subject add-on products).

[70] *See* CFPB, Supervisory Highlights: Summer 2013 (Aug. 2013), *https://files.consumerfinance.gov/f/201308_cfpb_supervisory-highlights_august.pdf* (providing findings related to service provider oversight reviews); *see also* CFPB Bulletin 2012–03 (April 12, 2012) *http://files.consumerfinance.gov/f/201204_cfpb_bulletin_service-providers.pdf* (providing the Bureau's expectations of service provider relationships).

[71] For example, the Bureau is aware that some of the National Credit Reporting Agencies provide Interactive Voice Response (IVR) phone support in Spanish.

[72] *See* CFPB, ECOA Baseline Review Module 2, 9 (Apr. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_supervision-and-examination-manual_ecoa-baseline-exam-procedures_2019-04.pdf* (instructing examiners to evaluate institutions' compliance program policies and procedures related to its third-party monitoring and audit functions).

mandate any particular approach to serving LEP consumers.[73]

II. Signing Authority

The Director of the Bureau, Kathleen L. Kraninger, having reviewed and approved this document, is delegating the authority to electronically sign this document to Grace Feola, a Bureau Federal Register Liaison, for purposes of publication in the **Federal Register**.

January 13, 2021.

Grace Feola,

Federal Register Liaison, Bureau of Consumer Financial Protection.

[FR Doc. 2021–01116 Filed 1–19–21; 8:45 am]

BILLING CODE 4810–AM–P

[73] This Statement does not impose any legal requirements on external parties, nor does it create or confer any substantive rights on external parties that could be enforceable in any administrative or civil proceeding.

DEPARTMENT OF EDUCATION

National Advisory Committee on Institutional Quality and Integrity

AGENCY: National Advisory Committee on Institutional Quality and Integrity (NACIQI), Office of Postsecondary Education, U.S. Department of Education.

ACTION: Announcement of the Senior Department Official's (SDO) decisions.

SUMMARY: This notice provides a link to the SDO's decision letters associated with recommendations from NACIQI's July 29 & 30, 2020 meeting.

SUPPLEMENTARY INFORMATION:

NACIQI's Statutory Authority and Function: NACIQI is established under section 114 of the HEA. NACIQI advises the Secretary of Education with respect to:

- The establishment and enforcement of the standards of accrediting agencies or associations under subpart 2, part H, Title IV of the HEA, as amended.
- The recognition of specific accrediting agencies or associations.
- The preparation and publication of the list of nationally recognized accrediting agencies and associations.
- The eligibility and certification process for institutions of higher education under Title IV of the HEA and part C, subchapter I, chapter 34, Title 42, together with recommendations for improvement in such process.
- The relationship between (1) accreditation of institutions of higher education and the certification and eligibility of such institutions, and (2) State licensing responsibilities with respect to such institutions.
- Any other advisory function relating to accreditation and institutional eligibility that the Secretary of Education may prescribe by regulation.

Link to the Senior Department Official's Decision Letters: After NACIQI made its recognition recommendations to the SDO, pursuant to 34 Code of Federal Regulations CFR 602.34(g), each agency and the Department staff had the opportunity to submit comments on NACIQI's recommendations to the SDO pursuant to 34 CFR 602.35. There was a separate SDO for the Higher Learning Commission (HLC). The SDO for HLC issued his decision on October 26, 2020. The SDO for all other agencies issued her decisions on October 28, 2020. A link to all the SDO decision letters, as well as a list of all the agencies reviewed at the July 29–30, 2020 NACIQI meeting, are provided below. None of the agencies reviewed chose to appeal the SDO Decisions to the Secretary pursuant to 34 CFR 602.37(a). *https://surveys.ope.ed.gov/erecognition/PublicDocuments.*

Application for Renewal of Recognition (State Agency for the Approval of Vocational Education)

Puerto Rico State Agency for the Approval of Public Postsecondary Vocational, Technical Institutions and Programs.

Applications for Renewal of Recognition (State Agency for the Approval of Nurse Education)

1. New York State Board of Regents, State Education Department, Office of the Professions (Nursing Education).
2. Missouri State Board of Nursing.

Application for Granting of Academic (Masters and Doctoral) Degrees by Federal Agencies and Institutions

1. National Intelligence University: Undergoing Substantive Change (Reorganization/Command Change).
2. U.S. Army Command and General Staff College: Undergoing Substantive Change (Curriculum Change).

Agency Under Review and Evaluation during its period of recognition by the Department's Office of Postsecondary Education Accreditation Group, in accordance with the procedures set forth in 34 CFR 602.33.

Higher Learning Commission (HLC).

Access to Records of the Meeting: The official report of the July 29 & 30, 2020 meeting is posted on the NACIQI website. In addition, pursuant to the Federal Advisory Committee Act (FACA), at 5 U.S.C. App. 10(b), the public may request to inspect records of the meeting at 400 Maryland Avenue SW, Washington, DC, by emailing *aslrecordsmanager@ed.gov* or by calling (202) 453–7415 to schedule an appointment.

FOR FURTHER INFORMATION CONTACT: George Alan Smith, Executive Director/Designated Federal Official, NACIQI, U.S. Department of Education, 400 Maryland Avenue SW, Room 271–03, Washington, DC 20202, telephone: (202) 453–7757, or email: *George.Alan.Smith@ed.gov.*

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You also may access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: 20 U.S.C. 1011c.

Christopher McCaghren,

Acting Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 2021–01222 Filed 1–19–21; 8:45 am]

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DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0012]

Agency Information Collection Activities; Comment Request; Example Application for the Emergency Assistance to Non-Public Schools Program

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is requesting the Office of Management and Budget (OMB) to conduct an emergency review of a new information collection.

DATES: The Department has requested emergency processing from OMB for this information collection request by January 14, 2021; and therefore, the

regular clearance process is hereby being initiated to provide the public with the opportunity to comment under the full comment period. Interested persons are invited to submit comments on or before March 22, 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–2021–SCC–0012. 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 Andrew Brake, 202–260–0998.

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: Example Application for the Emergency Assistance to Non-Public Schools Program.

OMB Control Number: 1810–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 20,000.

Total Estimated Number of Annual Burden Hours: 40,000.

Abstract: The Emergency Assistance to Non-Public Schools program is a reservation of funds under the Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (CRRSA Act) to provide services or assistance to non-public schools. Under the EANS program, we will award grants by formula to each Governor with an approved Certification and Agreement to provide services or assistance to eligible non-public schools to address the impact that the Coronavirus Disease 2019 (COVID–19) has had, and continues to have, on non-public school students and teachers in the State. The CRRSA Act requires that State's collect applications from non-public schools in order to award these funds. This request is being made to allow the distribution of an example application States can use to collect the needed information from eligible non-public schools. States are not required to use this application and may create their own.

Additional Information: An emergency clearance approval for the use of the system is described below due to the following conditions:

- The Department of Education (Department) requests that the following collection of information, the example application for the Emergency Assistance to Non Public Schools (EANS) Program under section 312(d) of the CRRSA Act, Public Law 116–260, be processed in accordance with section 1320.13 emergency processing of the Paperwork Reduction Act. Section 312(d)(3) of the CRRSA Act requires that any State educational agency receiving funds to provide services or assistance to non-public schools shall make an application for those services available to non-public schools no later than 30 days after the receipt of such funds. The Department announced the availability of the EANS funds on January 8, 2021 and will be awarding funds no later than 15 days after receipt of a Governor's application.

Dated: January 14, 2021.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2021–01192 Filed 1–19–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0175]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Work Colleges Application and Agreement

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before February 22, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed

information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Work Colleges Application and Agreement.

OMB Control Number: 1845–0153.

Type of Review: An extension 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. The Work Colleges Application and Agreement form is the tool for an institution to apply for participation in this program. The data will be used by the Department to assess an institution's preparedness to participate in this program and as a signed agreement to comply with all requirements for participating in the program. The data is used in conjunction with institutional program reviews to assess the administrative capability and compliance of the applicant.

Dated: January 13, 2021.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–01114 Filed 1–19–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0174]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Work Colleges Expenditure Report

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before February 22, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Work Colleges Expenditure Report.

OMB Control Number: 1845–0152.

Type of Review: An extension 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: January 13, 2021.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–01113 Filed 1–19–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Request for Information Related to High Energy Physics and Space-Based Astrophysics

AGENCY: Office of High Energy Physics (HEP), Office of Science (SC), U.S. Department of Energy (DOE), and the Astrophysics Division (APD) and Biological and Physical Sciences Division (BPS), Science Mission Directorate (SMD), National Aeronautics and Space Administration (NASA).

ACTION: Request for Information (RFI).

SUMMARY: The Office of High Energy Physics (HEP) in the Department of Energy (DOE) and the Astrophysics Division (APD) and Biological and

Physical Sciences Division (BPS) in the National Aeronautics and Space Administration (NASA) invite interested parties to provide information on topics that provide mutually beneficial collaborative activities that can further scientific advances in specific, focused areas in the fields of high energy physics and space-based astrophysics aligned with the science goals of the program offices. This information will inform the program offices (HEP, APD, and BPS) on potential partnerships and collaborative activities that may be pursued. As additional opportunities for mutually beneficial collaboration between the Parties continue to emerge, RFIs for subsequent topics may be released. Individuals or collaborations are welcome to respond.

DATES: Written comments and information are requested on or before March 8, 2021.

ADDRESSES: The DOE Office of Science is using the *http://www.regulations.gov* system for the submission and posting of public comments in this proceeding. All comments in response to this notice are therefore to be submitted electronically through *http://www.regulations.gov,* via the web form accessed by following the ''Submit a Formal Comment'' link near the top right of the **Federal Register** web page for this document.

Format: The comments and information provided should be in the form of a PDF file, with a minimum 12 point font size and one inch margins. The file should be a maximum of 11 pages, with the first page clearly listing the focus area, title of the information, author(s) and institution(s), and a short abstract. The body of the file (10 pages max) should provide the information requested, and responses to the specific questions should be clearly labeled according to the labels below.

FOR FURTHER INFORMATION CONTACT: Requests for additional information may be submitted to Dr. Kathy Turner at 301–903–1759 or by email at *HEP-APD-BPS-RFI2021@science.doe.gov.*

SUPPLEMENTARY INFORMATION: The DOE HEP and NASA APD and BPS program offices request information in the three (3) focused areas described below in which cooperation or partnerships between DOE and NASA can further scientific advances. The objective of the RFI is to gather information about these focused areas, including scientific and technology benefits and obstacles, how it will make use of each agency's capabilities, infrastructure and resources, and other pertinent information.

The information received in response to this RFI will inform and be considered by the DOE and NASA program offices regarding the potential development of partnerships and collaborative activities.

Please note that this RFI *is not* a Funding Opportunity Announcement, a Request for Proposals, or any other form of solicitation or bid of DOE or NASA to fund potential research and development work.

Focus Area 1

The radio quiet environment of the Moon's far side offers the potential for deployment of sensitive radio telescopes or sensors to explore the early eras of the universe or to test the standard cosmological model. Information from the community is requested for near term contributions or partnerships on planned and future lunar surface missions; longer term efforts on a future NASA lunar ground station, a lunar orbiting radio telescope, or lunar ground-based far side observatory are also of interest. Development of such a mission or observatory will be dependent on the National Academies of Science, Engineering, and Medicine (NASEM) Astronomy and Astrophysics Decadal Survey study (''Astro2020''), which is expected to report to the agencies in spring 2021. Particular areas of interest include sensor technology demonstrations and precursor or early science investigations as well as fully developed scientific studies on future missions.

Information is requested pertaining to the following specific questions:

Science Topics

a. What are key science topics aligned with HEP and/or APD science drivers which may significantly advance scientific knowledge using a lunar far side or orbiting observatory. What are the opportunities and challenges to make progress on these topics? Would the efforts to achieve these compelling science goals best be done on a lunar surface or an orbital platform?

b. Are precursor scientific measurements or demonstrations needed before lunar ground or orbiting platforms can be used, or will need to be used, to achieve the compelling science goals?

c. What key obstacles, impediments, or bottlenecks are there to advancing the scientific research?

Technology Capabilities

d. What are existing or near-term technology capabilities available in HEP and/or APD that can be used to advance these key science goals on lunar surface missions currently being developed? What longer term technology development is needed for future missions?

e. Are precursor technology developments or demonstrations needed before lunar ground or orbiting platforms would be effective?

f. What key obstacles, impediments, or bottlenecks are there to advancing the technology development?

Collaboration and Partnerships

g. What cooperation or partnerships between DOE and NASA could further the scientific and technology advances?

h. What mix of institutions or collaboration models could best carry out the envisioned research and/or development?

i. What resources, capabilities and infrastructure at DOE National Laboratories or the NASA Centers (including the Jet Propulsion Laboratory (JPL)) would be beneficial for and could accelerate or facilitate research in this topic?

Other

j. Are there other factors, not addressed by the questions above, which should be considered in planning HEP and APD activities in this subject area?

Focus Area 2

The International Space Station (ISS) provides a unique platform for space-based probes of fundamental physics in a microgravity environment. Example topics include the search for dark matter and dark energy, the direct detection of gravitational waves, and the test of the equivalence principle. Information from the community is requested regarding developing and carrying out small experiments on the ISS in areas of fundamental physics that are aligned with or are closely related to the science goals of HEP, APD, and/or BPS. Experiments on the ISS that make use of quantum sensor technologies and capabilities in the HEP, APD, or BPS community are of particular interest.

Information is requested pertaining to the following specific questions:

Science Topics

a. Key science topics aligned with HEP, APD, and/or BPS science drivers which may significantly advance scientific knowledge using the ISS platform. What are the opportunities and challenges to make progress on these topics?

b. Are precursor scientific measurements or demonstrations needed before the ISS platform can be

used, or needs to be used, to achieve the compelling science goals?

c. What key obstacles, impediments, or bottlenecks are there to advancing the scientific research?

Technology Capabilities

d. What are existing or near-term technology capabilities available in HEP, APD, or BPS that can be used to advance these key science goals? What longer term technology development is need for future missions?

e. How can quantum sensor technologies be used to carry out this science, with particular interest in applications unique to the microgravity environment?

f. Are precursor technology developments or demonstrations needed before the ISS platform would be effective?

g. What are key obstacles, impediments, or bottlenecks to advancing the technology development?

Collaboration and Partnerships

h. What cooperation or partnerships between DOE and NASA could further the scientific and technology advances?

i. What mix of institutions or collaboration models could best carry out the envisioned research and/or development?

j. What resources, capabilities and infrastructure at DOE National Laboratories or the NASA Centers (including the Jet Propulsion Laboratory (JPL)) would be beneficial for and could accelerate or facilitate research in this topic?

Other

k. Are there other factors, not addressed by the questions above, which should be considered in planning HEP, APD or BPS activities in this subject area?

Focus Area 3

DOE is partnering with NSF on the Vera C. Rubin Observatory, which is expected to start operations in Chile in FY2023. The study of the nature of dark energy is the primary science goal aligned with HEP. NASA is developing the Nancy Grace Roman Space Telescope, planned for launch in 2026, and is partnering with the European Space Agency on the Euclid mission, planned for launch in 2022. Both these space missions have the study of the nature of dark energy as a priority science driver. The data from each is also of interest to the wider astronomy community for many additional scientific studies.

Due to the complementary and synergistic capabilities and data, the scientific community expects to carry out dark energy investigations using all 3 sets of data. Information from the community is requested regarding efforts that will enhance or extend the science reach provided by these observatories when considered together, including development of a common library of simulations and/or capabilities to enable joint processing and analysis of the data.

Information is requested pertaining to the following specific questions:

Science Enhancements

a. What are the key dark energy science areas that will be enhanced by these activities? What level of scientific enhancement is expected by carrying them out after the datasets are public? What additional enhancements are expected if plans are put in place in the near term to enable joint data processing and analysis of public data sets?

b. What is the scope of work required, as well as the opportunities and costs?

c. What are key obstacles, impediments, or bottlenecks to advancing development of these plans?

d. Are there other science topics besides dark energy that drive the requirements for joint data processing or analysis?

Collaboration and Partnerships

k. What cooperation or partnerships between DOE and NASA could further the scientific and technology advances?

l. What mix of institutions or collaboration models could best carry out the envisioned research and/or development?

m. What resources, capabilities and infrastructure at DOE National Laboratories or the NASA Centers (including the Jet Propulsion Laboratory (JPL)) would be beneficial for and could accelerate or facilitate research in this topic?

n. Are there other factors, not addressed by the questions above, which should be considered in planning HEP and APD activities in this subject area?

General Information

Comments containing references, studies, research, and other empirical data that are not widely published should include copies of the referenced materials. Note that comments will be made publicly available as submitted. Any information that may be confidential and exempt by law from public disclosure should be submitted as described below.

Confidential Business Information: Pursuant to 10 CFR 1004.11, any person submitting information he or she believes to be confidential and exempt by law from public disclosure should submit via email: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Both DOE and NASA will make their own determination about the confidential status of the information and treat it according to its determination. Factors of interest to DOE and NASA when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

Signing Authority

This document of the Department of Energy was signed on January 14, 2021, by Chris Fall, Director for the Office of Science, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 14, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–01236 Filed 1–19–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD21–8–000; Docket No. ER02–2001–000]

Technical Conference on Reassessment of the Electric Quarterly Report Requirements; Supplemental Notice of Technical Conference

As announced in the Notice of Technical Conference issued on January 8, 2021, the Federal Energy Regulatory Commission staff will convene a technical conference on February 24, 2021 as part of a reassessment of the Electric Quarterly Report (EQR) requirements, in Docket No. AD21–8–000. The purpose of this technical conference is to provide a forum for Commission staff, filers, and data users to discuss potential changes to the current EQR data fields. This technical conference is intended to be the first in a series of conferences related to a reassessment of the EQR requirements.

All future notices, submittals, and issuances pertaining to the technical conferences will be issued in Docket No. AD21–8–000. There is an ''eSubscription'' link on the Commission's website that enables subscribers to receive email notification when a document is added to a subscribed docket(s).

Dated: January 13, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–01182 Filed 1–19–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–39–000]

Neptune Regional Transmission System, Long Island Power Authority v. PJM Interconnection, L.L.C.; Notice of Complaint

Take notice that on December 31, 2021, pursuant to sections 206 and 306, of the Federal Power Act, 16 U.S.C. 824e and 825e and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, Neptune Regional Transmission System and Long Island Power Authority (Complainants) filed a formal complaint against PJM Interconnection, L.L.C., (Respondent) alleging that the Respondent has unjust and unreasonable distortion of cost allocation assignments for the Regional Transmission Expansion Plan projects, all as more fully explained in the complaint.

The Complainant certifies that copies of the complaint were served on the contacts listed for Respondent in the Commission's list of Corporate Officials.

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. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

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.

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 Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov,* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on January 21, 2021.

Dated: January 13, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–01184 Filed 1–19–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–36–000]

Mankato Energy Center, LLC, Mankato Energy Center II, LLC; Notice of Institution of Section 206 Proceeding and Establishment of Paper Hearing Procedures

On January 11, 2021, the Commission issued an order in Docket No. EL21–36–000, instituting a proceeding under section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, to examine whether J.P. Morgan Investment Management Inc. (J.P. Morgan Investment) may stand in such relation to Mankato Energy Center, LLC and Mankato Energy Center II, LLC (Mankato Companies) that there is liable to be an absence of arm's-length bargaining in transactions between them as to make it necessary or appropriate in the public interest or for the protection of investors or consumers that J.P. Morgan Investment be treated as an affiliate of Mankato Companies under section 35.36(a)(9)(iii) of the Commission's regulations, 18 CFR 35.36(a)(9)(iii) (2020). *Mankato Energy Center, LLC,* 174 FERC 61,017 (2021).

The refund effective date in Docket No. EL21–36–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL21–36–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, within 21 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the

proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC 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 ''eFile'' link at *http://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Dated: January 13, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–01185 Filed 1–19–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER21–483–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: 3620R1 Kansas City Board of Public Utilities NITSA NOA to be effective 9/1/2020.
Filed Date: 1/13/21.
Accession Number: 20210113–5119.
Comments Due: 5 p.m. ET 2/3/21.

Docket Numbers: ER16–632–010.
Applicants: Blythe Solar II, LLC.
Description: Notice of Change in Status of Blythe Solar II, LLC.
Filed Date: 1/12/21.
Accession Number: 20210112–5188.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–534–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: 1978R9 Evergy Kansas Central, Inc. NITSA NOA—Toronto to be effective 9/1/2020.
Filed Date: 1/13/21.
Accession Number: 20210113–5016.
Comments Due: 5 p.m. ET 2/3/21.

Docket Numbers: ER21–543–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: 2066R9 Evergy Kansas Central, Inc. NITSA NOA—Muscotah to be effective 9/1/2020.
Filed Date: 1/13/21.
Accession Number: 20210113–5020.
Comments Due: 5 p.m. ET 2/3/21.

Docket Numbers: ER21–544–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: 2491R8 Evergy Kansas Central, Inc. NITSA NOA—Scranton to be effective 9/1/2020.
Filed Date: 1/13/21.
Accession Number: 20210113–5030.
Comments Due: 5 p.m. ET 2/3/21.

Docket Numbers: ER21–868–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: DEC-Lockhart NITSA SA No. 407 to be effective 1/1/2021.
Filed Date: 1/12/21.
Accession Number: 20210112–5168.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–869–000.
Applicants: Michigan Electric Transmission Company, LLC.
Description: § 205(d) Rate Filing: Filing of a Joint Use Pole Agreement to be effective 3/15/2021.
Filed Date: 1/12/21.
Accession Number: 20210112–5169.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–870–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: DEC-NCEMC Reimbursement Agreement RS No. 564 to be effective 3/14/2021.
Filed Date: 1/12/21.
Accession Number: 20210112–5179.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–871–000.
Applicants: Northern Indiana Public Service Company LLC, Indiana Crossroads Wind Farm LLC.
Description: Request for Authorization to Undertake Affiliate Sales of Northern Indiana Public Service Company LLC, et al.
Filed Date: 1/12/21.
Accession Number: 20210112–5185.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–872–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 3758 East River Electric & City of Pierre, SD Inter Agr to be effective 12/31/9998.
Filed Date: 1/13/21.
Accession Number: 20210113–5000.
Comments Due: 5 p.m. ET 2/3/21.

Docket Numbers: ER21–873–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA, SA #3836; Queue #Z1–050; Request for Expedited Comment Period to be effective 4/30/2014.
Filed Date: 1/13/21.
Accession Number: 20210113–5047.
Comments Due: 5 p.m. ET 2/3/21.

Docket Numbers: ER21–874–000.
Applicants: Louisville Gas and Electric Company.
Description: § 205(d) Rate Filing: LGE and KU Amended and Restated BREC IA to be effective 12/31/2020.
Filed Date: 1/13/21.
Accession Number: 20210113–5062.
Comments Due: 5 p.m. ET 2/3/21.

Docket Numbers: ER21–875–000.
Applicants: Kentucky Utilities Company.
Description: § 205(d) Rate Filing: LGE and KU Amended and Restated BREC IA_KU Concurrence to be effective 12/31/2020.
Filed Date: 1/13/21.
Accession Number: 20210113–5070.
Comments Due: 5 p.m. ET 2/3/21.

Docket Numbers: ER21–876–000.
Applicants: Kentucky Utilities Company.
Description: Tariff Cancellation: Cancellation of KU Rate Schedule FERC No. 405 to be effective 12/31/2020.
Filed Date: 1/13/21.
Accession Number: 20210113–5072.
Comments Due: 5 p.m. ET 2/3/21.

Docket Numbers: ER21–877–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: BPA NITSA (OR Wind) to be effective 12/15/2020.
Filed Date: 1/13/21.
Accession Number: 20210113–5092.
Comments Due: 5 p.m. ET 2/3/21.

Docket Numbers: ER21–878–000.
Applicants: Pacific Gas and Electric Company.
Description: § 205(d) Rate Filing: E&P Agreement for Oakland Energy Storage 1, LLC to be effective 1/14/2021.
Filed Date: 1/13/21.
Accession Number: 20210113–5114.
Comments Due: 5 p.m. ET 2/3/21.

Docket Numbers: ER21–879–000.
Applicants: Public Service Company of Colorado.
Description: § 205(d) Rate Filing: 2021–1–13 PSC–HLYCRS–SISA–Orchard Mesa–621–0.0.0 to be effective 1/14/2021.
Filed Date: 1/13/21.
Accession Number: 20210113–5122.
Comments Due: 5 p.m. ET 2/3/21.

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: January 13, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–01180 Filed 1–19–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OARM–2017–0752; FRL–10019–37–OMS]

Proposed Information Collection Request; Comment Request; Background Checks for Contractor Employees (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), ''Background Checks for Contractor Employees (Renewal)'' (EPA ICR No. 2159.08, OMB Control No. 2030–0043) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through September 30, 2021. 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 March 22, 2021.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OARM–2017–0752 online using *www.regulations.gov* (our preferred method), by email to *oei.docket@epa.gov,* 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: Denise Clarke, Policy Training and Oversight Division, Office of Acquisition Solutions (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–8414; email address: *clarke.denise@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

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 uses contractors to perform services throughout the nation with regard to environmental emergencies involving the release, or threatened release, of oil, radioactive materials, or hazardous chemicals that may potentially affect communities and the surrounding environment. The Agency may request contractors responding to any of these types of incidents to conduct background checks and apply Government-established suitability criteria in Title 5 CFR Administrative Personnel 731.104 *Appointments Subject to Investigation,* 732.201 *Sensitivity Level Designations and Investigative Requirements,* and 736.102 *Notice to Investigative Sources* when determining whether employees are acceptable to perform on given sites or on specific projects. In addition to emergency response contractors, EPA may require background checks for contractor personnel working in sensitive sites or sensitive projects. The background checks and application of the Government's suitability criteria must be completed prior to contract employee performance. The contractor shall maintain records associated with all background checks. Background checks cover citizenship or valid visa status, criminal convictions, weapons offenses, felony convictions, and parties prohibited from receiving federal contracts.

Form Numbers: None.

Respondents/affected entities: Private Contractors.

Respondent's obligation to respond: Required to obtain a benefit per Title 5 CFR Administrative Personnel 731.104 *Appointments Subject to Investigation,* 732.201 *Sensitivity Level Designations and Investigative Requirements,* and 736.102 *Notice to Investigative Sources.*

Estimated number of respondents: 1,000 (total).

Frequency of response: Annual.

Total estimated burden: 1,000 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $208,720 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in Estimates: There is no change in the hours in the total estimated respondent burden compared with the ICR currently approved by OMB.

Kimberly Patrick,

Director, Office of Acquisition Solutions.

[FR Doc. 2021–01241 Filed 1–19–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2020–0673; FRL–10019–78–OW]

Applying the Supreme Court's County of Maui v. Hawaii Wildlife Fund Decision in the Clean Water Act Section 402 National Pollutant Discharge Elimination System Permit Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of guidance.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is issuing a memorandum to provide guidance to the regulated community and permitting authorities on applying the recent decision of the United States Supreme Court in *County of Maui* v. *Hawaii Wildlife Fund,* 140 S. Ct. 1462 (2020), in the Clean Water Act Section 402 National Pollutant Discharge Elimination System (NPDES) permit program for point source discharges that travel through groundwater before reaching a water of the United States. Consistent with *EPA Guidance; Administrative Procedures for Issuance and Public Petitions,* published in the **Federal Register** on October 19, 2020, EPA solicited public comments on the draft guidance for thirty days, beginning on December 10, 2020. EPA has developed a responsiveness summary to address major concerns and comments, and it is available in the docket for this action. This guidance does not have the force and effect of law and it does not bind the public in any way. By issuing this guidance, the Agency intends only to provide clarity to the public regarding existing requirements under the law or Agency policies.

FOR FURTHER INFORMATION CONTACT: Scott Wilson, Office of Wastewater Management, Water Permits Division (MC4203M), Environmental Protection Agency. 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–6087; email address: *wilson.js@epa.gov.*

A. How can I get copies of this document and other related information?

You may access this document electronically at *https://www.epa.gov/npdes/releases-point-source-groundwater* or at *https://www.federalregister.gov.* EPA established an official public docket under Docket ID No. EPA–HQ–OW–2020–0673 which is accessible electronically at *http://www.regulations.gov* that will also contain copies of this **Federal Register** notice. The public docket does not include CBI or other information whose disclosure is restricted by statute. The telephone number for the Water Docket is (202) 566–2426.

Dated: January 13, 2021.

Anna Wildeman,

Acting Assistant Administrator, Office of Water.

[FR Doc. 2021–01254 Filed 1–19–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0765; FRL–10018–08–ORD]

Board of Scientific Counselors (BOSC) Executive Committee Meeting—January 2021

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of a virtual meeting of the Board of Scientific Counselors (BOSC) Executive Committee (EC) to review the draft reports of the Homeland Security (HS) and Safe and Sustainable Water Resources (SSWR) subcommittees. Due to unforeseen circumstances, EPA is announcing this meeting with less than 15 calendar days' notice.

DATES: The initial meeting will be held over one day via videoconference on Wednesday, January 27, 2021, from 2 p.m. to 5 p.m. (EDT). Attendees must register by January 26, 2021.

If an additional meeting is necessary to complete the draft reports a follow-up will be held on Thursday, February 11, 2021, from 3 p.m. to 5 p.m. (EDT). Attendees must register by February 10, 2021.

Meeting times are subject to change. These series of meetings are open to the public. Comments must be received by January 26, 2021, to be considered by the Executive Committee. Requests for the draft agenda or making a presentation at the meeting will be accepted until January 26, 2021.

ADDRESSES: Instructions on how to connect to the videoconference will be provided upon registration at *https://www.eventbrite.com/e/us-epa-bosc-executive-committee-meeting-tickets-130024345317.*

Submit your comments to Docket ID No. EPA–HQ–ORD–2015–0765 by one of the following methods:

- *www.regulations.gov:* Follow the online instructions for submitting comments.

Note: Comments submitted to the *www.regulations.gov* website are anonymous unless identifying information is included in the body of the comment.

- *Email:* Send comments by electronic mail (email) to: *ORD.Docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2015–0765.

Note: Comments submitted via email are not anonymous. The sender's email will be included in the body of the comment and placed in the public docket which is made available on the internet.

Instructions: All comments received, including any personal information provided, will be included in the public docket without change and may be made available online at *www.regulations.gov.* Information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute will not be included in the public docket, and should not be submitted through *www.regulations.gov* or email. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/dockets/.*

Public Docket: Publicly available docket materials may be accessed *Online* at *www.regulations.gov.*

Copyrighted materials in the docket are only available via hard copy. The telephone number for the ORD Docket Center is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer (DFO), Tom Tracy, via phone/voicemail at: (202) 564–6518; or via email at: *tracy.tom@epa.gov.*

Any member of the public interested in receiving a draft agenda, attending the meeting, or making a presentation at the meeting should contact Tom Tracy no later than January 26, 2021.

SUPPLEMENTARY INFORMATION: The Board of Scientific Counselors (BOSC) is a federal advisory committee that provides advice and recommendations to EPA's Office of Research and Development on technical and management issues of its research programs. The meeting agenda and materials will be posted to *https://www.epa.gov/bosc.*

Proposed agenda items for the meeting include, but are not limited to, the following: review the HS and SSWR draft reports.

Information on Services Available: For information on translation services, access, or services for individuals with disabilities, please contact Tom Tracy at (202) 564–6518 or *tracy.tom@epa.gov.*

To request accommodation of a disability, please contact Tom Tracy at least ten days prior to the meeting to give the EPA adequate time to process your request.

(Authority: Pub. L. 92–463, 1, Oct. 6, 1972, 86 Stat. 770)

Mary Ross,

Director, Office of Science Advisor, Policy and Engagement.

[FR Doc. 2021–01206 Filed 1–19–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2018–0604; FRL–10017–50]

C.I. Pigment Violet 29; Final Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of the final Toxic Substances Control Act (TSCA) risk evaluation of C.I. Pigment Violet 29. The purpose of conducting risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation, without consideration of costs or other nonrisk factors. EPA has determined that specific conditions of use of C.I. Pigment Violet 29 present an unreasonable risk of injury to health or the environment. For those conditions of use for which EPA has found an unreasonable risk, EPA must move to address that unreasonable risk through risk management measures enumerated in TSCA. EPA has also determined that specific conditions of use do not present unreasonable risk of injury to health or the environment. For those conditions of use for which EPA has found no unreasonable risk to health or the environment, the Agency's determination is a final Agency action and is issued via order in the risk evaluation.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0604, is available online at *http://www.regulations.gov* or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Seema Schappelle, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8006; email address: *schappelle.seema@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of interest to persons who are or may be interested in risk evaluations of chemical substances under TSCA, 15 U.S.C. 2601 *et seq.* Since other entities may also be interested in this final risk evaluation, the EPA has not attempted to describe all the specific entities that may be affected by this action.

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

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to ''determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.'' 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence and consider reasonably available information. 15 U.S.C. 2625(h), (i), and (k). TSCA section 6(i) directs that a determination of ''no unreasonable risk'' shall be issued by order and considered to be a final Agency action, while a determination of ''unreasonable risk'' is not considered to be a final Agency action. 15 U.S.C. 2605(i).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) Integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i) through (ii) and (iv) through (v). Each risk evaluation must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

The statute requires that the risk evaluation process be completed within a specified timeframe and provide an opportunity for public comment on a draft risk evaluation prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4).

Subsection 5.4.1 of the final risk evaluation for C.I. Pigment Violet 29 constitutes the order required under TSCA section 6(i)(1), and the ''no unreasonable risk'' determinations in that subsection are considered to be a final Agency action effective on the date

of issuance of the order. In conducting risk evaluations, ''EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use within the scope of the risk evaluation . . . .'' 40 CFR 702.47. Under EPA's implementing regulations, ''[a] determination by EPA that the chemical substance, under one or more of the conditions of use within the scope of the risk evaluation, does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final Agency action, effective on the date of issuance of the order.'' 40 CFR 702.49(d). For purposes of TSCA section 19(a)(1)(A), the date of issuance of the TSCA section 6(i)(1) order for C.I. Pigment Violet 29 shall be at 1:00 p.m. Eastern time (standard or daylight, as appropriate) on the date that is two weeks after the date when this notice is published in the **Federal Register**, which is in accordance with 40 CFR 23.5.

C. What action is EPA taking?

EPA is announcing the availability of the risk evaluation of the chemical substance identified in Unit II. In this risk evaluation EPA has made unreasonable risk determinations on some of the conditions of use within the scope of the risk evaluation for this chemical. For those conditions of use for which EPA has found an unreasonable risk of injury to health or the environment, EPA must initiate regulatory action to address those risks through risk management measures enumerated in 15 U.S.C. 2605(a).

EPA also is announcing the availability of the information required to be provided publicly with each risk evaluation, which is available online at *http://www.regulations.gov* in the dockets identified. 40 CFR 702.51. Specifically, EPA has provided:

- The scope document and problem formulation (in Docket ID No. EPA–HQ–OPPT–2016–0725);
- Draft risk evaluation, revised draft risk evaluation and final risk evaluation (in Docket ID No. EPA–HQ–OPPT–2018–0604);
- All notices, determinations, findings, consent agreements, and orders (in Docket ID No. EPA–HQ–OPPT–2018–0604);
- Any information required to be provided to the Agency under 15 U.S.C. 2603 (in Docket ID No. EPA–HQ–OPPT–2016–0725 and Docket ID No. EPA–HQ–OPPT–2018–0604);
- A nontechnical summary of the risk evaluation (in Docket ID No. EPA–HQ–OPPT–2018–0604);
- A list of the studies, with the results of the studies, considered in carrying out each risk evaluation (Risk Evaluation for C.I. Pigment Violet 29) in Docket ID No. EPA–HQ–OPPT–2018–0604);
- The final peer review report, including the response to peer review and public comments received during peer review (in Docket ID No. EPA–HQ–OPPT–2018–0604); and
- Response to public comments received on the draft scope, the draft risk evaluation and revised draft risk evaluation (in Docket ID No. EPA–HQ–OPPT–2018–0604).

II. TSCA Risk Evaluation

A. What is EPA's risk evaluation process for existing chemicals under TSCA?

The risk evaluation process is the second step in EPA's existing chemical process under TSCA, following prioritization and before risk management. As this chemical is one of the first ten chemical substances undergoing risk evaluation, the chemical substance was not required to go through prioritization (81 FR 91927, December 19, 2016) (FRL–9956–47). The purpose of conducting risk evaluations is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, not consider costs or other nonrisk factors, use reasonably available information and approaches in a manner that is consistent with the requirements in TSCA for the use of the best available science, and ensure decisions are based on the weight of the scientific evidence.

The specific risk evaluation process that EPA has established by rule to implement the statutory process is set out in 40 CFR part 702 and summarized on EPA's website at *http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca.* As explained in the preamble to EPA's final rule on procedures for risk evaluation (82 FR 33726, July 20, 2017) (FRL–9964–38), the specific regulatory process set out in 40 CFR part 702, subpart B will be followed for the first ten chemical substances undergoing risk evaluation to the maximum extent practicable.

Prior to the publication of this final risk evaluation, a draft risk evaluation and a revised draft risk evaluation were subject to peer review and public comment. EPA reviewed the peer review reports from the Science Advisory Committee on Chemicals (SACC), a Letter Peer Review, and public comments and has supplemented the risk evaluation in response to these comments as appropriate. Prior to the publication of the draft risk evaluation, EPA made available the scope and problem formulation, and solicited public input on uses and exposure. EPA's documents, the peer review report, and the public comments are in Docket EPA–HQ–OPPT–2018–0604 at *http://www.regulations.gov.* Additionally, information about the scope, problem formulation, and draft risk evaluation phases of the TSCA risk evaluation for this chemical is available at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-pigment-violet-29-anthra219-def6510.*

B. What is C.I. Pigment Violet 29?

C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d′e′f′] diisoquinoline-1,3,8,10(2H,9H)-tetrone) is a perylene derivative used to color materials and as an intermediate for other perylene pigments. C.I. Pigment Violet 29 is currently manufactured (including imported), processed, distributed, used, and disposed of as part of industrial, commercial, and consumer conditions of use. Leading applications for C.I. Pigment Violet 29 include use as an intermediate to create or adjust color of other perylene pigments, incorporation into paints and coatings used primarily in the automobile industry, incorporation into plastic and rubber products used primarily in automobiles and industrial carpeting, use in merchant ink for commercial printing, and use in consumer watercolors and artistic color.

Authority: 15 U.S.C. 2601 *et seq.*

Andrew Wheeler,

Administrator.

[FR Doc. 2021–01229 Filed 1–19–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0365; FRL–10018–32–ORD]

Board of Scientific Counselors (BOSC) Air and Energy Subcommittee Meeting—February 2021

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of a virtual meeting of the Board of Scientific Counselors (BOSC) Air and Energy (A–E) Subcommittee to review science for air quality decisions and next generation methods—wildfire focus.

DATES:

1. The initial meeting will be held over three days via videoconference:

a. Wednesday, February 17, 2021, from 12 p.m. to 5 p.m. (EDT);

b. Thursday, February 18, 2021, from 12 p.m. to 5 p.m. (EDT); and

c. Friday, February 19, 2021, from 12 p.m. to 5 p.m. (EDT).

Attendees must register by February 16, 2021.

2. A BOSC deliberation will be held on March 18, 2021 from 2 p.m. to 5 p.m. (EDT). Attendees must register by March 17, 2021.

3. A final summary teleconference will be held on April 2, 2021 from 2 p.m. to 5 p.m. (EDT). Attendees must register by April 1, 2021.

Meeting times are subject to change. This series of meetings are open to the public. Comments must be received by February 16, 2021, to be considered by the subcommittee. Requests for the draft agenda or making a presentation at the meeting will be accepted until February 16, 2021.

ADDRESSES: Instructions on how to connect to the videoconference will be provided upon registration at *https://www.eventbrite.com/e/us-epa-bosc-air-and-energy-subcommittee-meeting-tickets-121242446421.*

Submit your comments to Docket ID No. EPA–HQ–ORD–2015–0365 by one of the following methods:

• *www.regulations.gov:* Follow the online instructions for submitting comments.

Note: Comments submitted to the *www.regulations.gov* website are anonymous unless identifying information is included in the body of the comment.

• *Email:* Send comments by electronic mail (email) to: *ORD.Docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2015–0365.

Note: Comments submitted via email are not anonymous. The sender's email will be included in the body of the comment and placed in the public docket which is made available on the internet.

Instructions: All comments received, including any personal information provided, will be included in the public docket without change and may be made available online at *www.regulations.gov.* Information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute will not be included in the public docket, and should not be submitted through *www.regulations.gov* or email. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/dockets/.*

Public Docket: Publicly available docket materials may be accessed *Online* at *www.regulations.gov.*

Copyrighted materials in the docket are only available via hard copy. The telephone number for the ORD Docket Center is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT:

The Designated Federal Officer (DFO), Tom Tracy, via phone/voicemail at: (202) 564–6518; or via email at: *tracy.tom@epa.gov.*

Any member of the public interested in receiving a draft agenda, attending the meeting, or making a presentation at the meeting should contact Tom Tracy no later than February 16, 2021.

SUPPLEMENTARY INFORMATION: The Board of Scientific Counselors (BOSC) is a federal advisory committee that provides advice and recommendations to EPA's Office of Research and Development on technical and management issues of its research programs. The meeting agenda and materials will be posted to *https://www.epa.gov/bosc.*

Proposed agenda items for the meeting include, but are not limited to, the following: Science for air quality decisions and next generation methods—wildfire focus.

Information on Services Available: For information on translation services, access, or services for individuals with disabilities, please contact Tom Tracy at (202) 564–6518 or *tracy.tom@epa.gov.* To request accommodation of a disability, please contact Tom Tracy at least ten days prior to the meeting to give the EPA adequate time to process your request.

(Authority: Pub. L. 92–463, 1, Oct. 6, 1972, 86 Stat. 770)

Mary Ross,

Director, Office of Science Advisor, Policy and Engagement.

[FR Doc. 2021–01207 Filed 1–19–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0635; FRL–10018–94–ORD]

Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability and Health and Environmental Risk Assessment Subcommittee Meeting—February 2021

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of a series of virtual meetings of the Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability and Health and Environmental Risk Assessment (CSS–HERA) Subcommittee to review the recent progress and activities for High-Throughput Toxicology (HTT), Rapid Exposure Modeling and Dosimetry (REMD), Virtual Tissue Modeling (VTM) and Adverse Outcome Pathway (AOP) progress on the CSS StRAP. Due to unforeseen circumstances, EPA is announcing this meeting with less than 15 calendar days' notice.

DATES:

1. The initial meeting will be held over four days via videoconference:

a. Tuesday, February 2, 2021 from 12 p.m. to 5 p.m. (EDT);

b. Wednesday, February 3, 2021, from 12 p.m. to 5 p.m. (EDT);

c. Thursday, February 4, 2021, from 12 p.m. to 5 p.m. (EDT); and

d. Friday, February 5, 2021, from 12 p.m. to 5 p.m. (EDT).

Attendees must register by February 1, 2021.

2. A BOSC deliberation will be held on February 25, 2021 from 11 a.m. to 2 p.m. (EDT). Attendees must register by February 24, 2021.

3. A final summary teleconference will be held on March 11, 2021 from 2 p.m. to 5 p.m. (EDT). Attendees must register by March 10, 2021.

Meeting times are subject to change. This series of meetings are open to the public. Comments must be received by February 1, 2021 to be considered by the subcommittee. Requests for the draft agenda or making a presentation at the meeting will be accepted until February 1, 2021.

ADDRESSES: Instructions on how to connect to the videoconference will be provided upon registration at *https://www.eventbrite.com/e/us-epa-bosc-css-and-hera-subcommittee-meeting-tickets-121084839013.*

Submit your comments to Docket ID No. EPA–HQ–ORD–2015–0635 by one of the following methods:

• *www.regulations.gov:* Follow the online instructions for submitting comments.

Note: Comments submitted to the *www.regulations.gov* website are anonymous unless identifying information is included in the body of the comment.

• *Email:* Send comments by electronic mail (email) to: *ORD.Docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2015–0635.

Note: Comments submitted via email are not anonymous. The sender's email will be included in the body of the comment and placed in the public docket which is made available on the internet.

Instructions: All comments received, including any personal information provided, will be included in the public docket without change and may be made available online at *www.regulations.gov.* Information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute will not be included in the public docket, and should not be submitted through *www.regulations.gov* or email. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/dockets/.*

Public Docket: Publicly available docket materials may be accessed *Online* at *www.regulations.gov.*

Copyrighted materials in the docket are only available via hard copy. The telephone number for the ORD Docket Center is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer (DFO), Tom Tracy, via phone/voicemail at: (202) 564–6518; or via email at: *tracy.tom@epa.gov.*

Any member of the public interested in receiving a draft agenda, attending the meeting, or making a presentation at the meeting should contact Tom Tracy no later than February 1, 2021.

SUPPLEMENTARY INFORMATION: The Board of Scientific Counselors (BOSC) is a federal advisory committee that provides advice and recommendations to EPA's Office of Research and Development on technical and management issues of its research programs. Meeting agendas and materials will be posted to *https://www.epa.gov/bosc.*

Proposed agenda items for the meeting include, but are not limited to, the following: Recent progress and activities for HTT, REMD, VTM and AOP progress on the CSS StRAP.

Information on Services Available: For information on translation services, access, or services for individuals with disabilities, please contact Tom Tracy at (202) 564–6518 or *tracy.tom@epa.gov.* To request accommodation of a disability, please contact Tom Tracy at least ten days prior to the meeting to give the EPA adequate time to process your request.

Authority: Pub. L. 92–463, 1, Oct. 6, 1972, 86 Stat. 770)

Mary Ross,

Director, Office of Science Advisor, Policy and Engagement.

[FR Doc. 2021–01204 Filed 1–19–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10017–40–ORD]

Human Studies Review Board; Notification of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development announces the 2021 public meetings dates of the Human Studies Review Board (HSRB) to advise the Agency on the ethical and scientific review of research involving human subjects. Due to unforeseen circumstances, EPA is announcing this meeting with less than 15 calendar days' notice.

DATES: Four three-day virtual public meetings will be held on:

1. January 26–28, 2021;
2. April 20–22, 2021;
3. July 20–22, 2021; and
4. October 19–21, 2021.

Meetings will be held each day from 1 p.m. to 5:30 p.m. Eastern Time. Separate, subsequent teleconference meetings are planned for the HSRB to finalize its Reports of the three-day meetings that proceed these dates on March 18, 2021; June 17, 2021; September 16, 2021; and December 14, 2021; all from 2 p.m. to approximately 3:30 p.m. Eastern Time.

ADDRESSES: These meetings are open to the public and will be conducted entirely virtually and by telephone. For detailed access information and meeting materials please visit the HSRB website: *https://www.epa.gov/osa/human-studies-review-board.*

FOR FURTHER INFORMATION CONTACT: Any member of the public who wishes to receive further information should contact the HSRB Designated Federal Official (DFO), Thomas O'Farrell at the following telephone number: (202) 564–8451 or by email at: *ofarrell.thomas@epa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act 5 U.S.C. App.2 section 9. The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of third-party human subjects research that are submitted to the Office of Pesticide Programs (OPP) to be used for regulatory purposes.

Meeting access: These meetings will be open to the public. The full agenda with access information and meeting materials will be available seven calendar days prior to the start of each meeting at the HSRB website: *https://www.epa.gov/osa/human-studies-review-board.*

For questions on document availability, or if you do not have access to the internet, consult with the DFO, Thomas O'Farrell, listed under **FOR FURTHER INFORMATION CONTACT**.

Special Accommodations. For information on access or services for individuals with disabilities, or to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to each meeting to give EPA as much time as possible to process your request.

How may I participate in this meeting?

The HSRB encourages the public's input. You may participate in these meetings by following the instructions in this section.

1. *Oral comments.* To pre-register to make oral comments, please contact the DFO, Thomas O'Farrell, listed under **FOR FURTHER INFORMATION CONTACT**. Requests to present oral comments during the meetings will be accepted up to Noon Eastern Time, seven calendar days prior to each meeting date. To the extent that time permits, interested persons who have not pre-registered may be permitted by the HSRB Chair to present oral comments during the meetings at the designated time on the agenda. Oral comments before the HSRB are generally limited to five minutes per individual or organization. If additional time is available, further public comments may be possible.

2. *Written comments.* For the Board to have the best opportunity to review and consider your comments as it

deliberates, you should submit your comments prior to the meetings via email by Noon Eastern Time, seven calendar days prior to each meeting date. If you submit comments after these dates, those comments will be provided to the HSRB members, but you should recognize that the HSRB members may not have adequate time to consider your comments prior to their discussion. You should submit your comments to the DFO, Thomas O'Farrell listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

Topics for discussion. The agenda and meeting materials will be available seven calendar days in advance of each meeting at *https://www.epa.gov/osa/human-studies-review-board.*

Meeting minutes and final reports. Minutes of these meetings, summarizing the topics discussed and recommendations made by the HSRB, will be released within 90 calendar days of each meeting. These minutes will be available at *https://www.epa.gov/osa/human-studies-review-board.* In addition, information regarding the HSRB's Final Reports, will be found at *https://www.epa.gov/osa/human-studies-review-board* or can be requested from Thomas O'Farrell listed under **FOR FURTHER INFORMATION CONTACT**.

Jennifer Orme-Zavaleta,

EPA Science Advisor.

[FR Doc. 2021–01205 Filed 1–19–21; 8:45 am]

BILLING CODE 6560–50–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Sunshine Act Notice: Cancellation of Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 86 FR 2415, January 12, 2021.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: January 15, 2021 at 1:00 p.m. ET.

SUMMARY: The Equal Employment Opportunity Commission is issuing this notice to cancel the audio-only conference scheduled to be held at 1:00 p.m. on January 15, 2021.

CONTACT PERSON FOR MORE INFORMATION: Rachel V. See, Acting Executive Officer, (202) 921–2545.

Dated: January 15, 2021.

Rachel V. See,

Acting Executive Officer, Executive Secretariat.

[FR Doc. 2021–01342 Filed 1–15–21; 11:15 am]

BILLING CODE 6570–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0298; FRS 17386]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before March 22, 2021. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0298.

Title: Part 61, Tariffs (Other than the Tariff Review Plan).

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 2,925 respondents; 9,585 responses.

Estimated Time per Response: 1–50 hours.

Frequency of Response: On occasion, annual, biennial, and one-time reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. Sections 151–155, 201–205, 208, 251–271, 403, 502 and 503 of the Communications Act of 1934 (Act), as amended.

Total Annual Burden: 244,477 hours.

Total Annual Cost: $1,584,000.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: Respondents are not being asked to submit confidential information to the Commission. If the Commission requests respondents to submit information which respondents believe are confidential, respondents may request confidential treatment of such information under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: On October 9, 2020, the Commission released the 8YY (toll free) Access Charge Reform Order, FCC 20–143, that transitions intercarrier compensation for toll free services either to lower, uniform rate caps or to bill-and-keep over approximately three years as a means of curtailing abuse of the 8YY intercarrier compensation regime. The Order requires price cap and rate-of-return carriers to establish separate rate elements for certain interstate and intrastate toll free and non-toll free services. Carriers are also required to lower their 8YY database query charges over three years, and are prohibited from charging for more than one query per call. Competitive LECs assessing a tariffed intrastate or interstate Toll Free Database Query Charge must cap such charges and revise their tariffs to ensure that those charges do not exceed the rates charged by the competing incumbent LEC.

The information collected through carriers' tariffs is used by the

Commission and state commissions to determine whether services offered are just and reasonable, as the Act requires. The tariffs and any supporting documentation are examined in order to determine if the services are offered in a just and reasonable manner.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–01189 Filed 1–19–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 21–51; FRS 17405]

Federal Advisory Committee Act; Disability Advisory Committee; Announcement of First Meeting

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The Federal Communications Commission (Commission) hereby announces that the charter of the Disability Advisory Committee (hereinafter Committee) has been renewed pursuant to the Federal Advisory Committee Act (FACA) and following consultation with the Committee Management Secretariat, General Services Administration. The Commission also announces and provides an agenda for the first meeting of the fourth term of the Committee.

DATES: The Committee's first meeting will take place on Thursday, February 18, 2021. The meeting will come to order at 1:30 p.m. Eastern Time.

ADDRESSES: The Committee meeting will be held remotely, with video and audio coverage at *www.fcc.gov/live.*

FOR FURTHER INFORMATION CONTACT: Debra Patkin, Designated Federal Officer (DFO), Federal Communications Commission, Consumer and Governmental Affairs Bureau, (202) 870–5226, or email: *DAC@fcc.gov*; or Will Schell, Deputy DFO, at (202) 418–0767.

SUPPLEMENTARY INFORMATION: *Committee Renewal:* After consultation with the General Services Administration, the Commission renewed the charter on December 17, 2020 providing the Committee with authorization to operate for two years.

The mission of the Committee is to make recommendations to the Commission on the full range of disability access topics specified by the Commission and to facilitate the participation of consumers with disabilities in proceedings before the Commission. In addition, this Committee is intended to provide an effective means for stakeholders with interests in this area, including consumers with disabilities, to exchange ideas, which will in turn enhance the Commission's ability to effectively address disability access issues relevant to matters under its purview.

The Committee is organized under, and operates in accordance with, the provisions of the FACA (5 U.S.C. App. 2). The Committee will be solely advisory in nature. Consistent with FACA and its requirements, each meeting of the Committee will be open to the public unless otherwise noticed. A notice of each meeting will be published in the **Federal Register** at least fifteen (15) days in advance of the meeting. Records will be maintained of each meeting and made available for public inspection. All activities of the Committee will be conducted in an open, transparent, and accessible manner. The Committee shall terminate two years from the date that this renewal is effective (on or before December 17, 2022), or earlier upon the completion of its work as determined by the Chairman, unless its charter is renewed prior to the termination date.

During the Committee's fourth term, it is anticipated that the Committee will meet, either in-person in Washington, DC or, if appropriate, by teleconference, for at least three (3) one-day meetings.

In addition, as needed, working groups or subcommittees (ad hoc or steering) will be established to facilitate the Committee's work between meetings of the full Committee. All meetings, including those of working groups and subcommittees, will be fully accessible to individuals with disabilities.

First Meeting: The February 18, 2021 meeting is open to members of the general public. The meeting will be webcast with American Sign Language interpreters and open captioning at: *www.fcc.gov/*live. In addition, a reserved amount of time will be available on the agenda for comments and inquiries from the public. Members of the public may comment or ask questions of presenters via the email address *livequestions@fcc.gov.*

Requests for other reasonable accommodations or for materials in accessible formats for people with disabilities should be submitted via email to: *fcc504@fcc.gov* or by calling the Consumer and Governmental Affairs Bureau at (202) 418–0530. Such requests should include a detailed description of the accommodation needed and a way for the FCC to contact the requester if more information is needed to fill the request. Requests should be made as early as possible; last minute requests will be accepted but may not be possible to accommodate.

Proposed Agenda: At this meeting, the Committee is expected to discuss the roles and responsibilities of the Committee and its members; issues that the Committee will address; meeting schedules; and any other topics relevant to the Committee's work. The Committee may also receive briefings from Commission staff on issues of interest to the Committee and may discuss topics of interest to the committee, including, but not limited to, matters concerning communications transitions, telecommunications relay services, emergency access, and video programming accessibility.

Federal Communications Commission.

Suzanne Singleton,

Chief, Disability Rights Office, Consumer and Governmental Affairs Bureau.

[FR Doc. 2021–01244 Filed 1–19–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1198; FRS 17385]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before March 22, 2021. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1198.

Title: Section 90.525, Administration of Interoperability Channels; Section 90.529, State Licenses; and Section 90.531, Band Plan.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: State, local or tribal government, and Not-for-profit institutions.

Number of Respondents and Responses: 2,230 respondents; 2,230 responses.

Estimated Time per Response: 1 hour–2 hours.

Frequency of Response: On occasion reporting and one-time reporting requirements; third party disclosure.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in sections 4(i), 11, 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7), unless otherwise noted.

Total Annual Burden: 2,230 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: Section 90.525 of the Commission's rules requires approval of license applications for Interoperability channels in the 769–775 MHz and 799–805 MHz frequency bands by state-level agency or organization responsible for administering emergency communications. *Section 90.529* of the Commission's rules provides that each state license will be granted subject to the condition that the state certifies on or before each applicable benchmark date that it is providing or prepared to provide ''substantial service.'' *Section 90.531* of the Commission's rules sets forth the band plan for the 769 –775 MHz and 799–805 MHz public safety bands. This section covers channel designations for base and mobile use, narrowband segments, combined channels, channel pairing, internal guard band, and broadband. Narrowband general use channels, including the former narrowband reserve channels, and low power channels require regional planning committee concurrence and narrowband air-ground channels require state or regional planning committee concurrence.

Commission staff will use the information to assign licenses for interoperability and General Use channels, as well as renewal of State licenses. The information will also be used to determine whether prospective licensees operate in compliance with the Commission's rules. Without such information, the Commission could not accommodate State interoperability or regional planning requirements or provide for the efficient use of State frequencies. This information collection includes rules to govern the operation and licensing of 700 MHz band systems to ensure that licensees continue to fulfill their statutory responsibilities in accordance with the Communications Act of 1934, as amended. Such information will continue to be used to verify that applicants are legally and technically qualified to hold licenses, and to determine compliance with Commission rules.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–01188 Filed 1–19–21; 8:45 am]

BILLING CODE P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

TIME AND DATE: 10:00 a.m. on Tuesday, January 19, 2021.

PLACE: The meeting is open to the public. Out of an abundance of caution related to current and potential coronavirus developments, the public's means to observe this Board meeting will be via a webcast live on the internet and subsequently made available on-demand approximately one week after the event. Visit *http://fdic.windrosemedia.com* to view the live event. Visit *http://fdic.windrosemedia.com/index.php?category=FDIC+Board+Meetings* after the meeting. If you need any technical assistance, please visit our Video Help page at: *https://www.fdic.gov/video.html.*

Observers requiring auxiliary aids (*e.g.,* sign language interpretation) for this meeting should call 703–562–2404 (Voice) or 703–649–4354 (Video Phone) to make necessary arrangements.

STATUS: Open.

MATTERS TO BE CONSIDERED: Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session to consider the following matters:

Summary Agenda

No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of Minutes of a Board of Directors' Meeting Previously Distributed.

Memorandum and resolution re: Final Rule on Role of Supervisory Guidance.

Memorandum and resolution re: Notice of Proposed Rule on Rescission and Removal of Transferred OTS Regulations, Definitions for Regulations Affecting All State Savings Associations (Part 390 Subpart Q).

Memorandum and resolution re: Notice of Proposed Rulemaking on Removal of Transferred OTS Regulations Regarding Securities Offerings of State Savings Associations, Rescission of Statement of Policy on the Use of Offering Circulars, Proposed Rulemaking Regarding Securities Offerings by State Nonmember Banks and State Savings Associations, and Other, Technical Amendments.

Report of actions taken pursuant to authority delegated by the Board of Directors.

Discussion Agenda

Memorandum and resolution re: Revisions to the FDIC's Guidelines for Appeals of Material Supervisory Determinations.

CONTACT PERSON FOR MORE INFORMATION: Requests for further information concerning the meeting may be directed to Ms. Debra A. Decker, Deputy Executive Secretary of the Corporation, at 202–898–8748.

Dated at Washington, DC, on January 15, 2021.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2021–01369 Filed 1–15–21; 4:15 pm]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue, NW, Washington DC 20551–0001, not later than February 22, 2021.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *PSB Holdings, Inc., Wausau, Wisconsin;* to merge with Waukesha Bankshares, Inc., and thereby indirectly acquire Sunset Bank & Savings, both of Waukesha, Wisconsin.

Board of Governors of the Federal Reserve System, January 14, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–01199 Filed 1–19–21; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to implement the Treasury Securities and Agency Debt and Mortgage-Backed Securities Reporting Requirements (FR 2956; OMB No. 7100–NEW).

DATES: Comments must be submitted on or before March 22, 2021.

ADDRESSES: You may submit comments, identified by FR 2956, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be available at *https://www.reginfo.gov/public/do/PRAMain,* if approved. These documents will also be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations

received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Implement the Following Information Collection

Report title: Treasury Securities and Agency Debt and Mortgage-Backed Securities Reporting Requirements.

Agency form number: FR 2956.

OMB control number: 7100–NEW.

Frequency: Daily.

Respondents: Depository institutions that meet the reporting thresholds and daily transact in trading of marketable U.S. Treasury securities and the trading of the debt and mortgage-backed securities issued by agencies.

Estimated number of respondents: Treasury securities, 10; Agency debt and mortgage-backed securities, 12.

Estimated average hours per response: 3.

Estimated annual burden hours: 16,500.

General description of report: The proposed FR 2956 would collect detailed data on depository institutions' daily transactions of marketable U.S. Treasury securities and of the debt and mortgage-backed securities (MBS) issued by U.S. federal government agencies including government-sponsored enterprises (agencies). The report would have two parts: Part 1 would collect data on transactions in U.S. Treasury debt, and Part 2 would collect transactions in debt and MBS issued by agencies. Depository institutions subject to reporting under Parts 1 and 2 of the FR 2956 collection would be required to report all the transaction details, information, and fields as described in the applicable Trade Reporting and Compliance Engine (TRACE) technical documentation, FAQs, and guides located at *https://www.finra.org/filing-reporting/trace/documentation.* This information would include, but is not limited to, the Committee on Uniform Securities Identification Procedures (CUSIP) number or similar identifier, the transaction size (volume), price of the transaction, date of trade execution, time of execution, and date of settlement. The Board is proposing to implement the FR 2956 in 2021.

Every national bank, state member bank, state non-member bank, savings association, or U.S. branch and agency of a foreign bank filing a Notice of Government Securities Broker or Government Dealer Activities Form (From G–FIN; OMB No. 7100–0224) with average daily transaction volumes of over $100 million, for U.S. Treasury debt, or over $50 million, for agency-issued debt and MBS, during the prior fiscal year would be subject to the proposed reporting requirements. Depository institutions subject to the reporting requirements of the proposed FR 2956 would electronically report transactions through the Board's data collection vendor, the Financial Industry Regulatory Authority (FINRA), utilizing its Trade Reporting and Compliance Engine (TRACE).

Legal authorization and confidentiality: The FR 2956 is authorized by sections 2A and 11 of the Federal Reserve Act (''FRA''). Section 2A of the FRA requires that the Board and the FOMC maintain long-run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates. Section 11 of the FRA authorizes the Board to require reports from depository institutions as it may deem necessary and authorizes the Board to prescribe reports of liabilities and assets from insured depository institutions to enable the Board to discharge its responsibility to monitor and control monetary and credit aggregates. The obligation to respond to the FR 2956 would be mandatory. The information collected through the FR 2956 would not be considered confidential.

Consultation outside the agency: As part of an interagency workgroup, the Board has consulted with the U.S. Treasury Department, the U.S. Securities and Exchange Commission, the Commodity and Futures Trading Commission, and FINRA on this collection.

Board of Governors of the Federal Reserve System, January 14, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–01217 Filed 1–19–21; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

Revised Jurisdictional Thresholds for Section 8 of the Clayton Act

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The Federal Trade Commission announces the revised thresholds for interlocking directorates required by the 1990 amendment of Section 8 of the Clayton Act. Section 8 prohibits, with certain exceptions, one person from serving as a director or officer of two competing corporations if two thresholds are met. Competitor corporations are covered by Section 8 if each one has capital, surplus, and undivided profits aggregating more than $10,000,000, with the exception that no corporation is covered if the competitive sales of either corporation are less than $1,000,000. Section 8(a)(5) requires the Federal Trade Commission to revise those thresholds annually, based on the change in gross national product. The new thresholds, which take effect immediately, are $37,382,000 for Section 8(a)(1), and $3,738,200 for Section 8(a)(2)(A).

DATES: January 21, 2021.

FOR FURTHER INFORMATION CONTACT: Chris Grengs (202–326–2612), Bureau of Competition, Office of Policy and Coordination.

Authority: 15 U.S.C. 19(a)(5)

April J. Tabor,

Acting Secretary.

[FR Doc. 2021–01172 Filed 1–19–21; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission (FTC).

ACTION: Notice and request for comment.

SUMMARY: The FTC requests that the Office of Management and Budget (OMB) extend for three years the current Paperwork Reduction Act (PRA) clearance for information collection requirements contained in the Trade Regulation Rule entitled Power Output Claims for Amplifiers Utilized in Home Entertainment Products (Amplifier Rule or Rule). That clearance expires on January 31, 2021.

DATES: Comments must be received by February 22, 2021.

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. The *reginfo.gov* web link is a United States Government website produced by OMB and the General Services Administration (GSA). Under PRA requirements, OMB's Office of Information and Regulatory Affairs (OIRA) reviews Federal information collections.

FOR FURTHER INFORMATION CONTACT: Jock K. Chung, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Mail Code CC–9528, 600 Pennsylvania Ave. NW, Washington, DC 20580, (202) 326–2984.

SUPPLEMENTARY INFORMATION:

Title: Amplifier Rule, 16 CFR part 432.

OMB Control Number: 3084–0105.

Type of Review: Extension of a currently approved collection.

Estimated Annual Hours of Burden: 450 hours (300 testing-related hours; 150 disclosure-related hours).

Likely Respondents and Estimated Burden:

(a) Testing—High fidelity manufacturers—300 new products/year × 1 hour each = 300 hours; and

(b) Disclosures—High fidelity manufacturers—[(300 new products/year × 1 specification sheet) + (300 new products/year × 1 brochure)] × 15 minutes per specification sheet or brochure = 150 hours.

Frequency of Response: Periodic.

Estimated Annual Labor Cost: $26,130 per year ($15,897 for testing + $10,233 for disclosures).

Abstract: The Amplifier Rule assists consumers by standardizing the measurement and disclosure of power output and other performance characteristics of amplifiers in stereos and other home entertainment equipment. The Rule also specifies the test conditions necessary to make the disclosures that the Rule requires.

Request for Comment

On November 2, 2020, the FTC sought public comment on the information collection requirements associated with the Rule. 85 FR 69331. The Commission received no germane comments. Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone'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 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.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2021–01156 Filed 1–19–21; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Requirement for Negative Pre-Departure COVID–19 Test Result or Documentation of Recovery From COVID–19 for All Airline or Other Aircraft Passengers Arriving Into the United States From Any Foreign Country

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of agency order.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces an Agency Order requiring negative pre-departure COVID–19 test results or documentation of recovery from COVID–19 for all airline or other aircraft passengers arriving into the United States from any foreign country. This Order is issued to preserve human life; prevent the further introduction, transmission, and spread of the virus that causes COVID–19 into the United States, including new virus variants; preserve the health and safety of airline crew members, passengers, airport personnel, and communities; and preserve hospital, Healthcare, and emergency response resources within the United States.

DATES: This Order is effective January 26, 2021.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329. Email: *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION: This Notice and Order prohibit the introduction into the United States of any aircraft passenger departing from any foreign country unless the passenger: (1) Has a negative pre-departure test result for SARS–CoV–2, the virus that causes COVID–19 (Qualifying Test); or (2) written or electronic documentation of recovery from COVID–19 after previous SARS–CoV–2 infection in the form of a positive viral test result and a letter from a licensed health care provider or public health official stating that the passenger has been cleared for travel (Documentation of Recovery). The negative pre-departure test must be a viral test that was conducted on a specimen collected during the 3 calendar days preceding the flight's departure from a foreign country (Qualifying Test). Alternatively, if the passenger has recovered from COVID–19, the passenger may instead travel with written or electronic documentation of a positive viral test result that confirms previous SARS–CoV–2 infection and a letter from a licensed health care provider or public health official stating that the passenger has been cleared for travel (Documentation of Recovery). A passenger must retain written or electronic documentation reflecting the negative Qualifying Test result or Documentation of Recovery presented to the airline or other aircraft operator. A passenger must also produce such Qualifying Test result or Documentation of Recovery upon request to any U.S. government official or a cooperating state or local public health authority.

This Notice and Order constitute a controlled free pratique to any airline or other aircraft operator with an aircraft arriving into the United States. Pursuant to this controlled free pratique, the airline or other aircraft operator must comply with the following conditions to receive permission for the aircraft to enter and disembark passengers in the United States:

- Airline or other aircraft operator must verify that every passenger—2 years of age or older—onboard the aircraft has attested to receiving a negative Qualifying Test result or to having recovered from COVID–19 after previous SARS–CoV–2 infection and being cleared to travel by a licensed health care provider or public health official.
- Airline or other aircraft operator must confirm that every passenger

onboard the aircraft has documentation of a negative Qualifying Test result or Documentation of Recovery from COVID–19.

This Order establishes requirements for (1) airlines arriving into the United States from any foreign country and (2) passengers departing any foreign country with a final destination in the United States.

A copy of the Order and Attachment A are provided below and a copy of the signed order can be found at *https://www.cdc.gov/quarantine/fr-proof-negative-test.html.*

Centers for Disease Control and Prevention Department of Health and Human Services

Order Under Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 Code of Federal Regulations 71.20 & 71.31(b)

Requirement for Negative Pre-Departure Covid–19 Test Result or Documentation of Recovery From Covid–19 for All Airline or Other Aircraft Passengers Arriving Into the United States From Any Foreign Country [1]

Summary

Pursuant to 42 CFR 71.20 and as set forth in greater detail below, this Notice and Order prohibit the introduction into the United States of any aircraft passenger departing from any foreign country unless the passenger: (1) Has a negative pre-departure test result for SARS–CoV–2, the virus that causes COVID–19 (Qualifying Test); or (2) written or electronic documentation of recovery from COVID–19 after previous SARS–CoV–2 infection in the form of a positive viral test result and a letter from a licensed health care provider or public health official stating that the passenger has been cleared for travel (Documentation of Recovery).

The negative pre-departure test must be a viral test that was conducted on a specimen collected during the 3 calendar days preceding the flight's departure from a foreign country (Qualifying Test). Alternatively, if the passenger has recovered from COVID–19, the passenger may instead travel with written or electronic documentation of a positive viral test result that confirms previous SARS–CoV–2 infection and a letter from a licensed health care provider or public health official stating that the passenger has been cleared for travel (Documentation of Recovery). A passenger must retain written or electronic documentation reflecting the negative Qualifying Test result or Documentation of Recovery presented to the airline or other aircraft operator. A passenger must also produce such Qualifying Test result or Documentation of Recovery upon request to any U.S. government official or a cooperating state or local public health authority.

Pursuant to 42 CFR 71.31(b) and as set forth in greater detail below, this Notice and Order constitute a controlled free pratique to any airline or other aircraft operator with an aircraft arriving into the United States. Pursuant to this controlled free pratique, the airline or other aircraft operator must comply with the following conditions to receive permission for the aircraft to enter and disembark passengers in the United States:

- Airline or other aircraft operator must verify that every passenger—2 years of age or older—onboard the aircraft has attested to receiving a negative Qualifying Test result or to having recovered from COVID–19 after previous SARS–CoV–2 infection and being cleared to travel by a licensed health care provider or public health official.
- Airline or other aircraft operator must confirm that every passenger onboard the aircraft has documentation of a negative Qualifying Test result or Documentation of Recovery from COVID–19.

Statement of Intent

This Order shall be interpreted and implemented to achieve the following paramount objectives:

- Preservation of human life;
- Preventing the further introduction, transmission, and spread of the virus that causes COVID–19 into the United States, including new virus variants;
- Preserving the health and safety of crew members, passengers, airport personnel, and communities; and
- Preserving hospital, healthcare, and emergency response resources within the United States.

Definitions

Aircraft shall have the same definition as under 42 U.S.C. 40102(a)(6). ''Aircraft'' includes, but is not limited to, commercial, general aviation, and private aircraft destined for the United States from a foreign country.

Aircraft Operator means an individual or organization causing or authorizing the operation of an aircraft.

Airline shall have the same definition as under 42 CFR 71.1(b).

Attest/Attestation means having completed the attestation in Attachment A. Such attestation may be completed in written or electronic form. The attestation is a statement, writing, entry, or other representation under 18 U.S.C. 1001.[2]

Confirm that every passenger onboard the aircraft has documentation reflecting a negative Qualifying Test result means confirmation that:

(1) The personal identifiers (*e.g.,* name and date of birth) on the negative Qualifying Test result match the personal identifiers on the passenger's passport or other travel documents;

(2) if the passenger is arriving on a direct flight to the United States, the specimen was collected within the 3 calendar days preceding the flight's departure;

(3) if the passenger is arriving via one or more connecting flights, the specimen was collected within the 3 calendar days preceding the departure of the initial flight but only if

a. The connecting flights were booked as a single passenger record with a destination in the United States,

b. each connection is no longer than 24 hours, and

c. the airline or aircraft operator has instructed the passenger to comply—and uses reasonable efforts to facilitate compliance—with the safety protocols set forth in Runway to Recovery 1.1, December 21, 2020, available at *https://www.transportation.gov/briefing-room/runway-recovery-11,* during such connection(s);

(4) the test performed was a viral test (as defined below); and

(5) the test result states ''NEGATIVE,'' ''SARS–CoV–2 RNA NOT DETECTED,'' ''SARS–CoV–2 ANTIGEN NOT DETECTED,'' or ''COVID–19 NOT DETECTED.'' A test marked ''invalid'' is not acceptable.

Confirm that a passenger alternatively has written or electronic documentation of recovery from COVID–19 means confirmation that:

(1) The passenger has presented documentation of a positive test result and a signed letter on official letterhead that contains the name, address, and

[1] This Order supersedes the previous order signed by the U.S. Centers for Disease Control and Prevention (CDC) Director on December 25, 2020, requiring a negative pre-departure COVID–19 test result for all airline passengers arriving into the United States from the United Kingdom.

[2] CDC encourages airline or aircraft operator to incorporate the attestation into paperless check-in processes. Airline or aircraft operator may use a third party (including a third-party application) to collect attestations, including to provide translations. But airline or aircraft operator has sole legal responsibility to provide and collect attestations, to ensure the accuracy of any translation, and to comply with all other obligations under this Order. Airline or aircraft operator is responsible for any failure of a third party to comply with this Order. Airline or aircraft operator may not shift any legal responsibility to a third party.

phone number of a licensed healthcare provider or public health official stating that the passenger has been cleared for travel; [3]

(2) the positive test result occurred within the last three months (90 days) preceding the passenger's flight to the United States, or at such other intervals as specified in CDC guidance;

(3) the personal identifiers (*e.g.,* name and date of birth) on the positive test result and signed letter match the personal identifiers on the passenger's passport or other travel documents;

(4) the test performed was a viral test (as defined below); and

(5) the test result states ''POSITIVE,'' ''SARS–CoV–2 RNA DETECTED,'' ''SARS–CoV–2 ANTIGEN DETECTED,'' or ''COVID–19 DETECTED.'' A test marked ''invalid'' is not acceptable.

Foreign country means anywhere that is not a state, territory, or possession of the United States.

Negative Pre-departure Test Result for COVID–19 or negative Qualifying Test result means documentation of a negative COVID–19 test taken within the 3 calendar days preceding a flight's departure. Such documentation may be in paper or electronic format as required by this Order. Testing must be performed using a viral test. The documentation must also include sufficient verification information—such as the name and contact information for the laboratory or healthcare personnel who performed the test.

Viral test means a viral detection test for current infection (*i.e.,* a nucleic acid amplification test or a viral antigen test) approved or authorized by the relevant national authority for the detection of SARS–CoV–2.

United States has the same meaning as ''State'' and ''U.S. Territory'' in 42 CFR 71.1(b).

Exemptions

The following categories of individuals and organizations are exempt from the requirements of this Order:

- Crew members of airlines or other aircraft operators provided that they follow industry standard protocols for the prevention of COVID–19 as set forth in relevant Safety Alerts for Operators (SAFOs) issued by the Federal Aviation Administration (FAA).[4]
- Airlines or other aircraft operators transporting passengers with COVID–19 pursuant to CDC authorization and in accordance with CDC guidance.
- Federal law enforcement personnel while on official duty and carrying out a law enforcement function and members of the U.S. military (including aircraft operators), when traveling under competent orders—provided that the authority ordering the travel requires precautions to prevent the possible transmission of infection to others during the travel period in accordance with CDC guidance.
- Airlines or other aircraft operators granted specific waivers from the application of this Order based on CDC's determination that a foreign country lacks available SARS–CoV–2 testing capacity. Such waivers may be granted based on a specific request made by an airline or aircraft operator to the CDC and will be limited to 14 days unless renewed by CDC.[5]

Background

The COVID–19 pandemic has spread throughout the world. Individuals who travel may be at risk for exposure to SARS–CoV–2 before, during, and after travel. This could result in U.S.-bound travelers further spreading the virus to others during travel, upon arrival in the United States, and at their destinations.

Over the last few weeks, the United Kingdom (UK) has faced a rapid increase in COVID–19 cases in South East England, leading to enhanced epidemiological and virological investigations. On December 14, 2020, Public Health England announced that a new variant of SARS–CoV–2 had been identified across the southeast of England.[6] Preliminary analysis in the UK suggests that this SARS–CoV–2 variant may be more transmissible than previously circulating variants, with an estimated potential to increase the reproductive number (R_0) by 0.4–0.7 or greater with an estimated increased transmissibility of up to 70 percent.[7]

On December 19, 2020, in response to the emergence of the UK variant, the countries comprising the UK announced stricter measures to be applied from December 20 and over the coming weeks, with affected areas entering a 'Tier 4' level with movement restrictions within and between more and less heavily affected areas. These measures have included recommendations for residents of the most affected areas to restrict movements and travel, including international travel, outside of these areas. The government of Scotland announced a travel ban between Scotland and the rest of the UK. In addition, the Netherlands issued a travel ban from the UK effective through January 1, 2021, and Belgium temporarily halted flight and train travel from the UK. Other countries took similar measures to restrict travel from the UK.

A second new variant of SARS–CoV–2 was reported in the Republic of South Africa (RSA) on December 18, 2020, that also appears to spread more rapidly than earlier variants of the virus. The RSA variant is distinct from the UK variant but shares a mutation in the spike protein that appears to increase transmissibility. Since being identified, the new variant has spread inland from coastal regions of RSA and has become the predominant variant in some areas of the country.

During December 21–26, 2020, several countries implemented restrictions on travel from South Africa, including China, El Salvador, Germany, Guatemala, Israel, Panama, Sudan, Switzerland, Turkey, and the UK. The Netherlands imposed a ban on travel from RSA on December 21 but lifted the ban for both the UK and RSA on December 23, stating that travelers will instead need to present a negative COVID–19 test result obtained within 72 hours of their scheduled arrival in the Netherlands, followed by 10 days of self-quarantine. On December 28, Japan imposed a ban on entry of all foreign nationals through the end of January 2021. On December 28, the Government of South Africa announced new restrictions on businesses and public movement. As of January 7, 2021, Canada requires air passengers 5 years of age or older to test negative for COVID–19 before arrival. On January 8, the United Kingdom announced a pre-departure testing requirement for all inbound international travelers with limited exceptions; a 10-day post-arrival quarantine will still be required.

On December 25, 2020, CDC issued an Order requiring proof of a negative Qualifying Test result for all airline passengers arriving from the UK to the United States. Since then, cases of the UK and RSA variants have been discovered in four Canadian provinces, including in individuals with no travel history indicating spread in Canada.

[3] Health care providers and public health officials should follow CDC guidance in clearing patients for travel to the United States. Applicable guidance is available at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html.*

[4] *https://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/safo/all_safos/media/2020/SAFO20009.pdf.* Airlines, aircraft operators, and their crew members may follow even stricter protocols for safety, including testing protocols.

[5] Based on the rapidly evolving status of laboratory testing capacity in foreign countries, CDC has determined that 14 days, subject to renewal, is an appropriate length of time to allow for a waiver.

[6] *https://www.gov.uk/government/news/phe-investigating-a-novel-variant-of-covid-19.*

[7] *https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom.*

The UK variant has also been found in at least 50 countries and the RSA variant has also been detected in at least 15 countries. The first case of the UK variant in the United States was found in Colorado on December 29, in an individual with no known travel history. On December 30, a second case was reported in California. Since then, the UK variant strain has accounted for 72 cases in 10 U.S. states. Another new variant strain of concern initially detected in South America in March 2020 has been detected in at least 19 countries on 5 continents through late December and has mutations in the spike protein that raise concerns of increased infectivity.

While it is known and expected that viruses constantly change through mutation leading to the emergence of new variants, these new variants have emerged at a time when numbers of new cases in the United States have continued to increase at alarming rates. Additional new virus variants are also likely to emerge as the virus continues to evolve and mutate. Accordingly, further action is needed to help mitigate the spread of these and other new virus variants into the United States.

Based on increased transmissibility and spread of these new variants of SARS–CoV–2, and to reduce introduction and spread of these and future SARS–CoV–2 variants into the United States, expanding current UK pre-departure testing requirements to all foreign countries and U.S.-bound passengers is warranted. This approach to testing-based risk assessment has been addressed in CDC guidance and the Runway to Recovery guidance jointly issued by the Departments of Transportation, Homeland Security, and Health and Human Services.[8] Testing for SARS–CoV–2 infection is a proactive approach and not dependent on the infecting strain. Approximately 120 countries now use testing in some form to monitor risk and control introduction and spread. With case counts and deaths due to COVID–19 continuing to increase around the globe and the high proportion of infected people with asymptomatic or pre-symptomatic infections, the United States must take a dual approach to combatting the virus. This means concurrently mitigating and slowing the introduction and spread of SARS–CoV–2 and controlling transmission within U.S. communities that are currently being overwhelmed by a surge in infections, hospitalizations, and deaths.

Pre-departure testing may detect travelers infected with SARS–CoV–2 before they initiate their travel. CDC recommends viral testing and receipt of results 1–3 days[9] before departure for international travelers, particularly those traveling long distances or passing through transportation hubs such as airports where social distancing may be challenging. CDC modeling indicates that pre-departure testing is most effective when combined with self-monitoring.[10] Testing before departure results in the greatest reduction of transmission risk during travel when the specimen is collected close to the time of departure. Earlier testing (*i.e.,* more than 3 days before travel) provides little benefit beyond what self-monitoring alone can provide.

For persons previously diagnosed with COVID–19 who remain asymptomatic after recovery, CDC does not recommended retesting within 3 months after the date of symptom onset (or the date of first positive viral diagnostic test if their infection was asymptomatic) for the initial SARS–CoV–2 infection.[11] Persons who develop any symptoms of COVID–19 during this time period should not travel and seek care for testing and evaluation. This guidance may be updated as additional information about people who have recovered from COVID–19 becomes available.

Pre-departure testing does not eliminate all risk. However, when pre-departure testing is combined with other measures such as self-monitoring for symptoms of COVID–19, wearing masks, social distancing, and hand hygiene, it can make travel safer by reducing spread on conveyances, in transportation hubs, and at destinations. For international air travelers and others with higher risk of exposure, CDC additionally recommends a post-arrival test 3–5 days after arrival at destination, combined with self-monitoring and a 7-day period of staying home (or in a comparable location such as a hotel room) to further reduce the risk of translocating the virus into destination communities.[12]

As cases of COVID–19 continue to rise across the globe and travel volume increases, routine pre-departure testing of all U.S.-bound aircraft passengers is needed not only to reduce introduction of the two known SARS–CoV–2 variants from UK and RSA, but also future variants that might be more transmissible and cause more severe illness.

Action

For these reasons, I hereby determine that passengers covered by this Order are at risk of transmitting the new SARS–CoV–2 virus variants or other potential variants and that requiring such passengers to demonstrate either negative COVID–19 test results or recovery from COVID–19 after previous SARS–CoV–2 infection is needed as a public health measure to protect the health of fellow travelers and U.S. communities.

1. Requirements for Airlines & Other Aircraft Operators

Any airline or other aircraft operator with passengers arriving into the United States from a foreign country, for each passenger onboard the aircraft arriving into the United States, shall—

a. Verify that each passenger has attested to having received either a negative Qualifying Test result or to recovery from COVID–19 after previous SARS–CoV–2 infection and clearance to travel. Airlines or other aircraft operators must retain a copy of each passenger attestation for 2 years. The attestation is attached to this order as Attachment A.

b. Confirm that each passenger aged 2 years or older has documentation of a negative Qualifying Test result or Documentation of Recovery from COVID–19.

c. Not board any passenger without verifying the attestation and confirming the documentation as set forth in 1.a–b.

Any airline or other aircraft operator that fails to comply with section 1, ''Requirement for Airlines & Other Aircraft Operators,'' may be subject to criminal penalties under, *inter alia,* 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571.

2. Requirements for Aircraft Passengers

Any aircraft passenger departing from any foreign country with a destination in the United States shall—

(a) Provide an attestation to the CDC, through the airline or other aircraft operator, of having received a negative Qualifying Test result or of recovery from COVID–19 after previous SARS–CoV–2 infection and clearance to travel.

[8] Runway to Recovery 1.1, December 21, 2020, available at *https://www.transportation.gov/briefing-room/runway-recovery-11.*

[9] *https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-air-travel.html.*

[10] Johansson MA, Wolford H, Paul P, et al. Reducing travel-related SARS–CoV–2 transmission with layered mitigation measures: Symptom monitoring, quarantine, and testing, *available at https://www.medrxiv.org/content/10.1101/2020.11.23.20237412v1.*

[11] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.*

[12] *https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html.*

The attestation is attached to this order as Attachment A. Unless otherwise permitted by law, a parent or other authorized individual should attest on behalf of a passenger aged 2 to 17 years. An authorized individual may attest on behalf to any passenger who is unable to attest on his or her own behalf (*e.g.,* by reason of physical or mental impairment).

(b) Retain a copy of the negative Qualifying Test result or Documentation of Recovery from COVID–19 in his/her possession and present it for inspection to the airline and upon request by an agent of the U.S. government or a cooperating state or local public health authority.

Any passenger who fails to comply with the requirements of section 2, ''Requirements for Aircraft Passengers,'' may be subject to criminal penalties under, *inter alia,* 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571. Willfully giving false or misleading information to the government may result in criminal penalties under, *inter alia,* 18 U.S.C. 1001.

CDC may modify this Order by an updated publication in the **Federal Register** or by posting an advisory to follow at *www.cdc.gov.*

This Order shall be enforceable through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 271; and 42 CFR 71.2.

Effective Date

This Order shall enter into effect on January 26, 2021 and shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID–19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations; or (3) December 31, 2021.

Attachment A

Passenger Disclosure and Attestation to the United States of America

All airlines or other aircraft operators covered by the Order must provide the following disclosure to their passengers and collect the attestation prior to embarkation.

Airline and Aircraft Operator Disclosure Requirement

As required by United States federal law, all airlines or other aircraft operators must confirm either a negative COVID–19 test result or recovery from COVID–19 and clearance to travel and collect a passenger attestation on behalf of the U.S. Centers for Disease Control and Prevention (CDC) for certain passengers on aircraft departing from a foreign country and arriving in the United States.

Each individual 2 years of age or older must provide a separate attestation. Unless otherwise permitted by law, a parent or other authorized individual should attest on behalf of a passenger aged 2 to 17 years. An individual may attest on behalf of another passenger for whom the individual is authorized to submit the required information (for example, immediate family member(s), legal guardian, or travel agent), if that person is unable to attest on his or her own behalf (*e.g.,* because of physical or mental impairment).

The information provided must be accurate and complete to the best of the individual's knowledge.

Under United States federal law, each passenger must provide this attestation. Failure to provide this attestation, or submitting false or misleading information, could result in delay of travel, denial of boarding, denial of boarding on future travel, or put the passenger or other individuals at risk of harm, including serious bodily injury or death. Any passenger who fails to comply with these requirements may be subject to criminal penalties under, among others, 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571. Willfully providing false or misleading information may lead to criminal fines and imprisonment under, among others, 18 U.S.C. 1001. Providing this information can help protect you, your friends and family, your communities, and the United States. CDC appreciates your cooperation.

Passenger Attestation Requirement

I [name of passenger or authorized representative] have read the disclosure pertaining to my obligation to obtain a negative pre-departure test result for COVID–19 or to having recovered from COVID–19 after previous SARS–CoV–2 infection and being cleared to travel in order to board an aircraft departing from a foreign country and arriving in the United States.

Check One of the Options That Applies

[ ] I attest that I have received a negative pre-departure test result for COVID–19. The test was a viral test that was conducted on a specimen collected from me during the 3 calendar days preceding the flight's departure.

[ ] I attest that I have recovered from COVID–19 in the last 3 months (90 days), or the time period specified in current CDC guidance, after having previously tested positive for SARS–CoV–2 and have been cleared for travel by a licensed healthcare provider or public health official.

[ ] On behalf of [____], I attest that such person has received a negative pre-departure test result for COVID–19. The test was a viral test that was conducted on a specimen collected from that person during the 3 calendar days preceding the flight's departure.

[ ] On behalf of [____], I attest that such person has recovered from COVID–19 in the last 3 months (90 days), or the time period specified in current CDC guidance, after having previously tested positive for SARS–CoV–2 and has been cleared for travel by a licensed healthcare provider or public health official.

Date

Privacy Act Statement

The United States Centers for Disease Control and Prevention (CDC) requires airlines and other aircraft operators to collect this information pursuant to 42 CFR 71.20 and 71.31(b), as authorized by 42 U.S.C. 264. Providing this information is mandatory for all passengers arriving by aircraft into the United States. Failure to provide this information may prevent you from boarding the plane. Additionally, passengers will be required to attest to providing complete and accurate information, and failure to do so may lead to other consequences, including criminal penalties. CDC will use this information to help prevent the introduction, transmission, and spread of communicable diseases by performing contact tracing investigations and notifying exposed individuals and public health authorities; and for health education, treatment, prophylaxis, or other appropriate public health interventions, including the implementation of travel restrictions.

The Privacy Act of 1974, 5 U.S.C. 552a, governs the collection and use of this information. The information maintained by CDC will be covered by CDC's System of Records No. 09–20–0171, Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR parts 70 and 71. *See* 72 FR 70867 (Dec. 13, 2007), as amended by 76 FR 4485 (Jan. 25, 2011) and 83 FR 6591 (Feb. 14, 2018). CDC will only disclose information from the system outside the CDC and the U.S. Department of Health and Human Services as the Privacy Act permits, including in accordance with the routine uses published for this system in the **Federal Register**, and as authorized by law. Such lawful purposes may include, but are not

limited to, sharing identifiable information with state and local public health departments, and other cooperating authorities. CDC and cooperating authorities will retain, use, delete, or otherwise destroy the designated information in accordance with federal law and the System of Records Notice (SORN) set forth above. You may contact the system manager at *dgmqpolicyoffice@cdc.gov* or by mailing Policy Office, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329, if you have questions about CDC's use of your data.

Authority

The authority for these orders is Sections 361 and 365 of the Public Health Service Act (42 U.S.C. 264) and 42 CFR 71.20 & 71.31(b).

Dated: January 13, 2021.

Nina B. Witkofsky,

Acting Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2021–01067 Filed 1–15–21; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 85 FR 70630–70633, dated November 5, 2020) is amended to reflect the reorganization of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title for the *National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (CVJ)* and insert the following title *National Center for HIV, Viral Hepatitis, STD, and TB Prevention (CVJ).*

Revise the mission statement for the *National Center for HIV, Viral Hepatitis, STD, and TB Prevention (CVJ)* and insert the following:

National Center for HIV, Viral Hepatitis, STD, and TB Prevention (CVJ). The National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) maximizes public health and safety nationally and internationally through the elimination, prevention, and control of disease, disability, and death caused by Human Immunodeficiency Virus Infection (HIV), non-HIV retroviruses, viral hepatitis, other sexually transmitted diseases (STDs), and tuberculosis (TB). In carrying out its mission, NCHHSTP: (1) Builds capacity and enhances public health infrastructure for preventing and treating HIV, viral hepatitis, STDs, and TB; (2) coordinates activities and programs across CDC and with other Department of Health and Human Services Operating Divisions in order to maximize the public health impact of HIV, viral hepatitis, STDs, and TB interventions; (3) conducts surveillance and research to determine the distribution, determinants, and burden of HIV, viral hepatitis, STDs, and TB; (4) conducts program evaluation to improve programs and activities relating to the prevention of HIV, viral hepatitis, STDs, and TB, and determine their impact; (5) provides reference laboratory and clinical diagnostic services for HIV, viral hepatitis, STDs, and TB to relevant stakeholders; (6) promotes collaboration and service integration among HIV, viral hepatitis, STDs, and TB programs; (7) engages external partners to develop and implement effective HIV, viral hepatitis, STDs, and TB policies, research, and programs; (8) engages partners, to promote health equity and reduce health disparities among those affected by HIV, viral hepatitis, STDs, and TB; (9) provides technical assistance and training in the diagnosis, treatment, and prevention of HIV, viral hepatitis, STDs, and TB; (10) conducts public health communication activities to disseminate research findings and increase awareness of HIV, viral hepatitis, STDs, and TB; (11) conducts operational, behavioral, and biomedical research to improve the distribution, diagnosis, prevention, and control of HIV, viral hepatitis, STDs, and TB; (12) provides scientific leadership regarding public health ethics and protection of human subjects linked to HIV, viral hepatitis, STDs, and TB; (13) translates research findings into public health practice and policy for HIV, viral hepatitis, STDs, and TB prevention; (14) plans, coordinates, and guides programs and activities with external partners, federal agencies, and other organizations related to HIV, viral hepatitis, STDs, and TB prevention, care, and treatment; (15) leads and participates in the development, implementation, and evaluation of policies and guidelines related to HIV, viral hepatitis, STDs, and TB; (16) provides scientific leadership regarding screening, treatment, immunization, and other prevention interventions relevant to HIV, viral hepatitis, STDs, and TB; (17) assures all public health decisions are based on the highest quality scientific data, openly and objectively derived; (18) provides leadership to assist international partners in establishing and maintaining, HIV, viral hepatitis, STDs, and TB screening, treatment, immunization, and other prevention and control programs; (19) ensures that programmatic and scientific activities are aligned with, and in support of, CDC's overall mission, goals, and strategic imperatives; (20) allocates and tracks CDC resources and contributes to the development of CDC's short-, medium- and long-term strategic plans for preventing the spread of HIV, viral hepatitis, STDs, and TB; (21) collaborates with other federal agencies, domestic and international governmental and non-governmental organizations to advance CDC and NCHHSTP health protection goals; and (22) coordinates oversight of the NCHHSTP Federal Advisory Committees.

Delete in its entirety the titles and mission and function statement for the *Office of the Director (CVJ1)* and insert the following:

Office of the Director (CVJ1). (1) Provides leadership and guidance on the development of goals and objectives, policies, program planning and development, and program management and operations of the activities of NCHHSTP and manages, directs, coordinates, and evaluates the center's activities; (2) plans and coordinates the annual program planning process; (3) coordinates with Office of the Director (OD), Centers/Institute/Offices (CIOs), and divisions in determining and interpreting operating policy and in ensuring their respective management input for specific program activity plans; (4) facilitates closer linkages between HIV, non-HIV retroviruses, STDs, viral hepatitis, and TB, surveillance activities and prevention programs at all levels, and facilitates collaboration, integration, and multi-disciplinary approaches to enhance the effectiveness of HIV, STD, viral hepatitis, and TB prevention programs; (5) facilitates collaboration among, and integration of, science and prevention programs throughout NCHHSTP and enhances the coordination and integration of HIV, STD, viral hepatitis, and TB prevention services for individuals and populations at

increased risk for more than one of these infections; (6) coordinates the integration of CDC funding of state and local health departments for HIV, STD, viral hepatitis, and TB prevention; (7) maximizes center-wide collaboration to promote and support Program Collaboration and Service Integration (PCSI) in state and local HIV, viral hepatitis, STD and TB programs to increase efficiencies and provide comprehensive evidence based prevention services to impacted populations; (8) develops partnership objectives and strategies for advancing center priorities (*e.g.,* on cross-cutting functions PCSI, reducing health disparities, etc.) and leverages OD resources to address these objectives and strategies; (9) coordinates and tracks health equity science and program activities within the center; (10) coordinates and tracks science and program activities that concern or address social determinants of health within NCHHSTP and other programs; (11) collaborates with the CDC OD and other CDC components on health equity activities, and works with the CDC OD to monitor progress in meeting Executive Orders related to improving minority health; (12) develops partnerships with other federal agencies and nongovernmental organizations working on similarly-affected populations; (13) supports research, surveillance, education, training, and program development to achieve health equity and reduce health disparities; (14) sponsors workgroups, meetings, and conferences related to health equity; (15) promotes a diverse public health workforce through internships, fellowships, training programs, and other activities; (16) ensures process consistency for laboratory related functions within NCHHSTP and across the CIOs; (17) facilitates cross-center decision-making regarding laboratory activities; (18) monitors the performance of funded extramural research projects in the areas of HIV, viral hepatitis, STD and TB; (19) collaborates with other federal agencies to advance prevention through healthcare; (20) coordinates and supports cross-cutting strategic initiatives in support of NCHHSTP divisions and partners; and (21) works across the agency to advance prevention priorities.

Delete item (3) of the functional statement for the *Office of the Associate Director for Science (CVJ12), and insert the following:* (3) Facilitates communication regarding scientific and programmatic services across the Deputy Director of Infectious Diseases (DDID).

Delete in its entirety the titles and mission and function statements for the *Division of HIV/AIDS Prevention—Intervention and Support (CVJB).*

Delete in its entirety the titles and mission and function statements for the *Division of HIV/AIDS Prevention—Surveillance and Epidemiology (CVJC)* and insert the following:

Division of HIV Prevention (CVJC). (1) Conducts national HIV surveillance, oversees the implementation of HIV prevention and control programs, conducts HIV research, and evaluates the impact of division's program and research activities in collaboration with other CDC CIOs; (2) provides consultation, financial, and technical services to assist others in the planning, development, implementation, evaluation and overall improvement of HIV prevention programs; (3) conducts research into factors affecting the prevention of HIV; (4) provides strategic vision, planning, and coordination for implementation of policies and programmatic activities that address the Ending the HIV Epidemic initiative in collaboration with the center, CDC OD, and other CIO; (5) provides strategic direction of program-led science by overseeing the refinement of the Division of HIV Prevention's (DHP) scientific research agenda and coordination of DHP priorities; (6) counsels leadership in building and aligning strategic partnerships at the executive-level and communicates internally and externally about partnership priorities; (7) works closely with CDC stakeholders on HIV surveillance and epidemiologic investigations that require laboratory collaboration, and on activities related to the investigation and prevention of HIV-related opportunistic infections; (8) promotes linkages between health departments' HIV programs, and other governmental and nongovernmental partners who are vital to HIV prevention efforts; (9) develops preventive health services models, recommendations, and guidelines on the prevention of HIV and associated illnesses; (10) monitors surveillance of risk behaviors associated with HIV transmission, infectious diseases, and other complications of HIV; (11) develops methods and guidance, and provides technical assistance to support health departments to build capacity for cluster and outbreak response; (12) determines risk factors and transmission patterns of HIV by conducting HIV surveillance, epidemiologic investigations, and research studies; (13) works closely with other governmental and nongovernmental agencies, and the health care community to enhance and evaluate HIV prevention services in public and private health care delivery systems; (14) implements national HIV prevention public information programs and assists in developing strategic communications activities and services at the national level to inform and educate the American public about HIV, especially clinical providers, persons with HIV and groups at high risk for acquiring HIV; (15) manages, develops and directs the implementation of the division data policy, management, and governance, provides IT coordination and support for enterprise level shared services, and coordinates with other parts of CDC to ensure adherence to CDC's IT governance and data modernization policies; (16) provides information on HIV to CDC partners, scientific communities, and the general public through publications and presentations; and (17) collaborates with UNAIDS, the World Health Organization and other partners on HIV surveillance and epidemiology.

Office of the Director (CVJC1). (1) Plans, directs, and evaluates activities of the division; (2) serves as the division's liaison to the center policy office, the CDC OD, HHS, GAO and OIG, CDC Washington and the Office of Appropriations to address inquiries, develop the President's budget, review legislation, and support outreach to educate policy makers; (3) manages strategic planning and coordinates related reporting; (4) identifies, analyzes and addresses policy barriers and leads legal assessment efforts; (5) provides strategic direction, goals, and priorities to build and evaluate the effectiveness of division partnerships, in coordination with DHP branches and offices, including expanding public private partnerships, community-level partnerships, and engaging special populations; (6) monitors internal and external environmental shifts to identify and analyze potential and real reputational risk issues and develops responses to anticipated issues to lessen their impact; (7) provides critical vision and communication counsel to DHP leadership, aligns messaging across the division, and develops, coordinates, and finalizes strategic communication plans, messaging, partner communications, social media, and other communication materials; (8) advances DHP programmatic priorities through proactive stakeholder communication and liaises with the Center News Media team; (9) develops goals and objectives and provides guidance in national HIV prevention policy formulation and program planning and development; (10) leads the development and

provides oversight of the research agenda and ensures the scientific integrity of research, surveillance, evaluation, and other scientific aspects of HIV prevention, and coordinates these activities with other center divisions, CIOs, federal agencies and other prevention partners as needed; (11) oversees and coordinates prevention and control program implementation and coordinates activities with other center divisions, CIOs, federal agencies, and other prevention partners; (12) provides oversight for the integrity and quality of division science, including review of protocols and other scientific products and projects, scientific clearance, and compliance with all federal rules and regulations regarding research and non-research projects, and conducts scientific training; (13) coordinates international HIV activities of the division and ensures inter-divisional coordination within the center and CDC, as appropriate; (14) in the international setting, evaluates biomedical, structural, or combination interventions to prevent HIV infection and reduce HIV morbidity and mortality; (15) in the international setting, conducts and facilitates diagnostic evaluations and epidemiologic investigations to increase the diagnosis and prevention of HIV infection; (16) provides support and guidance for program management and operations, including the coordination and development of CDC and division-wide training and educational programs, workforce development and succession planning; (17) provides management, oversight, and services support for intramural and extramural program management; (18) provides health equity strategic vision for the division, offices, and branches and collaborates with branches to monitor progress toward achieving national agency, center and division health equity goals; (19) leads the development and provides oversight of the health equity research and programmatic agenda for the division, and serves as liaison to key stakeholder groups related to health inequities and HIV issues; (20) oversees and coordinates the development, maintenance, and reporting of national indicators for the prevention of HIV by working with HHS, other federal agencies, and partners; (21) provides support and reviews logic models and performance measures for Notice of Funding Opportunity Announcements for the division; (22) conducts data driven reviews for program planning and performance assessment; (23) oversees, develops, and directs the division's data policy framework, data management framework, and data governance implementation; (24) coordinates with other parts of CDC to ensure adherence to CDC's IT governance and data modernization policies; (25) manages the acquisition, receipt, quality assessment, and provisioning of non-CDC data resources; and (26) provides division-level IT/Informatics coordination and support for enterprise-level shared services.

HIV Research Branch (CVJCB). (1) Designs and conducts clinical, epidemiologic, implementation, health services, and behavioral research studies and trials to increase HIV diagnosis, prevention, and treatment, and to optimize health outcomes of people with HIV; (2) conducts implementation research to understand and evaluate strategies to increase uptake, delivery and sustainability of HIV prevention interventions; (3) designs and conducts research to understand determinants of disparities, including social determinants of health, and to promote health equity in HIV prevention and treatment; (4) conducts studies to evaluate, improve, and standardize laboratory technologies used for diagnosis and monitoring of HIV infection and for supporting adherence to biomedical HIV prevention and treatment interventions; (5) conducts demonstration projects of novel prevention strategies delivered by health departments, community-based organizations (CBO), healthcare organizations, and other providers; (6) contributes to the field of HIV prevention by producing and disseminating scientific evidence and by providing expert consultation to stakeholders; (7) collaborates with key stakeholders in identifying research priorities and in designing and conducting research; (8) supports partners in investigating unusual HIV transmission and cluster and outbreak investigations; and (9) participates in the development of guidelines, based on scientific investigations and clinical trials, for HIV prevention and for prevention of adverse outcomes of HIV infection.

Behavioral and Clinical Surveillance Branch (CVJCC). (1) Conducts surveillance of behaviors related to acquisition or transmission of HIV infection in high risk populations to evaluate the impact of the national or jurisdiction's overall prevention portfolio to direct prevention resource allocation; (2) develops, uses, and disseminates methods to monitor behaviors associated with HIV transmission or acquisition; (3) conducts clinical surveillance through in-depth interviews of persons with diagnosed HIV to assess access to medical care and prevention services, adherence to therapy, and behavioral risk associated with HIV transmission; (4) conducts clinical surveillance through in-depth chart reviews of persons with diagnosed HIV in selected sites to monitor morbidity and mortality and to assess access to and quality of care; (5) develops, uses, and disseminates methods to monitor clinical care and health outcomes for people with diagnosed HIV; (6) conducts behavioral or clinical surveillance in special populations of epidemiologic importance; (7) maintains, analyzes, and disseminates information from national surveys of behaviors associated with HIV testing, prevention, acquisition, or transmission; (8) collaborates with internal and external partners to ensure high quality behavioral and clinical monitoring systems, including screening for, and monitoring of comorbidities in key populations; (9) oversees and manages intramural and extramural funding, ensures regulatory compliance, provides technical assistance, and monitors program implementation related to behavioral and clinical surveillance; (10) provides support for outbreak response; and (11) provides subject matter expertise and support related to high risk populations and to medical care for people with HIV.

Quantitative Sciences Branch (CVJCD). (1) Designs, develops, and implements statistical, data science, economic, cost, and resource allocation strategies, models, and methodologies; (2) collaborates with scientists, program experts, and senior public health officials throughout the division to apply quantitative science models and methodologies to HIV surveillance and prevention studies and prevention program activities; (3) develops and implements mathematical models to project the effects of prevention and care interventions on future HIV incidence, prevalence, transmission rates, and costs associated with HIV to determine the most efficient allocation of HIV prevention resources; (4) develops and reviews the statistical content of study designs and protocols, analysis plans, and scientific and communication products; and (5) applies novel analytic algorithms and visualization approaches to extract actionable HIV-prevention-related information from suitable non-traditional data types and sources.

HIV Surveillance (CVJCE). (1) Conducts population based, national HIV surveillance to monitor and characterize HIV trends, transmission risk, clinical outcomes, and

antiretroviral resistance to guide public health action at the federal, state, and local levels; (2) develops and implements HIV surveillance technical guidance, methods, protocols, and program standards for analysis and data system applications for the collection, evaluation, analysis, security and confidentiality, and dissemination of HIV surveillance data; (3) maintains, analyzes, integrates and disseminates information from the national HIV surveillance and related systems; (4) promotes uses of surveillance data to inform HIV prevention and care efforts, resource allocation, public health policy development and evaluation; (5) conducts projects for populations of epidemiologic importance and advancement of surveillance methods; (6) evaluates HIV surveillance systems, develops and implements improved surveillance methodologies, and conducts data driven technical assistance; (7) oversees and manages extramural funding for surveillance activities and provides programmatic, budgetary, and technical assistance to state and local health departments and other external partners to ensure high-quality state, local and national HIV surveillance data; (8) collaborates with internal and external partners and supports cluster and outbreak detection and investigation; and (9) collaborates with internal and external stakeholders to enhance surveillance quality, data use, and provide expert consultation.

Laboratory Branch (CVJCG). (1) Conducts studies of HIV and other human and zoonotic retroviruses, including the diseases they cause and their modes of transmission, through virus detection, isolation, and characterization by virologic, molecular, and cellular biologic methods; (2) collaborates with DHP and other investigators to conduct HIV epidemiologic and surveillance studies as they pertain to testing, prevention, and intervention strategies; (3) conducts and supports field and clinical studies for HIV prevention; (4) develops collaborations with other CDC and non-CDC scientists to promote scientific progress and accomplishments; (5) collaborates with industry to promote commercialization of useful technology, methodologies, or reagents of public health importance; (6) serves as a reference laboratory for state and local health departments; (7) conducts studies related to the development, evaluation, improvement, and standardization of laboratory technologies used for the diagnosis, surveillance, and monitoring of HIV infection both independently and in collaboration with the biotechnology industry; (8) performs HIV testing in support of the diagnostic, surveillance, and epidemiologic requirements of CDC-based and CDC-affiliated studies of HIV; (9) provides diagnostic services to other federal agencies, academic centers, CDC-affiliated studies with other countries, and community organizations, as appropriate; (10) develops and evaluates novel biomedical prevention and treatment modalities in preclinical animal models; (11) evaluates and develops HIV testing technologies; (12) researches, develops, and evaluates bioinformatics tools to better understand HIV spread to inform prevention efforts; (13) provides antiretroviral drug testing in support of clinical, preclinical, and surveillance activities; and (14) collaborates with internal and external partners and supports cluster and outbreak detection and investigation.

HIV Prevention Capacity and Development Branch (CVJCH). (1) Assesses HIV prevention and treatment training and technical assistance needs of DHP program funding recipients, clinicians, and other HIV prevention service providers and develops and delivers strategies and products to address identified needs; (2) develops, maintains, and manages systems to ensure that health department and CBO staff receive appropriate and timely training and technical assistance; (3) provides subject matter expertise on HIV prevention and treatment to ensure that training and technical assistance products developed by capacity building providers are aligned with HHS and CDC strategic goals and objectives, center and DHP priorities, and support the training and technical assistance needs of DHP program funding recipients, clinicians, and other HIV prevention service providers; (4) collaborates with DHP staff and capacity building providers to synthesize research findings and disseminate technical assistance and training products relevant to the needs of HIV prevention programs and clinicians; and (5) manages national conference contract and support services.

Prevention Communications Branch (CVJCI). (1) Develops, disseminates, and evaluates evidence-based HIV messages, communication campaigns, programs, and partnership efforts through multiple channels to stakeholders, health care providers, persons at risk for and living with HIV, and the general public; (2) maintains division communication infrastructure, including social media, Web, and SharePoint channels, the curation of CDC's HIV print inventory, and oversight of the HIV subject matter expertise of CDC–INFO; and (3) collaborates and consults with CDC staff, HHS, state and local health departments, and other groups and organizations involved in HIV prevention communication activities to devise and facilitate technical assistance systems and activities related to the application of social marketing and communication science to prevention programs and policies.

Program Development and Implementation Branch (CVJCJ). (1) In collaboration with state and local public health and non-governmental national, regional, and local partners, CIOs, and other federal agencies, develops and implements programs, policies, and activities that enable and mobilize affiliates and communities to become involved with, and support, strategic community planning that improves HIV prevention programs and activities; (2) plans, develops, implements, and manages strategies and resources that build a comprehensive public health-private sector partnership to prevent HIV and its complications; (3) provides technical consultation and assistance to local, state, and territorial health departments, integrated HIV prevention and care planning groups, non-governmental, other prevention partners, and tribal governments and organizations in operational aspects of HIV prevention; (4) monitors implementation and maintenance of HIV prevention programs through the application of program science to ensure operational objectives are being met; (5) establishes guidance and policies for implementation and continuation of local, state, and territorial HIV prevention programs; (6) provides technical review of grant applications and prevention work plans; (7) coordinates program development and implementation with local, state, and territorial integrated HIV prevention and care planning groups; (8) facilitates linkages with HIV and other infectious diseases prevention programs at all levels to maximize coordination of harm reduction and intervention strategies tailored for populations with complex psychosocial prevention needs; (9) works with national partners to foster HIV prevention capabilities and activities in affected communities; (10) monitors the progress of funded recipients implementing HIV prevention programs and activities; (11) promotes and facilitates the application of social marketing principles to HIV prevention at the state and local levels; (12) plans, implements, and manages DHP's programmatic notice of funding opportunities (NOFOs) for health

departments, community-based organizations, and national partners and providers; (13) provides monitoring and oversight to programmatic NOFO activities throughout the funded lifecycle; (14) supports the federal Ending the HIV Epidemic workforce that provides technical consultation and direct assistance to state, local health departments implementing HIV prevention programs; and (15) assesses training, capacity building and technical assistance needs and develops strategies to address the training of recipient organizations and other external partners involved in HIV prevention programs and activities.

Translation and Evaluation Branch (CVJCK). (1) Collaborates with DHP, CDC, HIV prevention program recipients, and national partners to systematically collect, process, and use HIV prevention program data and research findings for program planning, monitoring, evaluation, and improvement; (2) identifies and prioritizes program needs and research gaps, synthesizes research and program findings, selects and translates HIV prevention research findings, and collaborates within DHP to support development and dissemination of guidelines, research syntheses and effective strategies for HIV prevention programs; (3) creates, maintains and regularly updates a public-facing platform to disseminate evidence-based prevention strategies and research syntheses aligned with DHP and national prevention priorities to internal and external stakeholders; (4) creates and manages a continuously updated multi-level coded cumulative database of the HIV prevention research literature in support of systematic reviews and guideline development as well as internal and public inquiries; (5) seeks to advance the methodology of HIV prevention evaluation through CDC evaluation activities and with the field of program evaluation more broadly; (6) seeks to improve data quality and support through providing assistance to recipients to help design and implement data collection, design local evaluations, and dissemination packages; (7) collects information to verify that what is developed, translated and disseminated is feasible, programmatically effective, and plays a role in improving health outcomes; (8) plans, develops, implements, and manages research dissemination strategies and resources that build a research to practice infrastructure to prevent HIV and its complications; (9) monitors implementation and establishes protocols for implementation of behavioral, biomedical, structural evidence-based and evidence-informed approaches by HIV prevention programs to determine if said approaches may be successfully implemented under real world conditions; (10) collaborates and consults with CDC staff, other Public Health Service agencies, state and local health departments, CBOs, and other groups and organizations involved in HIV prevention activities to support technical assistance systems and other activities related to the application of evidence-informed and evidence-based prevention programs and policies; (11) provides scientific expertise, quality assurance and clearance for products and processes related to systematic review, research synthesis, and guidelines methodologies; and (12) collaborates within DHP to provide technical consultation and assesses and determines the training, capacity building, and technical assistance needs for organizations implementing behavioral, biomedical, and structural evidence-based and evidence- informed approaches to meet the unique HIV prevention needs of local jurisdictions based upon risk factors and demographics.

Detection and Response Branch (CVJCL). (1) Develops and disseminates analytic methods for detecting and prioritizing clusters and outbreaks and understanding transmission patterns, molecular epidemiology, and drug resistance; (2) analyzes data to identify and monitor priority clusters and support public health action; (3) provides technical assistance and other support for health departments on detecting clusters and outbreaks; (4) develops, evaluates, and disseminates methods for responding to clusters and outbreaks; (5) develops guidance and provides technical assistance to support health departments to build capacity for cluster response and response planning, including community engagement; (6) leads cross-division collaboration and communication about cluster and outbreak detection and response and builds DHP capacity to support response, including training and rostering staff; (7) provides technical assistance and other support for health departments on responding to clusters and outbreaks and disseminates findings of these responses; (8) analyzes information from cluster detection and response to inform efforts to prevent clusters and outbreaks; (9) provides scientific and programmatic oversight and guidance for DHP informatics systems for cluster detection and response and collaborates with other DHP branches and offices on these systems; and (10) collaborates with other branches and offices in DHP, divisions in the center, and CIOs to harmonize scientific agendas and programmatic priorities and addresses community engagement and policy issues related to cluster detection and response.

Delete item (2) of the functional statement for the *Division of Adolescent and School Health (CVJJ),* and insert the following: (2) Identifies and monitors priority sexual health risks and related health behaviors among youth that result in the transmission of HIV, other sexually transmitted infections and unintended pregnancy.

Delete item (2) of the functional statement for the *Program Development and Services Branch (CVJJB),* and insert the following: (2) Uses the results of surveillance and evaluation research and research syntheses to improve the impact of school- and community-based interventions designed to reduce priority health risks among youth and to promote changes in behaviors related to HIV, other sexually transmitted diseases, and unintended pregnancy.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

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BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Monitoring and Compliance for Office of Refugee Resettlement Care Provider Facilities (New Collection)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is inviting public comments on the proposed collection. The request consists of several forms that allow the Unaccompanied Alien Children (UAC) Program to monitor its care provider facilities for compliance with federal and state laws and regulations, licensing and accreditation standards, ORR policies and procedures, and child welfare standards.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described in this notice.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description

The components of this information request include:

1. Corrective Action Report (Form M–1): This instrument is used by ORR Monitoring Team staff (includes federal and contractor staff), ORR Federal Field Specialists, and ORR Project Officers to document care provider non-compliance with minimum standards for the care and timely release of UAC; federal and state laws and regulations; licensing standards; ORR policies and procedures; and child welfare standards. Care providers respond to each corrective action cited by ORR staff by entering a detail corrective action plan into the instrument and attaching any relevant supporting documents. Then, ORR staff document when each corrective action plan is completed to ORR's satisfaction and enter a final determination.

2. FFS Compliance and Safety Site Visit Report (Form M–3A): This instrument is used by ORR Federal Field Specialists to document site visit observations and interview responses.

3. Out-of-Network Site Visit Report (Form M–3B): This instrument is used by ORR Federal Field Specialists to document site visit observations and interview responses for out-of-network providers.

Checklists for a Child-Friendly Environment

These instruments are used by care providers on a voluntary basis to help ensure compliance with ORR policies and procedures related to maintaining a safe, child-friendly environment. ORR may also ask care providers to complete the checklist prior to a site visit.

4. Checklist for a Child-Friendly Environment—Care Provider Facility (Form M–4A)

5. Checklist for a Child-Friendly Environment—Individual Foster Home (Form M–4B)

Incident Reviews

These instruments are used by ORR care provider staff to provide information to ORR on allegations of sexual abuse or sexual harassment that occurred in ORR care that were investigated by local child protective services, state licensing, local law enforcement, the HHS Office of the Inspector General, and/or the Federal Bureau of Investigation. Care providers submit the instrument to ORR's Prevention of Sexual Abuse Team for review. Incident reviews help ensure that care providers have appropriate protective measures in place to prevent a similar incident from occurring again.

6. UAC Incident Review (Form M–5A): This instrument is completed for allegations of sexual abuse or sexual harassment that occurred in ORR care between two children.

7. Adult Incident Review (Form M–5B): This instrument is completed for allegations of sexual abuse or sexual harassment that occurred in ORR care between a child and an adult.

Monitoring Notes

These instruments are used by ORR Monitoring Team staff (includes federal and contractor staff) to compile comprehensive notes and information related to biennial monitoring visits. There are separate instruments tailored specifically for monitoring of long term foster care (LTFC) programs and/or remote monitoring visits.

8. Monitoring Notes (Form M–6A)

9. Remote Monitoring Notes (Form M–6B)

10. Long Term Foster Care Monitoring Notes (Form M–6C)

11. Long Term Foster Care Remote Monitoring Notes (Form M–6D)

Site Visit Guides

These instruments are completed by care provider staff as part of the pre-monitoring process for biennial site visits and provide ORR Monitoring Team staff with information and supporting documents related to the overall functioning and oversight of the care provider program. There are separate instruments tailored specifically for monitoring of LTFC programs, home study and post-release (HS/PRS) service providers, and/or voluntary agencies (primary grantees for LTFC and transitional foster care sub-grantees).

12. Site Visit Guide (Form M–7A)

13. Remote Monitoring Site Visit Guide (Form M–7B)

14. Long Term Foster Care Site Visit Guide (Form M–7C)

15. Long Term Foster Care Remote Site Visit Guide (Form M–7D)

16. Home Study and Post-Release Services Site Visit Guide (Form M–7E)

17. Voluntary Agency Site Visit Guide (Form M–7F)

Case File Checklists

These instruments are used by ORR Monitoring Team staff (includes federal and contractor staff) during biennial site visits to document care provider compliance with ORR policies and procedures related to case file maintenance. There are separate instruments tailored specifically for monitoring of LTFC programs, and HS/PRS providers, plus an addendum for secure and staff secure programs.

18. UAC Case File Checklist (Form M–8A)

19. Long Term Foster Care Case File Checklist (Form M–8B)

20. Home Study and Post-Release Services Case File Checklist (Form M–8C)

21. Secure and Staff Secure Addendum to Case File Checklist (Form M–8D)

On Site Monitoring Checklists

These instruments are used by ORR Monitoring Team staff (includes federal and contractor staff) to document their findings during the walkthrough portion of biennial site visits. There are separate instruments tailored specifically for monitoring of foster homes and PRS home observations.

22. On Site Monitoring Checklist (Form M–9A)

23. Foster Home On Site Monitoring Checklist (Form M–9B)

24. Post-Release Services Home Observation (Form M–9C)

Personnel File Checklists

These instruments are completed by care provider staff and ORR Monitoring Team staff (includes federal and contractor staff) during biennial site visits to ensure that programs are meeting ORR policies and procedures related to the maintenance of personnel files. There are separate instruments tailored specifically for HS/PRS provider files and LTFC parent files.

25. Personnel File Checklist (Form M–10A)

26. Supplement to Personnel File Checklist (Form M–10B)

27. Home Study and Post-Release Services Personnel File Checklist (Form M–10C)

28. Long Term Foster Care Foster Parent Checklist (Form M–10D)

Program Staff Questionnaires

These instruments are used by ORR Monitoring Team staff (includes federal and contractor staff) during biennial site visits to interview and document responses from various care provider program staff.

29. Program Director Questionnaire (Form M–11A)
30. Long Term Foster Care Program Director Questionnaire (Form M–11B)
31. Clinician Questionnaire (Form M–11C)
32. Long Term Foster Care Clinician Questionnaire (Form M–11D)
33. Case Manager Questionnaire (Form M–11E)
34. Long Term Foster Care Case Manager Questionnaire (Form M–11F)
35. Education Staff Questionnaire (Form M–11G)
36. Long Term Foster Care Education Questionnaire (Form M–11H)
37. Medical Coordinator Questionnaire (Form M–11I)
38. Youth Care Worker Questionnaire (Form M–11J)
39. Prevention of Sexual Abuse Compliance Manager Staff Questionnaire (Form M–11K)
40. Secure Detention Officer Questionnaire (Form M–11L)
41. Long Term Foster Care Home Finder Questionnaire (Form M–11M)
42. Long Term Foster Care Independent Living Life Skills Staff Questionnaire (Form M–11N)
43. Long Term Foster Care Foster Parent Questionnaire (Form M–11O)

Child Questionnaires

These instruments are used by ORR Monitoring Team staff (includes federal and contractor staff) during biennial site visits to interview and document responses from UAC.

44. UAC Questionnaire—Ages 6–12 Years Old (Form M–12A)
45. UAC Questionnaire—Ages 13 and Older (Form M–12B)
46. Long Term Foster Care Client Questionnaire (Form M–12C)
47. Secure Client Questionnaire (Form M–12D)

Service Provider Questionnaires

These instruments are used by ORR Monitoring Team staff (includes federal and contractor staff) during biennial site visits to interview and document responses from various service providers.

48. Home Study and Post-Release Services Director Questionnaire (Form M–11A)
49. Home Study and Post-Release Services Caseworker Questionnaire (Form M–13B)
50. Legal Service Provider Questionnaire (Form M–13C)
51. Long Term Foster Care Legal Service Provider Questionnaire (Form M–13D)
52. Case Coordinator Questionnaire (Form M–13E)

Monitoring Visit Planning

These instruments are used by ORR Monitoring Team staff (includes federal and contractor staff) to plan and track biennial site visits for each fiscal year. These forms will be housed in ORR's new database, UAC Path.

53. Monitoring Visit (Form M–14)
54. Monitoring Schedule (Form M–15)

Respondents: ORR grantee and contractor staff, foster parents, and UAC.

Annual Burden Estimates

ESTIMATED BURDEN HOURS AND OPPORTUNITY COSTS FOR RESPONDENTS

Information collection title	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual total burden hours
Corrective Action Report (Form M–1)	216	0.5	5.00	540.00
FFS Compliance and Safety Site Visit Report (Form M–3A)	216	12.0	1.00	2,592.00
Out-of-Network Site Visit Report (Form M–3B)	24	5.0	1.00	120.00
Checklist for a Child-Friendly Environment (Form M–4)	216	12.0	0.25	648.00
Incident Reviews (Forms M–5A to M–5B)	216	0.3	1.50	97.20
Site Visit and Remote Monitoring Site Visit Guides (Forms M–7A to M–7B)	93	1.0	12.00	1,116.00
LTFC Site Visit and LTFC Remote Monitoring Site Visit Guides (Forms M–7C to M–7D)	15	1.0	6.00	90.00
HS/PRS Site Visit Guide (Form M–7E)	30	1.0	6.00	180.00
Voluntary Agency Site Visit Guide (Form M–7F)	5	1.0	8.00	40.00
UAC Case File Checklist (Form M–8A)	93	5.0	1.00	465.00
Long Term Foster Care File Checklist (Form M–8B)	15	5.0	1.00	75.00
Home Study and Post-Release Services Case File Checklist (Form M–8C)	30	5.0	1.00	150.00
Secure and Staff Secure Addendum to Case File Checklist (Form M–8D)	4	5.0	1.00	20.00
Program Staff Questionnaires (Form M–11A–K)	756	1.0	1.00	756.00
Secure Detention Officer Questionnaire (Form M–11L)	1	1.0	1.00	1.00
Long Term Foster Care Home Finder Questionnaire (Form M–11M)	15	1.0	1.00	15.00
Long Term Foster Care Independent Living Life Skills Staff Questionnaire (Form M–11N)	15	1.0	1.00	15.00
Long Term Foster Care Foster Parent Questionnaire (form M–11O)	30	1.0	0.75	22.50
UAC Questionnaires (Forms M–12A–B)	460	1.0	0.50	230.00
Long Term Foster Care Client Questionnaire (M–12C)	75	1.0	0.50	37.50
Secure Client Questionnaire (Form M–12D)	5	1.0	0.50	2.50
Home Study and Post-Release Services Director Questionnaire (Form M–13A)	30	1.0	1.00	30.00
Home Study and Post-Release Services Caseworker Questionnaire (Form M–13B)	90	1.0	1.00	90.00
Legal Service Provider Questionnaire (Form M–13C)	93	1.0	1.00	93.00
Long Term Foster Care Legal Service Provider Questionnaire (Form M–13D)	15	1.0	0.75	11.25
Case Coordinator Questionnaire (Form M–13E)	108	1.0	1.00	108.00
Estimated Annual Burden Hours Total:				7,544.95

ESTIMATED BURDEN HOURS AND OPPORTUNITY COSTS FOR CONTRACTOR MONITORS

Information collection title	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual total burden hours
Corrective Action Report (Form M–1)	4	25.0	22.00	2,200.00
Monitoring and Remote Monitoring Notes (Forms M–6A to M–6B)	4	7.0	12.00	336.00
LTFC Monitoring and LTFC Remote Monitoring Notes (Forms M–6C to M–6D)	4	1.0	12.00	48.00
Site Visit and Remote Monitoring Site Visit Guides (Forms M–7A to M–7B)	4	7.0	28.00	784.00
LTFC Site Visit and LTFC Remote Monitoring Site Visit Guides (Forms M–7C to M–7D)	4	1.0	21.00	84.00
HS/PRS Site Visit Guide (Form M–7E)	4	2.0	21.00	168.00
Voluntary Agency Site Visit Guide (Form M–7F)	4	0.0	28.00	0.00
UAC Case File Checklist (Form M–8A)	4	33.0	6.00	792.00
Long Term Foster Care File Checklist (Form M–8B)	4	5.0	3.00	60.00
Home Study and Post-Release Services Case File Checklist (Form M–8C)	4	11.0	1.00	44.00
Secure and Staff Secure Addendum to Case File Checklist (Form M–8D)	4	1.0	1.00	4.00
On Site Monitoring Checklist (Form M–9A)	4	7.0	4.00	112.00
Foster Home On Site Monitoring Checklist (Form M–9B)	4	2.0	0.50	4.00
Post-Release Services Home Observation (Form M–9C)	4	4.0	0.50	8.00
Personnel File Checklist (Form M–10A)	4	31.0	1.00	124.00
Supplement to Personnel File Checklist (Form M–10B)	4	54.0	1.00	216.00
Home Study and Post-Release Services Personnel File Checklist (Form M–10C)	4	6.0	1.00	24.00
Long Term Foster Care Foster Parent Checklist (Form M–10D)	4	2.0	0.50	4.00
Program Staff Questionnaires (Form M–11A–K)	4	54.0	1.00	216.00
Secure Detention Officer Questionnaire (Form M–11L)	4	0.1	1.00	0.40
Long Term Foster Care Home Finder Questionnaire (Form M–11M)	4	1.0	1.00	4.00
Long Term Foster Care Independent Living Life Skills Staff Questionnaire (Form M–11N)	4	1.0	1.00	4.00
Long Term Foster Care Foster Parent Questionnaire (form M–11O)	4	2.0	0.75	6.00
UAC Questionnaires (Forms M–12A–B)	4	33.0	0.50	66.00
Long Term Foster Care Client Questionnaire (M–12C)	4	5.0	0.50	10.00
Secure Client Questionnaire (Form M–12D)	4	0.4	0.50	0.80
Home Study and Post-Release Services Director Questionnaire (Form M–13A)	4	2.0	0.50	4.00
Home Study and Post-Release Services Caseworker Questionnaire (Form M–13B)	4	6.0	1.00	24.00
Legal Service Provider Questionnaire (Form M–13C)	4	7.0	1.00	28.00
Long Term Foster Care Legal Service Provider Questionnaire (Form M–13D)	4	1.0	0.75	3.00
Case Coordinator Questionnaire (Form M–13E)	4	8.0	1.00	32.00
Monitoring Visit (Form M–14)	4	8.0	0.50	16.00
Monitoring Schedule (Form M–15)	4	0.3	0.33	0.40
Estimated Annual Burden Hours Total:				5,427

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores* v. *Reno Settlement Agreement*, No. CV85–4544–RJK (C.D. Cal. 1996).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–01142 Filed 1–19–21; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation

AGENCY: Department of Health and Human Services (HHS), Food and Drug Administration (FDA).

ACTION: Notice; requests for proposals.

SUMMARY: On September 24, 2020, the Department issued two requests for proposals for the reimportation of insulin and the personal importation of prescription drugs on its website. The Department is issuing this Notice to include a revised version of the September 24, 2020 proposals in the **Federal Register**.

DATES: Proposals submitted in response to the requests for proposals shall be accepted and reviewed on a rolling basis, and until further notice.

ADDRESSES: Responses to the requests for proposals should be submitted to *import@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Nick Uehlecke, 200 Independence Ave SW, Washington, DC 20201; or by email at *import@hhs.gov;* or by telephone at 1–877–696–6775.

SUPPLEMENTARY INFORMATION: On September 24, 2020, the Department issued two requests for proposals for the reimportation of insulin and the personal importation of prescription drugs on its website. The proposals were issued consistent with FDA's authorities under sections 801 and 804 of the Food, Drug, and Cosmetic Act, 21 U.S.C. 381, 384. The Department is issuing this Notice to include revised versions of these proposals in the **Federal Register**.

Dated: January 13, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–01125 Filed 1–19–21; 8:45 am]

BILLING CODE 4150–26–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions, and Delegations of Authority

Part R (Health Resources and Services Administration) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services) (60 FR 56605, as amended November 6, 1995; as last amended at 85 FR 34210–34212 dated June 3, 2020) is amended to reorganize sections of the Office of the Administrator, the Federal Office of Rural Health Policy, the Healthcare Systems Bureau, the Maternal and Child Health Bureau, and the Bureau of Primary Health Care.

Key functional changes include establishing the Office of Special Health Initiatives, the Office of Provider Support, and the Office for the Advancement of Telehealth within the Office of the Administrator; abolishing the Healthcare Systems Bureau; and renaming two Offices within the Bureau of Primary Health Care to increase attention and focus on Health Center Program compliance and funding oversight.

This reorganization establishes, updates, realigns, and/or deletes the organization, functions, and delegation of authority for the (1) Office of the Administrator (RA); (2) Office of Special Health Initiatives (RA4); (3) Office for the Advancement of Telehealth (RA3); (4) Federal Office of Rural Health Policy (RH); (5) Office of Provider Support (RD); (6) Healthcare Systems Bureau (RR); (7) Bureau of Primary Health Care (RC); and (8) Maternal and Child Health Bureau (RM).

Chapter RA—Office of the Administrator

Section RA.10 Organization

Delete the organization for the Office of the Administrator (RA) in its entirety and replace with the following:

(1) Immediate Office of the Administrator (RA);

(2) Office of Communications (RA6);

(3) Office of Legislation (RAE);

(4) Office of Planning, Analysis and Evaluation (RA5);

- Office of Policy Analysis (RA53);
- Office of Research and Evaluation (RA56);
- Office of External Engagement (RA57);
- Office of Performance and Quality Measurement (RA58);
- Office of Strategic Initiatives (RA59);

(5) Office of Civil Rights, Diversity and Inclusion (RA2);

(6) Office for the Advancement of Telehealth (RA3);

(7) Office of Special Health Initiatives (RA4);

- Office of Pharmacy Affairs (RA41);
- Office of Global Health (RA42);
  - Division of Global Health (RA421); and
- Division of Injury Compensation Programs (RA43).

(8) Office of Health Equity (RAB); and

(9) Office of Women's Health (RAW).

Section RA.20 Function

Delete the functional statement for Immediate Office of the Administrator (RA) and replace; delete the functional statements for the Office of Global Health (RAI), and replace with the Office of Special Health Initiatives (RA4); and add the functional statement for the Office for the Advancement of Telehealth (RA3).

Immediate Office of the Administrator (RA)

The Immediate Office of the Administrator for the Health Resources and Services Administration (HRSA) leads and directs programs and activities of the agency and advises the Office of the Secretary of Health and Human Services on policy matters concerning them. Specifically, the Immediate Office of the Administrator: (1) Provides consultation and assistance to senior agency officials and others on clinical, health care delivery, and health workforce issues; (2) serves as the agency's focal point on efforts to strengthen the practice of public health as it pertains to the HRSA mission; (3) establishes and maintains communication with health organizations in the public and private sectors; (4) coordinates the agency's policy development, data strategy, evaluation and research planning processes; (5) manages the legislative analysis and engagement for the agency; (6) administers HRSA's equal opportunity and civil rights activities; (7) provides overall leadership, direction, coordination and planning in support of the agency's special health initiatives; (8) manages programs to advance the use of telehealth and coordination of health information technology; (9) manages HRSA's global health issues; (10) leads HRSA's efforts to improve the health, wellness, and safety of women and girls through policy, programming and outreach/education; (11) provides leadership and policy development in the administration of the 340B Drug Pricing Program; (12) oversees efforts to address the special needs of minority and disadvantaged populations, including coordination of tribal activities for HRSA; (13) provides cross-cutting leadership on HRSA's behavioral health and oral health programs; and (14) administers the National Vaccine Injury Compensation Program.

Office for the Advancement of Telehealth (RA3)

The Office for the Advancement of Telehealth (1) ensures successful dissemination of appropriate information technology advances, such as telehealth or electronic health records systems; (2) monitors the health information technology policy and activities of other HHS components for useful application in rural areas; (3) provides overall direction and leadership over the management of programs to advance the use of telehealth and coordination of health information technology; and (4) serves as the operational focal point for coordinating and advancing the use of telehealth technologies across all of HRSA's programs including, but not limited to, the provision of health care at a distance (telemedicine), distance based learning to improve the knowledge of agency grantees and others, and improved information dissemination to both consumers and providers about the latest developments in telemedicine.

The Office for the Advancement of Telehealth carries out the following functions: (1) Develops and coordinates telehealth network and telehealth resource centers grant programs; (2) provides professional assistance and support in developing telehealth initiatives; and (3) administers grant programs to promulgate and evaluate the use of appropriate telehealth

technologies among HRSA grantees and others.

Office of Special Health Initiatives (RA4)

Office of the Director (RA4)

The Office of Special Health Initiatives (OSHI) provides a crosscutting focal point for HRSA to deliver on population health and Secretarial priorities, especially those that may be more clinical in nature. Specifically, OSHI (1) coordinates and collaborates with components in the Department of Health and Human Services (HHS) that align with the work of OSHI; (2) serves as the principal advisor within HRSA on global health issues; (3) provides agency-wide leadership and policy development in the administration of the 340B Drug Pricing Program to promote access to clinically and cost effective pharmacy services to the country's most vulnerable patient populations; (4) serves as the lead on behavioral health issues that span HRSA; (5) provides cross-cutting leadership on HRSA oral health programs; and (6) directs and administers the National Vaccine Injury Compensation Program.

Office of Pharmacy Affairs (RA41)

The Office of Pharmacy Affairs promotes access to clinical and cost effective pharmacy services to enable participating entities to stretch scarce federal resources in order to serve more patients, expand their services, or offer additional services. Specifically, the Office of Pharmacy Affairs: (1) Manages the 340B Drug Pricing Program involvement of pharmaceutical manufacturers that participate in the Medicaid program, through Pharmaceutical Pricing Agreements; (2) maintains a publicly accessible database of participating covered entities, sites, and contract pharmacies; (3) publishes guidelines/regulations to assist in the understanding and participation in the 340B Program; (4) maintains a Prime Vendor Program to increase the value of the 340B Program; (5) provides technical assistance to Program stakeholders to support their appropriate and best use of the 340B Program; (6) fosters mutually productive relationships with federal and private sector partners; (7) provides a national platform for the coordination and development of leading practices for pharmacy services; (8) promotes comprehensive and efficient pharmacy management application and systems use to ensure safe and effective medication use; (9) manages quality improvement activities; and (10) promotes program integrity compliance and improvement activities.

Office of Global Health (RA42)

The Office of Global Health provides expertise and advises HRSA on global health issues. Specifically, the Office of Global Health: (1) Provides leadership, coordination, and advancement of global health programs relating to sustainable health systems for vulnerable and at-risk populations; (2) provides leadership within HRSA for the support of global health and coordinates policy development with the HHS Office of Global Affairs, other departmental agencies, bilateral/multilateral organizations, and other international organizations and partners; (3) monitors HRSA's border health activities and investments, in partnership with HRSA's Office of Regional Operations, to promote collaboration and improve health care access to those living along the U.S. borders, such as the U.S.-Mexico border and the U.S. Affiliated Pacific Islands; (4) provides management and oversight of international programs aimed at improving quality and innovation in human resources for health, health workforce recruitment, education, retention, and applied research systems; (5) supports and conducts programs associated with the international migration and recruitment of health personnel, foreign, and immigrant health workers; (6) provides support for the agency's international travel and the Department of State's International Visitors Leadership Program; and (7) provides national leadership, including serving as the Deputy Principal representative and providing support to the HRSA Administrator, implements training, and systems strengthening functions of the Global HIV/AIDS Program as part of the President's Emergency Plan for AIDS Relief (PEPFAR).

Division of Global Programs (RA421)

The Division of Global HIV/AIDS Program provides national leadership, implements training, and systems strengthening functions of the Global HIV/AIDS Program as part of PEPFAR. This includes strengthening health systems for delivery of prevention, care and treatment services for people with HIV/AIDS in PEPFAR-funded countries and providing management and oversight of international programs aimed at improving quality and innovation in health professions education and training. The Division shares lessons learned from both the domestic and Global HIV/AIDS Programs grant recipient community.

The Division of Global HIV/AIDS Program provides leadership in improving care, treatment, and support services for people with HIV/AIDS outside of the United States and its territories. Specifically, the Division: (1) In coordination with the Department of State's Office of the Global AIDS Coordinator, plans, develops, implements, evaluates, and coordinates the activities of the clinical assessment system strengthening; (2) provides guidance and expertise to funded programs; (3) develops funding opportunity announcements and program guidance documents; (4) conducts on-site program reviews and reviews of pertinent and required reports, and activities to assess compliance with program policies and country priorities; (5) in conjunction with other division, bureau, and agency entities, assists in the planning and implementation of priority HIV activities such as workgroups, meetings, and evaluation projects; (6) collaborates with other federal agencies and in-country partners in the implementation of the PEPFAR program, and (7) provides management and oversight of international programs aimed at improving quality and innovation in health professions education, retention, training, faculty development, and applied research systems.

Division of Injury Compensation Programs (RA43)

The Division of Injury Compensation Programs, on behalf of the Secretary of HHS, administers and implements all statutory and charter authorities related to the operations of the National Vaccine Injury Compensation Program, the Countermeasures Injury Compensation Program, and the HHS Medical Review Claims Panel by: (1) Evaluating claims for compensation filed under the National Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program through medical review and assessment of compensability for all complete claims; (2) processing awards for compensation made under the National Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program; (3) promulgating regulations to develop and revise Vaccine and Countermeasures Injury Tables; (4) providing professional and administrative support to the Advisory Commission on Childhood Vaccines (ACCV) and the Medical Claims Review Panel; (5) maintaining responsibility for activities related to the ACCV including the development of policy, regulations, budget formulation, and legislation; the development and

renewal of its charter and action memoranda to the Secretary; and the analysis of its findings and proposals; (6) developing and maintaining all automated information systems necessary for program implementation; (7) developing and disseminating program information; (8) maintaining a working relationship with the Department of Justice (DOJ) and the U.S. Court of Federal Claims through the DOJ, in the administration and operation of the National Vaccine Injury Compensation Program; (9) providing management, direction, budgetary oversight, coordination, and logistical support for the Medical Expert Panel, as well as Clinical Reviewer contracts; (10) developing, reviewing, and analyzing pending and new legislation relating to program changes, new initiatives, the ACCV, and changes to the Vaccine and Countermeasures Injury Tables, in coordination with the Office of the General Counsel; (11) providing programmatic outreach efforts to maximize public exposure to private and public constituencies; (12) providing submission of special reports to the Secretary of HHS, the Office of Management and Budget, Congress, and other governmental bodies; and (13) providing guidance in using the results and decisions of the Medical Claims Review Panel to HHS Operating Divisions to improve the quality of health care in its facilities and by its practitioners.

Chapter RH—Federal Office of Rural Health Policy

Section RH.10 Organization

Delete the organization for the Federal Office of Rural Health Policy (RH) in its entirety and replace with the following:

The Federal Office of Rural Health Policy (RH) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Federal Office of Rural Health Policy includes the following components:

(1) Office of the Associate Administrator (RH);

(2) Hospital State Division (RH1);

(3) Community-Based Division (RH2);

(4) Policy Research Division (RH5);

(5) Administrative Operations Division (RH6); and

(6) Rural Strategic Initiatives Division (RH7).

Section RH.20 Function

Delete the functional statement for the Office of the Associate Administrator and replace with the following:

Federal Office of Rural Health Policy

Office of the Associate Administrator (RH)

The Federal Office of Rural Health Policy (FORHP) is responsible for the overall leadership and management of the Office. FORHP serves as a focal point within HHS for rural health-related issues and as a principal source of advice to the Secretary for coordinating efforts to strengthen and improve the delivery of health services to populations in the nation's rural areas. FORHP provides leadership within HHS and with stakeholders in providing information and counsel related to access to, and financing and quality of, health care to rural populations. Specifically, the Office of the Associate Administrator (1) Provides staff support to the National Advisory Committee on Rural Health and Human Services; (2) stimulates and coordinates interaction on rural health activities and programs in the agency, Department and with other federal agencies; (3) directs and oversees the development and implementation of a research agenda that supports delivery of health services in rural areas; (4) provides overall direction and leadership over the management of nationwide community-based rural health grants programs; (5) provides overall direction and leadership over the management of a program of state grants which supports collaboration within state offices of rural health; (6) provides overall direction and leadership over the Office's administrative and management functions; and (7) provides overall direction and leadership over the Office's new rural health program initiatives created as a result of agency, Department and/or administrative priorities.

Chapter RD—Office of Provider Support

Chapter RD.00 Mission

The Office of Provider Support ensures resiliency of the nation's health care systems and infrastructure by supporting health care entities in the U.S. to prevent, prepare for and respond to coronavirus disease 2019 (COVID–19).

Section RD.10 Organization

Establish the Office of Provider Support organization as follows:

The Office of Provider Support (RD) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Office of Provider Support includes the following components:

(1) Office of the Associate Administrator (RD);

(2) Division of Provider Support (RD1);

(3) Division of Customer Support (RD2); and

(4) Division of Data Analytics and Program Integrity (RD3).

Section RD. Function

Establish the function of the Office of Provider Support (RD) as follows:

Office of Provider Support (RD)

The Office of Provider Support ensures resiliency of the nation's health care systems and infrastructure by supporting health care entities in the U.S. to prevent, prepare for and respond to coronavirus. The Office reimburses health care providers for health care related expenses or lost revenues attributable to coronavirus and to provides claims reimbursement for health care entities for COVID–19 testing and treatment for uninsured individuals.

Office of the Associate Administrator (RD)

The Office of the Associate Administrator provides overall leadership, direction, coordination, and planning in support of the programs designed to make payments to health care providers for expenses and lost revenue related to COVID–19 and to reimburse health care entities' claims for COVID–19 testing and/or treatment of uninsured individuals, helping to ensure a sustained, robust health care system. The Office guides and directs the development of policy priorities for the allocation of payments and claims reimbursements and ensures the proper management of programs. Specifically, the Office of the Associate Administrator: (1) Provides overall direction and leadership over the management of funds to reimburse health care providers for expenses and lost revenue related to COVID–19; (2) provides overall direction and leadership over the management of funds dedicated specifically for the testing and treatment of the uninsured individuals with possible or actual cases of COVID–19; (3) directs data collection and analysis in support of program execution; (4) provides oversight of an audit protocol and plan that monitors proper execution of funds; (5) ensures compliance with regulations and limits risk through establishment and maintenance of a system of internal controls; (6) maintains effective relationships within HRSA and with other federal and nonfederal agencies, state, and local governments, and other public and private organizations associated with the response to COVID–

19; (7) plans, directs, coordinates, and evaluates the Office's administrative and management functions, *e.g.,* budget, personnel, procurements, delegations of authority, and responsibilities related to the awarding of program funds; (8) represents the Office, agency, and federal government, as designated, with other federal and non-federal agencies, state and local governments, and other public and private organizations concerned with the response to COVID–19 and the resiliency of the national healthcare systems; and (9) coordinates, reviews, and provides clearance of correspondence and official documents entering and leaving the Office.

Division of Policy and Program Operations (RD1)

The Division of Policy and Program Operations is the focal point for the policy development, program operations, and communications operations for Office programs. Specifically, the Division of Policy and Program Operations: (1) Works with the contractor to ensure effective and efficient program operations; (2) leads and coordinates the analysis, development, and drafting of policies impacting Office programs; (3) analyzes issues arising from legislation, budget proposals, regulatory actions and other program or policy actions; (4) works collaboratively with other components within HRSA and HHS, and with other federal agencies, state and local governments, and public and private organizations on issues affecting Office programs and policies; (5) keeps Congress apprised of programs and activities as necessary; (6) links Office programs to HRSA-wide policy development, analyses, and evaluation as applicable; (7) serves as a key point of contact to coordinate, review and clear congressional, Executive Branch and other stakeholder group inquiries in conjunction with the agency and the Department; (8) serves as a key point of contact to coordinate activities related to congressional inquiries, and other stakeholder groups in conjunction with the agency and Department; and (9) assumes special projects or takes the lead on certain issues as tasked by the Office's leadership.

Division of Customer Support (RD2)

The Division of Customer Support serves as the organizational focal point for the Office's centralized, comprehensive customer service function to support recipients or potential recipients of program funds. The Division provides responses to provider inquiries that arrive at the Office through a variety of channels including providers, health delivery entities, stakeholders, Congress, and others.

Division of Data Analytics and Program Integrity (RD3)

The Division of Data Analytics and Program Integrity is responsible for the collection, management, and analysis of the data needed for the Provider Relief Fund and COVID–19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration of the Uninsured Program, and for ensuring the overall integrity of the programs and payments made. Specifically, the Division of Data Analytics and Program Integrity: (1) Maintains data and analytic capabilities to inform policy decisions and to support Office functions; (2) develops and manages Office data strategy; and (3) develops and manages Office program and payment integrity strategy.

Chapter RC—Bureau of Primary Health Care

Section RC.10 Organization

Delete the organization for the Bureau of Primary Health Care (RC) in its entirety and replace with the following:

The Bureau of Primary Health Care (RC) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Bureau of Primary Health Care (RC) includes the following components:

(1) Office of the Associate Administrator (RC);

(2) Division of Workforce Management (RC2);

(3) Division of National Hansen's Disease Program (RC4);

(4) Office of Strategic Business Operations (RCA);

(5) Office of Health Center Investment Oversight (RCC);

(6) Office of Health Center Program Monitoring (RCF);

(7) Office of Policy and Program Development (RCH); and

(8) Office of Quality Improvement (RCK).

Section RC.20 Function

Delete the functional statement for the Bureau of Primary Health Care (RC) in its entirety and replace with the following:

Bureau of Primary Health Care

Office of the Associate Administrator (RC)

Provides overall leadership, direction, coordination, and planning in support of BPHC programs. Specifically, the Office of the Associate Administrator: (1) Establishes program goals, objectives, and priorities, and provides oversight to their execution; (2) plans, directs, coordinates, supports, and evaluates bureau wide management activities; (3) maintains effective relationships within HRSA and with other HHS organizations, other federal agencies, state and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the nation's underserved and vulnerable populations; and (4) manages the National Hansen's Disease Program in accordance with regulations of the Public Health Service (PHS) Act.

Division of Workforce Management (RC2)

The Division of Workforce Management plans, directs, and coordinates bureau-wide administrative management activities and serves as the organizational focus for bureau workforce staff development and evaluation efforts in support of organizational goals and objectives. Specifically, the Division of Workforce Management: (1) Serves as the Bureau of Primary Health Care's principal source for administrative and management advice, analysis, and assistance; (2) provides strategic guidance and coordinates personnel activities for the bureau, including the allocation of personnel resources; (3) develops policies and procedures for internal operations, interpreting and implementing management policies, procedures and systems; (4) develops and coordinates bureau program and administrative delegations of authority activities; (5) provides guidance to the bureau on financial management activities; (6) provides bureau-wide support services such as continuity of operations and emergency planning, procurement planning and coordination, supply management, equipment utilization, workforce planning, printing, property management, space management, and management reports; (7) plans and implements strategies for development of staff and succession planning; and (8) coordinates bureau administrative management and workforce activities with other components within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations, as appropriate.

Division of National Hansen's Disease Program (RC4)

The National Hansen's Disease Program, in accordance with regulations

and the PHS Act, Sec. 320 as amended by Public Law 105–78, Sec. 211, (1) provides care and treatment for persons with Hansen's Disease (leprosy), including managing a national short-term and outpatient health care delivery program providing specialized services to persons with Hansen's Disease; (2) conducts and promotes the coordination of research (including clinical research), investigations, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of Hansen's disease and other mycobacterial diseases and complications related to such diseases; (3) conducts training in the diagnosis and management of Hansen's disease and related complications; (4) provides education and training to staff from the outpatient Hansen's Disease Clinics and to private physicians; (5) operates and oversees the National Hansen's Disease Museum and Cemetery; (6) consults on the coordination of activities within HRSA and HHS and with other federal agencies, state, and local governments, and other public and private organizations involved in Hansen's Disease activities; (7) manages a network of contracted outpatient clinics providing care to persons with Hansen's Disease; and (8) manages and coordinates the National Hansen's Disease Program's administrative and operational activities with HRSA and HHS, other federal agencies, state and local governments; and other public and private organizations involved in Hansen's Disease activities.

Office of Strategic Business Operations (RCA)

The Office of Strategic Business Operations serves as the organizational focus for the development of the Bureau of Primary Health Care external affairs, organizational data development and analysis, and management information systems to meet the goals and objectives of the bureau. Specifically, the Office of Strategic Business Operations: (1) Serves as the bureau's focal point for communication and program information dissemination; (2) serves as the bureau's Executive Secretariat and focal point for records management policies and guidance; (3) leads strategic data analytics for bureau operations; (4) monitors bureau activities in relation to HRSA and HHS Strategic Plans; (5) serves as the bureau focal point for the design and implementation of management information systems to assist and improve program performance and internal operations; and (6) consults and coordinates bureau external affairs, business analytics, and information systems with other components within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations.

Office of Health Center Investment Oversight (RCC)

The Office of Health Center Investment Oversight oversees the Bureau of Primary Health Care's primary health care service delivery programs, including initiatives focused on special populations and associated activities within all HHS Regions. Specifically, the Office of Health Center Investment Oversight: (1) Oversees bureau primary health care service delivery programs for compliance with funding requirements; (2) monitors the performance of bureau primary health care service delivery programs, making programmatic recommendations and providing assistance to improve performance, where appropriate; (3) reviews findings, analyzes data, and provides recommendations through periodic and episodic grantee funding progress assessments; and (4) provides consultation to and coordinates activities within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations involved in the implementation of bureau primary health care service delivery programs.

Office of Health Center Program Monitoring (RCF)

The Office of Health Center Program Monitoring oversees the Bureau of Primary Health Care's primary health care service delivery programs, including those focused on special populations, and associated activities within all HHS Regions. Specifically, the Office of Health Center Program Monitoring: (1) Oversees bureau primary health care service delivery programs for compliance with program requirements; (2) provides assistance on program-related statutory/regulatory policy and program requirements; (3) reviews findings, analyzes data, and provides recommendations through periodic and episodic grantee compliance assessments; and (4) provides consultation to and coordinates activities within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations involved in the implementation of bureau primary health care service delivery programs.

Office of Policy and Program Development (RCH)

The Office of Policy and Program Development serves as the organizational focus for the development of the Bureau of Primary Health Care programs and policies. Specifically, the Office of Policy and Program Development: (1) Leads and monitors the strategic development of primary care programs, including health centers, special population programs, and other health systems; (2) provides assistance to communities, community-based organizations, and bureau programs related to the development and expansion of primary care; (3) develops bureau capital programs and oversees loan guarantee programs, including the awarding of new grants under section 1610(b) of the PHS Act, under the Health Care and Other Facilities grant program, and under the Patient Protection and Affordable Care Act, Public Law 111–148; (4) leads and coordinates the analysis, development, and drafting of budget and policy impacting bureau programs; (5) provides support to the National Advisory Council on Migrant Health; (6) performs environmental scanning on issues that affect bureau programs; and (7) consults and coordinates with other components within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations on issues affecting bureau programs and policies.

Office of Quality Improvement (RCK)

The Office of Quality Improvement serves as the organizational focus for program quality including clinical and operational quality improvement, patient safety and risk management, data reporting, and program evaluation. Specifically, the Office of Quality Improvement: (1) Provides leadership for implementing bureau clinical quality improvement strategies/initiatives, including health information technology; (2) oversees the bureau's Federal Tort Claims Act medical malpractice liability programs, reviewing risk management and patient safety activities to improve policies and programs for primary health care services, including clinical information systems; (3) leads and coordinates the bureau's national and state technical assistance/programs and activities, including those focused on special populations; (4) identifies, provides assistance, and supports bureau programs around quality improvement and performance reporting activities; (5) oversees bureau programs related to health information technology and quality improvement; (6) serves as the bureau's focal point for the design and implementation of program evaluations and research; (7) coordinates and supports emergency preparedness and

response for bureau programs; and (8) coordinates bureau/quality improvement and performance reporting activities within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the nation's underserved and vulnerable populations.

Chapter RM—Maternal and Child Health Bureau

Section RM.20 Function

Delete the functional statement for the Division of Child, Adolescent and Family Health (RM3) and replace with the following:

Division of Child, Adolescent and Family Health (RM3)

The Division of Child, Adolescent and Family Health provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on the promotion of health and prevention of disease and injury among children, adolescents, young adults and their families with special emphasis on the development and implementation of family-centered, comprehensive, coordinated, community-based, and culturally competent systems of care for such populations. Specifically, the Division: (1) Administers a program which supports the development of systems of care and services for children, adolescents, young adults, and their families; (2) develops policies and guidelines and promulgates standards for professional services and effective organization and administration of health programs for children, adolescents, young adults, and their families; (3) accounts for the administration of funds and other resources for grants, contracts, and programmatic consultation and assistance; (4) coordinates with the Maternal and Child Health Bureau Divisions and Offices in promoting program objectives and the mission of the bureau; (5) serves as the focal point within the bureau in implementing programmatic statutory requirements for state programs for children, adolescents, young adults, and their families; (6) provides consultation and technical assistance to state programs for children, adolescents, young adults, and their families and to local communities, consistent with a bureau-wide technical assistance consultation plan, working with other agencies and organizations; (7) provides liaison with public, private, professional and voluntary organizations on programs designed to improve services for children, adolescents, young adults, and their families; (8) carries out a national program supporting Child Death Review systems; (9) carries out a national program on school health activities; (10) carries out a national program designed to improve the provision of emergency medical services for children; (11) administers the Poison Control Program; (12) carries out a national program designed to improve the provision of oral health services for children; (13) carries out a national program on injury prevention for children and adolescents; (14) coordinates within this agency and with other federal programs (particularly Title XIX of the Social Security Act) to extend and improve comprehensive, coordinated services and promote integrated state-based systems of care for children, adolescents, young adults, and their families; (15) disseminates information on preventive health services and advances in the care and treatment of children, adolescents, young adults, and their families; (16) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to health services for children, adolescents, young adults, and their families; and (17) administers funds and other resources for grants, contracts, and cooperative agreements.

Chapter RR—Healthcare Systems Bureau

Section RR.10 Organization

Delete the organization for the Healthcare Systems Bureau (RR) in its entirety.

Section R.30, Delegation of Authority

All delegations of authority and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, if allowed, provided they are consistent with this reorganization.

This reorganization is effective upon date of signature.

Authority: 44 U.S.C. 3101

Dated: January 14, 2021.

Alex M Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–01227 Filed 1–15–21; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

January 7, 2021.

AGENCY: Office of the General Counsel, Office of the Secretary, HHS.

SUMMARY: This document revises and restates the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Office of the General Counsel (OGC), to reflect, among other things, OGC participation in the Inter-Agency False Claims Act Working Group and re-allocation of responsibilities concerning certain requests under the Freedom of Information Act. Issuance of this Statement of Organization rescinds all prior Statements of Organization.

SUPPLEMENTARY INFORMATION: The Office of the Secretary (OS)'s Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Office of the General Counsel (OGC), should now read as follows:

Section I. Mission. The Mission of the Office of the General Counsel and the General Counsel, who is the special advisor to the Secretary on legal matters, is to provide all legal services and advice to the Secretary, Deputy Secretary, and all subordinate organizational components of the Department.

Section II. Organization. The Office of the General Counsel, under the supervision of a General Counsel, consists of:

1. The General Counsel and Immediate Office of the General Counsel
2. Divisions in the Office of the General Counsel
3. Ten Regional Offices

Subsection A. The Immediate Office of the General Counsel

1. The Immediate Office of the General Counsel. The Immediate Office of the General Counsel shall consist of the General Counsel, his or her executive assistant, a Principal Deputy General Counsel, such other Deputy General Counsel, both non-career and career, as the Secretary deems appropriate and appoints, Associate and Assistant Deputy General Counsel, Senior Counsel, and such other attorneys and assistants as the General Counsel deems appropriate, and the Office of Legal Resources (OLR).

a. The General Counsel. The General Counsel is the chief legal officer of the

Department and is directly responsible to the Secretary.

b. Principal Deputy General Counsel. The Principal Deputy General Counsel shall be the second-ranking legal officer of the Department and is directly responsible to the General Counsel and the Secretary. He or she may act in the stead of the General Counsel when the General Counsel is absent or unavailable.

c. Deputy General Counsel. The Deputy General Counsel report to the General Counsel and each shall be responsible for overseeing such substantive areas as designated by the General Counsel. In certain instances, a Deputy General Counsel may be appointed by the Secretary or assigned by the General Counsel to serve as the chief counsel of an operating division.

(1) Non-Career Deputy General Counsel. Non-career Deputy General Counsel report to the General Counsel and each shall be responsible for overseeing the substantive legal areas and corresponding OGC components designated by the General Counsel.

(2) Career Deputy General Counsel. There shall be two career Deputy General Counsel who report to the General Counsel. First, a Deputy General Counsel who shall oversee OLR, the General Law Division (GLD), the ten Regional Offices, and will be generally responsible for OGC management and operations subject to the direction of the General Counsel. Second, a Deputy General Counsel who shall oversee litigation and the National Complex Litigation and Investigations Division (NCLID).

d. Associate General Counsel. Associate General Counsel either head a Division within OGC or are located in the Immediate Office. In either event, Associate General Counsel report to the General Counsel or to such Deputy General Counsel as the General Counsel may designate.

e. Associate or Assistant Deputy General Counsel to the General Counsel. The General Counsel may designate one or more attorneys to act as his or her special assistant and to carry the title of Associate Deputy General Counsel or Assistant Deputy General Counsel, all of whom shall report directly to the General Counsel or to such Deputy General Counsel as the General Counsel may designate.

f. Senior Counsel or Senior Advisor to the General Counsel. Senior Counsel or Senior Advisor to the General Counsel perform such duties as may be assigned to them by the General Counsel, Deputy General Counsel, or Associate General Counsel. At least one Senior Counsel or Senior Advisor should have a security clearance of the level and type deemed appropriate by the General Counsel.

g. Office of Legal Resources. The Office of Legal Resources within the Immediate Office of the General Counsel, headed by a director, is responsible for providing personnel, budget, correspondence, and information technology support to the Office of the General Counsel.

2. Relation of Immediate Office to the Divisions and Regions. Each division and each region is under the general supervision of the General Counsel and the assigned Deputy General Counsel, unless that Division is headed by a Deputy General Counsel. Each Divisional Associate General Counsel and Regional Chief Counsel reports directly to the assigned Deputy General Counsel on substantive legal matters, litigation strategy, and other matters as directed by the General Counsel.

3. Order of Succession.

a. General Counsel Vacancy. In the event of the General Counsel's absence, or in the event of a ''vacancy'' in the position of General Counsel as a result of death, resignation, or an inability to perform the functions and duties of the office, the Principal Deputy General Counsel shall act in the General Counsel's stead, or serve as the Acting General Counsel as dictated by the Vacancies Reform Act of 1998, 5 U.S.C. 3345 *et seq.*

b. Principal Deputy General Counsel Vacancy. In the event of the absence of or vacancies in offices of both the General Counsel and the Principal Deputy General Counsel, the non-career Deputy General Counsel with the greatest seniority in that position shall perform the functions of or serve as the Acting General Counsel as dictated by the Vacancies Reform Act of 1998. In the event that the disabilities or vacancies extend to or include all non-career deputies, then the career Deputy General Counsel with the greatest seniority in that position shall act in or serve as the Acting General Counsel as dictated by the Vacancies Reform Act of 1998.

Subsection B. Divisions in the Office of the General Counsel

The Office of the General Counsel's nine divisions are as follows: General Law Division (GLD); the Children, Families and Aging Division (CFAD); the Ethics Division (ETHICSD); the Food and Drug Division (FDD); the Public Health Division (Ph.D.); the Legislative Division (LEGD); the Centers for Medicare & Medicaid Services Division (CMSD); the Civil Rights Division (CRD); and National Complex Litigation and Investigations Division (NCLID). Each Division shall be headed by either an Associate General Counsel or Deputy General Counsel, as determined by the General Counsel.

1. The General Law Division shall be headed by an Associate General Counsel who reports to the General Counsel through a career Deputy General Counsel. The Division consists of two branches, each headed by a Deputy Associate General Counsel reporting to the Associate General Counsel:

a. Claims and Employment Law Branch
b. Procurement, Fiscal, and Information Law Branch

2. The Children, Families, and Aging Division shall be headed by an Associate General Counsel who reports to the General Counsel through a designated Deputy General Counsel.

3. The Ethics Division shall be headed by an Associate General Counsel who reports to the General Counsel. The Division consists of two branches, each headed by a Deputy Associate General Counsel reporting to the Associate General Counsel:

a. Ethics Advice and Policy Branch
b. Ethics Program Administration Branch

The Associate General Counsel and Deputy Associate for Ethics Advice and Policy simultaneously serve by secretarial delegation as the Department's Designated Agency Ethics Official and Alternate Designated Agency Ethics Official, respectively.

4. The Food and Drug Division shall be headed by a Chief Counsel who shall be either a Deputy General Counsel or Associate General Counsel. In the event that the Chief Counsel is an Associate General Counsel, he or she shall report to the General Counsel through a designated Deputy General Counsel. The Division consists of two major branches, each of which is headed by a Deputy Associate General Counsel who reports to the Chief Counsel, as follows:

a. Litigation Branch
b. Program Review Branch, divided into the following three sub-branches:
(1) Foods & Veterinary Medicine
(2) Drugs and Biologics
(3) Tobacco & Devices

5. The Public Health Division shall be headed by an Associate General Counsel who reports to the General Counsel through a designated Deputy General Counsel. The Division is divided into four branches, each of which is headed by a Deputy Associate General Counsel reporting to the Associate General Counsel:

a. Indian Health Service Branch
b. Centers for Disease Control and Prevention Branch

c. National Institutes of Health Branch
d. Public Health and Science Branch

6. The Legislation Division shall be headed by an Associate General Counsel who reports to the General Counsel through a designated Deputy General Counsel.

7. The Centers for Medicare & Medicaid Services Division shall be headed by a Chief Legal Officer who shall be either a Deputy General Counsel or an Associate General Counsel. The Division consists of three major organizational groups, each of which is headed by a Deputy Associate General Counsel reporting to the Associate General Counsel or the Deputy General Counsel through an Associate General Counsel, as follows:

a. Litigation Group
b. Program Review Group
c. Program Integrity Group

8. The Civil Rights Division shall be headed by an Associate General Counsel who reports to the General Counsel through a designated Deputy General Counsel, and by a Deputy Associate General Counsel who reports to the Associate General Counsel.

9. The National Complex Litigation and Investigations Division (NCLID) has an Associate General Counsel who reports to General Counsel through a career Deputy General Counsel. In addition, NCLID has a Deputy Associate General Counsel for E-Discovery who reports to the Associate General Counsel.

Subsection C. Regional Offices

There are ten regional offices. Each regional office has a Chief Counsel who reports to the General Counsel through a designated career Deputy General Counsel. Regional offices may also have one or more Deputy Chief Counsel who report to the Chief Counsel. The regional offices are located in the following cities and provide legal services to the Department in the following states and territories:

1. Region I—Boston (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont)
2. Region II—New York City (New York, New Jersey, Puerto Rico, Virgin Islands)
3. Region III—Philadelphia (Delaware, Maryland, Pennsylvania, Virginia, West Virginia, District of Columbia)
4. Region IV—Atlanta (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee)
5. Region V—Chicago (Illinois, Indiana, Ohio, Michigan, Minnesota, Wisconsin)
6. Region VI—Dallas (Arkansas, Louisiana, New Mexico, Oklahoma, Texas)
7. Region VII—Kansas City, MO (Iowa, Kansas, Missouri, Nebraska)
8. Region VIII—Denver (Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming)
9. Region IX—San Francisco (Arizona, California, Hawaii, Nevada, Guam, American Samoa, Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau)
10. Region X—Seattle (Alaska, Idaho, Oregon, Washington)

Section III. Functions

A. General Counsel and Immediate Office of the General Counsel

1. The General Counsel. The General Counsel is authorized to promulgate such directives and issue such legal opinions as may be necessary to carry out the responsibilities of the Office. The General Counsel directly (or through attorneys in the Office of the General Counsel), undertakes the following activities unless an applicable statute provides otherwise or the General Counsel has delegated the responsibility elsewhere:

a. Furnishes all legal services and advice to the Secretary, Deputy Secretary, and all offices, branches, or units of the Department in connection with the operations and administration of the Department and its programs, except with respect to functions expressly delegated by statute to the Inspector General.

b. Furnishes legal services and advice on such other matters as may be submitted by the Secretary, the Deputy Secretary, any other senior leaders, and other persons authorized by the Secretary to request such service or advice.

c. Represents the Department in all litigation when such direct representation is not precluded by law, and in other cases, making and supervising all contacts with attorneys responsible for the conduct of such litigation.

d. Acts as the Department's sole representative in communicating with the Department of Justice, including all United States Attorneys, on all civil matters and on all criminal matters, other than those criminal matters referred to the Department of Justice by the Inspector General.

e. Acts as the Department's sole representative in communicating with Office of White House Counsel or the Offices of General Counsel for any other Department or Agency.

f. Performs all liaison functions in connection with legal matters involving the Department, and formulating or reviewing requests for formal opinions or rulings by the Attorney General and the Comptroller General.

g. Issues pre-enforcement rulings or advisory opinions to the public on questions of law, except to the extent that that such authority has previously been delegated to the Inspector General under section 1128D of the Social Security Act.

h. Authorizes indemnification, as appropriate, pursuant to 45 CFR pt. 36.

i. Conducts internal investigations at the request of the Secretary or Deputy Secretary, or for matters that could lead to litigation.

j. Drafts all proposals for legislation originating in the Department and reviewing all proposed legislation submitted to the Department or to any operating agency of the Department for comment; preparing reports and letters to congressional committees, the Office of Management and Budget, and others on proposed legislation; and prescribing procedures to govern the routing and review, within the Department, of material relating to proposed Federal legislation.

k. Performs liaison functions with the Office of the Federal Register, National Archives and Records Service.

l. Reviews and approves all administrative complaints and enforcement actions by any agency within the Department before those complaints are filed or transmitted, or enforcement actions instituted to ensure that the complaint or enforcement action is legally sound.

m. Leads all negotiations on behalf of any agency within the Department.

n. Supervises all legal activities of the Department and its operating agencies.

o. Ensures that no one in the Department, other than those in OGC or expressly authorized by statute to do so, provides any legal advice to anyone in the Department or uses any title that implies that they are functioning as a departmental lawyer.

2. Principal Deputy General Counsel. The Principal Deputy General Counsel is the second ranking legal officer in the Department and performs the functions of the General Counsel in his or her absence or disability, including recusal, and, unless otherwise noted, oversees for the General Counsel all litigation involving the Department, its officers, inferior officers, and employees.

3. Deputy General Counsel. The Deputy General Counsel assist the General Counsel in carrying out his or her responsibilities and performs such duties as the General Counsel or

Principal Deputy General Counsel may assign. The Associate General Counsel for a Division shall report to the General Counsel through one or more Deputy General Counsel, as may be assigned by the General Counsel. Regional Chief Counsel shall report to the General Counsel through a career Deputy General Counsel.

B. Functions, Authorities and Responsibilities of the Division

The Divisions within OGC provide legal counsel to their clients, as described below, subject to the professional supervision and control of the General Counsel and assigned Deputy General Counsel.

1. *General Law Division.* The General Law Division, acting through its Associate General Counsel, performs the following:

a. Provides legal services on business management activities and administrative operations throughout the Department, including employment, compensation, personnel, appropriations, real and personal property (including National Environmental Policy Act), procurement, information, travel, and certain claims by and against the Department.

b. Represents the Department in all aspects of administrative litigation before the Merit Systems Protection Board (MSPB), Equal Employment Opportunity Commission (EEOC), and in labor arbitrations, as needed. Acts as agency counsel in support of the Department of Justice on employment cases filed in federal court.

c. Represents the Department in bid protests filed before the Comptroller General and contract disputes filed before the Civilian Board of Contract Appeals. Acts as agency counsel in support of the Department of Justice in bid protests and contract disputes filed before the U.S. Court of Federal Claims and appealed to the Federal Circuit.

d. Except as noted, provides legal services to Department Freedom of Information Act (FOIA) Officers on the disclosure of agency records requested under FOIA, and communicates with the Department of Justice on the administration of the Freedom of Information Act.

e. Provides legal services to the Department on the Privacy Act of 1974, as amended, the Paperwork Reduction Act, the Federal Records Act, and the Government in the Sunshine Act.

f. Provides all legal services with respect to the formation, maintenance, and administration of the advisory committees under the Federal Advisory Committee Act.

g. Acts as the Department Claims Officer, responsible for adjudicating all administrative claims filed under the Federal Tort Claims Act, approval of claims filed under the Federal Medicare Recovery Claims Act in amounts of at least $20,000 but not exceeding $300,000, tort liability claims under the U.S. Constitution and other laws under which claims for money damages may be filed with the Department, as provided by 5 U.S.C. 5584, 10 U.S.C. 2774, except for claims arising under the Social Security Act. Also responsible for making final determinations on legally enforceable non tax debts owed to the United States government arising from HHS programs under the Federal Claims Collection Act, as amended, 31 U.S.C. 3711 *et seq.,* on the compromise of, and the suspension or termination of collection activities for, claims in amounts of $100,000 or less, exclusive of interest, and on the waiver of interest.

2. *Children, Families, and Aging Division.* The Children, Families, and Aging Division Provides legal services to the Administration for Children and Families and its various agencies including the Office of Refugee Resettlement and Administration for Community Living.

3. *Ethics Division.* The Ethics Division administers and oversees Department-wide implementation of comprehensive government ethics program requirements under the Ethics in Government Act of 1978, as amended, Executive Order 12731, and implementing regulations at 5 CFR part 2638. The Division, without limitation, performs the following:

a. Provides legal advice and policy guidance on interpretation and compliance issues involving the criminal conflict of interest statutes, 18 U.S.C. 210–219, political activity restrictions, anti-lobbying provisions, outside activity limitations, travel reimbursement guidelines, procurement integrity rules, financial disclosure obligations, and standards of ethical conduct matters including gifts between employees and from outside sources, conflicting financial interests and impartiality concerns, misuse of position and agency resources, and outside employment, fundraising, testimony, and teaching, speaking or writing, to Department officials, agency personnel, advisory committees and others.

b. Reviews executive branch public financial disclosure reports submitted by Presidential nominees/appointees subject to Senate confirmation, non-career SES and Schedule C political appointees, OGC career SES officials, and Op/Staff Division ethics officials (DECs) to assess potential violations of applicable laws or regulations, ensure transparency through accurate reporting, provide counseling on the avoidance of conflicts, and, if necessary, recommending appropriate corrective action, including drafting waivers, disqualification statements, ethics agreements, and certificate of divestiture materials; ensuring identical review and counseling responsibilities with respect to both the public and confidential financial disclosure forms filed by career employees are performed Department-wide by the DECs.

c. Plans, develops, and provides initial ethics orientation for new employees, annual ethics training for employees who file financial disclosure forms and others occupying certain sensitive positions, initial and annual ethics training for members of federal advisory committees, and specialized, topic-specific training on post-employment restrictions, political activity restrictions, insider trading, and procurement integrity rules.

d. Monitors component ethics programs and reviewing compliance with core ethics program elements, including advice, financial disclosure, outside activities, conflict of interest waivers, ethics agreements and travel payments from non-federal sources.

e. Communicates on matters related to government ethics with the Office of Counsel to the President, the Office of Government Ethics, the Office of Special Counsel, the Office of the Inspector General, Special Investigations Unit, the Office of Personnel Management, and the General Services Administration.

f. Develops component-specific conduct regulations and implementing procedures.

4. *Food and Drug Division.* The Food and Drug Division acts as the Commissioner's legal advisor and provides legal services to FDA. FDD, for example, performs the following:

a. Represents the FDA in connection with judicial and administrative proceedings involving programs administered by the FDA. Provides legal advice and policy guidance for programs administered by the FDA.

b. Acts as the Department and FDA's sole liaison to the Department of Justice and other Federal Departments for programs administered by FDA; all criminal prosecutions, investigations, and civil matters may only be referred to the Department of Justice through the Chief Counsel.

c. Drafts or reviews all proposed and final regulations and **Federal Register** notices prepared by FDA.

d. Performs legal research and gives legal opinions on regulatory issues, actions, and petitions submitted to FDA.

e. Reviews proposed legislation affecting FDA that originates in the Department or on which Congress requests the views of the Department.

f. Provides legal advice and assistance to the Office of the Secretary on matters within the expertise of the Chief Counsel.

5. *Public Health Division.* The Public Health Division provides legal services to all Public Health Service agencies (except to the Food and Drug Administration) and their programs, including the Office of the Surgeon General and the Commissioned Corps of the U.S. Public Health Service. Represented Public Health Service agencies include, but are not limited to the (i) the Office of the Assistant Secretary for Health, and its various programs, (ii) the Office of the Secretary's Office of Minority Health, (iii) the Centers for Disease Control and Prevention, (iv) the National Institutes of Health, (v) the Health Resources and Services Administration, (vi) the Indian Health Service, (vii) the Substance Abuse and Mental Health Services Administration, (viii) the Agency for Healthcare Research and Quality, and (ix) the Office of the Assistant Secretary for Preparedness and Response. In addition, the Public Health Service Division serves as the lead office within the Office of the General Counsel for grants-related and intellectual property issues, other than federal court or PTAB litigation.

6. *Legislation Division.* The Legislation Division performs the following:

a. Drafts all proposed legislation originating in the Department, reviewing specifications for such proposed legislation, and reviewing all proposed legislation submitted to the Department or to any constituent unit of the Department for comment.

b. Prepares or reviews reports and letters to Congressional Committees, the Office of Management and Budget, and others on proposed legislation.

c. Reviews proposed testimony of Department officials before Congressional Committees relating to pending or proposed legislation.

d. Acts as Department liaison with the Office of Management and Budget on legislative matters.

e. Prescribes procedures to govern the routing and review, within the Department, of material relating to proposed Federal legislation.

7. *Centers for Medicare & Medicaid Services Division.* The Centers for Medicare & Medicaid Services Division, acting through the Deputy General Counsel serving as the CMS Chief Legal Officer or an Associate General Counsel,

a. Acts as the CMS Administrator's legal advisor.

b. Represents CMS and the Office of the National Coordinator for Health Information Technology (''ONC'') in court proceedings and administrative hearings with respect to programs administered by CMS or ONC.

c. Provides legal advice and policy guidance for programs administered by CMS and ONC.

d. Acts as the Department's and CMS's and ONC's liaison to the Department of Justice and other Federal Departments for programs administered by those operating divisions.

e. Drafts or reviews all proposed and final regulations and **Federal Register** notices prepared by CMS, ONC, and other agencies.

f. Performs legal research and gives legal opinions on regulatory issues, actions, and petitions submitted to CMS and ONC.

g. Reviews proposed legislation affecting CMS, ONC, Office of Medicare Hearing Appeals (OMHA) and DAB that originates in the Department or on which Congress requests the views of the Department.

h. Provides legal advice and assistance to the Office of the Secretary on matters within the expertise of the CMS Chief Legal Officer.

i. Provides legal advice and assistance to the Office of the Secretary on matters relating to the COVID–19 Provider Relief Fund (PRF) and similar provider relief programs, including advice regarding the administration of the PRF, civil litigation relating to the PRF, and fraud and abuse involving PRF payments.

8. *Civil Rights Division.* The Civil Rights Division provides legal services for the Office for Civil Rights (OCR) and provides advice with respect to the civil rights laws to all agencies and offices within the Department. Among other things, CRD evaluates complaints, determines whether there is legal basis to proceed (which determination is binding on OCR), assists OCR in developing and implementing investigation plans, and clears the imposition of any civil money penalties. CRD likewise represents the Department in administrative proceedings and federal litigation, together with the Department of Justice. CRD provides these legal services with respect to:

a. Traditional civil rights laws such as, by way of example, title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.* and 47 U.S.C. 225, 661), section 1557 of the Affordable Care Act (42 U.S.C. 18116).

b. Conscience statutes, such as the Church Amendments, the Weldon Amendment, and the Coats-Snowe Amendment.

c. The Health Insurance and Portability and Accountability Act of 1996 (Social Security Act § 1171 *et seq.*), the Health Information Technology for Economic and Clinical Health (HITECH) Act, and the rules implementing them.

9. *National Complex Litigation and Investigations Division.* The National Complex Litigation and Investigations Division provides legal services across the Department, as directed by the General Counsel or Principal Deputy General Counsel. In that regard, NCLID, performs the following:

a. Coordinates litigation spanning multiple OGC divisions, regional offices, or geographic areas.

b. Reviews all FOIA requests for documents generated by the Secretary or Acting Secretary, or the Chief of Staff, current or former, to either. All productions of documents from the Secretary, Acting Secretary, or Chief of Staff, current or former, must be approved by a career Deputy General Counsel or his or her designee.

c. Serves as the General Counsel's representative(s) to the Inter-Agency False Claims Act Working Group.

d. Provides legal services in connection with complex litigation or anticipated complex litigation by or against the Department. Such litigation may include cases for which other OGC divisions or OGC regions request NCLID participation; cases spanning multiple OGC divisions or regional offices, or cases outside the scope of other OGC divisions or regional offices.

e. Conducts internal investigations at the request of the Secretary or Deputy Secretary, or on matters that could lead to litigation or warrant prompt review.

f. Administers the OGC-wide e-discovery program, and coordinates the use of e-discovery technology with other HHS staff and operating divisions.

g. Identifies and supports the implementation of best practices for litigation management, e-discovery, and virtual staffing across OGC.

C. Functions, Authorities and Responsibilities of the Regions

The Chief Counsel of each Region is HHS' legal representative in that Region. Regional offices within OGC provide a

full range of legal services including, by way of example, legal counsel to their departmental clients and client agencies in the regions, as described below, subject to the professional supervision and direction of the General Counsel.

The Office of the General Counsel's ten regional offices provide legal advice, administrative and judicial litigation support and counseling services to the regional components of the Department. Regional attorneys provide general law support to regional clients and handle work in most areas within HHS' jurisdiction with particular emphasis on litigation for, among others, CMS, ACF, OCR, CDC, and IHS. Regional offices also provide leadership with respect to bankruptcy cases. In the area of civil rights, they work in close consultation with the Associate General Counsel for the Civil Rights Division to ensure that the regional positions align closely with those of the Division thereby fostering national uniformity. In other areas, the Divisions and Regions work collaboratively to provide consistent, uniform legal advice.

Dated: January 11, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–00883 Filed 1–19–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Financial Resources; Statement of Organization, Functions, and Delegations of Authority

SUMMARY: The Department of Health and Human Services (HHS) is updating and realigning a portion of two offices within the Office of the Assistant Secretary for Financial Resources (ASFR), Office of the Secretary: the Immediate Office (AM) and the Office of Finance (AMS) ASFR is modifying its structure to move the Division of Enterprise Risk Management from the Office of Finance to the Immediate Office and establish the Division of Administrative Operations and Grants Quality Service Management Office within the Immediate Office (AM).

FOR FURTHER INFORMATION CONTACT: Christine Jones, Deputy Assistant Secretary Operations and Management, ASFR, 200 Independence Ave, SW, Washington, DC 20201, (202) 690–6061.

SUPPLEMENTARY INFORMATION: Part A (Office of the Secretary), Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AM, Office of Financial Resources, as last amended at 76 FR 69741–42, dated November 9, 2011, and 74 FR 57679–82, dated November 9, 2009. This reorganization modifies ASFR's structure to elevate key Department and Government-wide functions and improve operational functionality by creating the Division of Administrative Operations and the Grants Quality Services Management Office (QSMO) within the Immediate Office of the Assistant Secretary and realigning the Division of Enterprise Risk Management (ERM) from the Office of Finance to the Immediate Office of the Assistant Secretary for Financial Resources This reorganization will make the following changes under Chapter AM, Office of Financial Resources:

I. Under Section AM.10 Organization, insert the following:

A. Immediate Office of the Assistant Secretary (AM). The Immediate Office (IO) is headed by the Deputy Assistant Secretary for Operations and Management and includes the:

- Division of Administrative Operations
- Grants QSMO Office
- Division of Enterprise Risk Management

II. Under Section AM.20 Functions, insert the following sections:

A. Immediate Office of the Assistant Secretary (AM). The Immediate Office (IO) is responsible for support, operations, and coordination required to execute the mission of ASFR including implementation of HHS's Enterprise Risk Management (ERM) program and oversight of the Grants QSMO Office.

(1) Division of Administrative Operations. The Division:

(a) Provides operational support for the ASFR;

(b) Coordinates administrative and operational issues across ASFR.

(c) Leads strategic planning for ASFR;

(d) Serves as the liaison with internal and external stakeholders regarding operational matters;

(e) Leads ASFR workforce development initiatives; and

(f) Leads other activities that enhance ASFR's management and operations

(2) Division of Enterprise Risk Management. The Division:

(a) Coordinates across HHS to establish, and communicate, and sustain HHS's ERM vision, culture, strategy, and framework;

(b) Designs, implements, and matures an ERM capability across HHS, including governance and community management;

(c) Develops and shares tools, guidance, and best practices regarding ERM;

(d) Provides technical assistance and direction to HHS Operating Divisions (OPDIVs) and Staff Divisions (STAFFDIVs) on implementing ERM;

(e) Facilitates strategic initiatives across HHS's risk portfolio including guiding updates of the agency's risk profile, and management's prioritization of risks and opportunities;

(f) Leads the Department's efforts to meet the ERM requirement in OMB Circular A–123, ''Management's Responsibility for Enterprise Risk Management and Internal Control'';

(g) Prepares reports, briefings, and makes recommendations to senior HHS leadership, OPDIVs, STAFFDIVs and other stakeholders on ERM related activities; and

(h) Leads activities that enhance HHS implementation and integration of ERM into business operations.

(3) The Grants Quality Service Management Office (Grants QSMO). The Office:

(a) Offers and manages a marketplace of solutions for common technology, services, or fully managed services to respond to agency needs;

(b) Guides and governs the long-term sustainability of the services and solutions;

(c) Works with agencies on alternative strategies to help them build a business case if a marketplace for a particular solution is not yet available;

(d) Administers a customer engagement and feedback model that allows for continuous improvement and performance management of solutions;

(e) Drives the implementation of standards that produce efficiencies in process and scale and that are established through the collaborative governance process; and

(f) Analyzes the status of the government-wide grants management ecosystem and present information and recommendations to HHS executives and other inter-government stakeholders to inform strategic decisions on federal investments in technology and services for grants management.

III. Under D Chapter AMS, Office of Finance (AMS) section AMS.00 Mission:

A. Replace Section 1. Immediate Office (AMS) with:

1. Immediate Office (AMS). The Immediate Office (IO) is responsible for support and coordination to execute the mission of OF:

(1) Provides leadership for the HHS CFO community;

(2) Leads strategic planning for the HHS CFO community and the Office of Finance;

(3) Serves as the liaison with internal and external stakeholders regarding financial management matters;

(4) Provides operational support for the OF;

(5) Leads workforce development initiatives for the OF;

(6) Advises the ASFR/CFO regarding financial management matters affecting the Department; and

(7) Leads other activities that enhance OF's management and operations

IV. Delegations of Authority: All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

Authority: 44 U.S.C. 3101

Dated: January 11, 2021.

S. W. Rowell,

Assistant Secretary for Administration.

[FR Doc. 2021–01226 Filed 1–15–21; 11:15 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging 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 Aging Special Emphasis Panel RADx clinical trials.

Date: February 26, 2021.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892. (Video Meeting)

Contact Person: Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, (301) 496–9374, *grimaldim2@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 12, 2021.

Miguelina Perez,

Program Analyst,Office of Federal Advisory Committee Policy.

[FR Doc. 2021–00987 Filed 1–19–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIH)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Tawanda Abdelmouti, Assistant Project Officer, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892 or call non-toll-free number (301) 435–0978 or Email your request, including your address to: *abdelmot@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, 0925–EXTENSION, exp., date 5/31/2021, National Institutes of Health (NIH).

Need and Use of Information Collection: We are not requesting changes for this submission. The proposed information collection provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions. This information, however, is not statistical surveys that yield quantitative results, which can be generalized to the population of study. This feedback will provide information about the NIH's customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the NIH and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the NIH's services will be unavailable.

The NIH will only submit a collection for approval under this generic clearance if it meets the following:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of

respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;

• The collections are non-controversial and do not raise issues of concern to other Federal agencies;

• Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;

• Personally Identifiable information (PII) is collected only to the extent necessary and is not retained;

• Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;

• Information gathered will not be used for the purpose of substantially informing influential policy decisions; and

• Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results. As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 49,333.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of collection	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Customer Satisfaction Surveys	1,000	1	30/60	500
In-Depth Interviews (IDIs) or Small Discussion Groups	1,000	1	90/60	1,500
Focus Groups	1,000	1	90/60	1,500
Usability and Pilot Testing	150,000	1	5/60	12,500
Conference/Training—Pre-and Post-Surveys	100,000	2	10/60	33,333
Total	253,000	353,000	.....	49,333

Dated: January 13, 2021.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2021–01255 Filed 1–19–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0037; OMB No. 1660–0137]

Agency Information Collection Activities: Proposed Collection; Comment Request; Emergency Notification System (ENS)

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: 30 Day notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the Emergency Notification System (ENS).

DATES: Comments must be submitted on or before March 22, 2021.

ADDRESSES: To avoid duplicate submissions to the docket, please use the following means to submit comments: Submit comments at *www.regulations.gov* under Docket ID FEMA–2020–0037. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID and 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 read the Privacy and Security Notice that is available via a link on the homepage of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Melton Roland, ENS Program Manager, FEMA/ORR, *Melton.Roland@fema.dhs.gov,* or telephone 540–665–6152. You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: FEMA's Office of Response & Recovery (ORR) owns and operates the Emergency Notification System (ENS). FEMA Directive 262–3, Emergency Notification System, designates ENS as the agency solution for all notification and alerts activities. The ENS sends electronic notifications and relays messages, whether critical in nature, routine, or for testing purposes with appropriate authorization, to DHS employees and contractors, as well as emergency response personnel. In accordance with Executive Order 12656, as amended, Presidential Policy Directive 40, and Federal Continuity Directive (FCD)-1, all DHS organizational components must have in place a viable Continuity of Operations Planning (COOP) capability and plan that ensures the performance of their essential functions during any emergency or situation that could

disrupt normal operations. An effective ENS solution is a critical part of this plan.

Collection of Information

Title: Emergency Notification System (ENS).

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0137.

FEMA Forms: None.

Abstract: The Emergency Notification System has been deemed the standard notification tool for FEMA. The purpose of this notification tool is to activate teams and disseminate information. The respondents to this information are Mobile Operation Centers and Regions that use this information to make decisions on how to meet operational missions. This revision includes a new form for data gathering, which includes the Privacy Act Statement, Paperwork Reduction Act, and Retention Period information for members of the public that receive ENS Notifications.

Affected Public: State, Local or Tribal Government; Federal Government.

Estimated Number of Respondents: 700.

Estimated Number of Responses: 700.

Estimated Total Annual Burden Hours: 183.2.

Estimated Total Annual Respondent Cost: $6,247.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $214,651.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Maile Arthur,

Acting Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2021–01144 Filed 1–19–21; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2020–0019]

Cybersecurity and Infrastructure Security Agency; Notice of President's National Security Telecommunications Advisory Committee Meeting

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: Notice of Federal Advisory Committee Act (FACA) meeting; request for comments.

SUMMARY: CISA is publishing this notice to announce the following President's National Security Telecommunications Advisory Committee (NSTAC) meeting. This meeting is open to the public.

DATES:

Meeting Registration: Registration to attend the meeting is required and must be received no later than 5:00 p.m. Eastern Time (ET) on February 3, 2021. For more information on how to participate, please contact *NSTAC@cisa.dhs.gov.*

Speaker Registration: Registration to speak during the meeting's public comment period must be received no later than 5:00 p.m. ET on February 3, 2021.

Written Comments: Written comments must be received no later than 5:00 p.m. ET on February 3, 2021.

Meeting Date: The NSTAC will meet on February 10, 2021, from 1:00 p.m. to 2:00 p.m. ET. The meeting may close early if the committee has completed its business.

ADDRESSES: The meeting will be held via conference call. For access to the conference call bridge, information on services for individuals with disabilities, or to request special assistance to participate, please email *NSTAC@cisa.dhs.gov* by 5:00 p.m. ET on February 3, 2021.

Comments: Members of the public are invited to provide comment on the issues that will be considered by the committee as listed in the **SUPPLEMENTARY INFORMATION** section below. Associated materials that participants may discuss during the meeting will be available at *https://www.cisa.gov/national-security-telecommunications-advisory-committee* for review by January 26, 2021. Comments may be submitted by 5:00 p.m. ET on February 3, 2021, and must be identified by Docket Number CISA–2020–0019. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting written comments.
- *Email: NSTAC@cisa.dhs.gov.* Include the Docket Number CISA–2020–0019 in the subject line of the email.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the Docket Number for this action. Comments received will be posted without alteration at *www.regulations.gov,* including any personal information provided.

Docket: For access to the docket and comments received by the NSTAC, please go to *www.regulations.gov* and enter docket number CISA–2020–0019.

A 10-minute public comment period is scheduled from 1:25 p.m. to 1:35 p.m. ET. Speakers who wish to participate in the public comment period must register by emailing *NSTAC@cisa.dhs.gov* by no later than 5:00 p.m. ET on February 3, 2021. Speakers are requested to limit their comments to three minutes and will speak in order of registration. Please note that the public comment period may end before the time indicated, following the last request for comments.

FOR FURTHER INFORMATION CONTACT: Sandra Benevides, 202–603–1225, *sandra.benevides@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION: The NSTAC was established by Executive Order (E.O.) 12382, 47 FR 40531 (September 13, 1982), as amended and continued under the authority of E.O. 13889, dated September 27, 2019. Notice of this meeting is given under FACA, 5 U.S.C. Appendix (Pub. L. 92–463). The NSTAC advises the President on matters related to national security and emergency preparedness (NS/EP) telecommunications and cybersecurity policy.

Agenda: The NSTAC will hold a conference call on Wednesday, February 10, 2021. The meeting is open to the public and will include: (1) A status update from the NSTAC Communications Resiliency Subcommittee; and (2) a deliberation and vote on the *NSTAC Letter to the*

President on NS/EP Communications Priorities.

Sandra J. Benevides,

Designated Federal Officer, NSTAC, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security.

[FR Doc. 2021–01237 Filed 1–19–21; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7034–N–02]

30-Day Notice of Proposed Information Collection: Request for Withdrawals From Replacements Reserves/ Residual Receipts Funds; OMB Control No.: 2502–0555

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* February 22, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/Start* Printed Page 15501PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on August 7, 2020 at 85 FR 47980.

A. Overview of Information Collection

Title of Information Collection: Request for Withdrawals from Replacements Reserves/Residual Receipts Funds.

OMB Approval Number: 2502–0555.

OMB Expiration Date: 02/29/2020.

Type of Request: Reinstatement, with change, of previously approved collection for which approval has expired.

Form Number: HUD–9250.

Description of the need for the information and proposed use: Project owners are required to submit this information and supporting documentation when requesting a withdrawal for funds from the Reserves for Replacement and/or Residual Receipt escrow accounts. HUD or the lender/servicer reviews this information to ensure that funds are withdrawn and used in accordance with regulatory and administrative policy.

Respondents (*i.e. affected public*): Not-for-profit institutions.

Estimated Number of Respondents: 30,620.

Estimated Number of Responses: 8,267.

Frequency of Response: Various.

Average Hours per Response: 1.

Total Estimated Burden Hours: 8,267.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(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.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2021–01200 Filed 1–19–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2020–N001; FXES11130300000–201–FF03E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, 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 February 22, 2021.

ADDRESSES: *Document availability and comment submission:* Submit requests for copies of the applications and related documents, as well as any comments, by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* TEXXXXXX; see table in **SUPPLEMENTARY INFORMATION**):

- *Email: permitsR3ES@fws.gov.* Please refer to the respective application number (*e.g.,* Application No. TEXXXXXX) in the subject line of your email message.
- *U.S. Mail:* Regional Director, Attn: Nathan Rathbun, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458.

FOR FURTHER INFORMATION CONTACT: Nathan Rathbun, 612–713–5343 (phone); *permitsR3ES@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:

Background

The Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found 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 Applications Available for Review and Comment

We invite local, State, and Federal agencies; Tribes; and the public to comment on the following applications:

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE71524B	Theresa Burke, Charleston, WV.	Gray bat (*Myotis grisescens*), Indiana bat (*M. sodalis*), northern long-eared bat (*M. septentrionalis*), Virginia big-eared bat (*Corynorhinus towsendii virginianus*).	AL, AR, CT, DE, GA, IL, IN, IA, KY, MD, MA, MI, MS, MO, NH, NJ, NY, NC, OH, PA, RI, SC, TN, VT, VA, WV, WI.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, mist-net, band, radio-tag, release.	Renew.
TE120231	John Timpone, Wenatchee, WA.	Gray bat (*Myotis grisescens*), Indiana bat (*M. sodalis*), northern long-eared bat (*M. septentrionalis*).	AL, AR, CT, DE, GA, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, NE, NH, NJ, NY, NC, ND, OH, OK, PA, RI, SC, SD, TN, VT, VA, WV, WI.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, mist-net, band, radio-tag, release.	Renew.
TE38842A	Sanders Environmental, Inc., Bellefonte, PA.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*M. septentrionalis*).	AL, AR, GA, IL, IN, IA, KY, LA, MI, MN, MS, MO, NC, OH, OK, SC, TN, WI.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, mist-net, band, radio-tag, release.	Renew.
TE06809A	USDA Forest Service, North Central Research Station, Columbia, MO.	Gray bat (*Myotis grisescens*), Indiana bat (*M. sodalis*), northern long-eared bat (*M. septentrionalis*), Ozark big-eared bat (*Corynorhinus towsendii ingens*).	AL, AR, GA, IL, IN, IA, KS, KY, MI, MO, NC, OH, OK, PA, SC, TN, VA, WI, WV.	Conduct presence/absence surveys, document habitat use, conduct scientific research and population monitoring, evaluate impacts.	Capture; handle; mist-net; harp trap; band; radio-tag; collect hair, serum, guano, microbial skin swabs, and wing biopsy samples; PIT tag; hold; release.	Renew.
TE66724A	Cleveland Metroparks, Strongsville, OH.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*M. septentrionalis*).	OH	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, mist-net, band, radio-tag, release.	Renew.
TE105320	Tragus Environmental Consulting, Inc., Akron, OH.	Gray bat (*Myotis grisescens*), Indiana bat (*M. sodalis*), northern long-eared bat (*M. septentrionalis*).	AL, AR, GA, IA, IL, IN, KY, LA, MA, ME, MD MI, MN, MO, MS, NC, ND, NH, NJ, NY, PA, OH, OK, RI, SC, SD, TN, VA, VT, WI, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, mist-net, band, radio-tag, release.	Renew.
TE144832	Detroit Zoological Society, Royal Oak, MI.	Karner blue butterfly (*Lycaeides melissa samuelis*), Piping plover (*Charadrius melodus*).	MI	Capture, ship, house, feed, breed, rear larvae, overwinter, release, and monitor.	Capture, ship, house, feed, breed, rear larvae, overwinter, release, and monitor.	Amend, Renew.
TE31310A	Minnesota Pollution Control Agency, Saint Paul, MN.	Topeka shiner (*Notropis topeka*)	MN	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, release.	Renew.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE07730A	Redwing Ecological Services, Inc., Louisville, KY.	30 freshwater mussel species, relict darter (*Etheostoma chienense*), tuxedo darter (*Etheostoma lemniscatum*), Cumberland darter (*Etheostoma susanae*), Kentucky arrow darter (*Etheostoma spilotum*), palezone shiner (*Notropis albizonatus*), Scioto madtom (*Noturus trautmam*), blackside dace (*Phoxinus cumberlandensis*),Big Sandy crayfish (*Cambarus callainus*).	IA, IL, IN, KY, MI, MN, MO, PA, TN, WI, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, collect, handle, release.	Renew.
PER0002332	Minnesota Department of Natural Resources, Lake City, MN.	Spectaclecase (*Cumberlandia monodonta*), snuffbox (*Epioblasma triquetra*), Higgins eye (*Lampsilis higginsii*), sheepnose (*Plethobasus cyphyus*), winged mapleleaf (*Quadrula fragosa*).	IA, MN, WI	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts, headstart.	Collect, handle, release, transport, hold, mark, tissue sample, buccal swab, translocate, headstart.	New.
TE06841A	U.S. Fish and Wildlife Service, Ecological Services Field Office, Columbus, OH.	American burying beetle (*Nicrophorus americanus*).	OH	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, release.	Renew.

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. Moreover, 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 permits to any of the applicants 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.*).

Lori Nordstrom,

Assistant Regional Director, Ecological Services.

[FR Doc. 2021–01137 Filed 1–19–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT924000 L14400000.FR0000 20XL1109AF; MO# 4500150792; MTM–108489]

Initial Classification for State In Lieu Selection and Notice of Termination of Proposed Classification, Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of classification.

SUMMARY: The Montana Department of Natural Resources and Conservation (State) has filed a petition for classification and application to obtain public land and mineral estate in lieu of lands to which the State was entitled but did not receive under its Statehood Act. This classification, made under Section 7 of the Taylor Grazing Act of June 8, 1934, satisfies in full the obligation to the State. This notice also terminates the classification of lands included in the State's application that are not needed to fulfill the obligation.

DATES: Written comments requesting administrative review regarding the initial classification of lands and minerals may be submitted to the Secretary of the Interior on or before February 22, 2021. In the absence of any requests for administrative review, this initial classification will become final on February 22, 2021. Lands not needed to fulfill the obligation will be opened to the operation of the public land laws on February 22, 2021.

ADDRESSES: Requests for administrative review may be submitted to the Secretary of the Interior, 1849 C Street NW, c/o Bureau of Land Management HQ–300, Washington, DC 20240. Electronic mail, facsimile, or telephone requests will not be accepted.

FOR FURTHER INFORMATION CONTACT: Jim Ledger, Branch of Lands, Realty, and Renewable Energy, telephone: (406) 329–3733, email: *jledger@blm.gov.* Persons who use a telecommunications device for the deaf may call the Federal Relay Service (FRS) at 1–800–877–8339 to leave a message or question. The FRS is available 24 hours a day, 7 days a week. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Sections 2275 and 2276 of the Revised Statutes, as amended (43 U.S.C. 851 and 852), provide authority for the State of Montana to receive title to public land in lieu of lands to which it was entitled under the Enabling Act of 1889 (25 Stat. 676).

Section 7 of the Taylor Grazing Act of June 8, 1934, (43 U.S.C. 315 *et seq.*) requires that such public land and/or minerals identified for proposed transfer out of Federal ownership under this authority must first be classified. The Bureau of Land Management (BLM) is classifying these lands and minerals pursuant to 43 CFR 2400 and Section 7 of the Taylor Grazing Act of June 8, 1934. The BLM has completed a review and environmental analysis (EA) on a portion of the lands included in the proposed classification dated October 17, 2016 (81 FR 71529), extended by the notice published November 15, 2017 (82

FR 52937), and is hereby classifying 5,816.63 acres as suitable for conveyance. The EA considered a number of issues, including public access, in accordance with Secretary's Order 3373 and resulted in a Finding of No Significant Impact.

For a period of 30 days from the date of publication of this notice, this Initial Classification is subject to the exercise of administrative review and modification by the Secretary of the Interior as provided for under 43 CFR 2461.3. All persons who wish to request the Secretary of the Interior conduct an administrative review of the finding that these lands are suitable for conveyance to the State may present their views to the address given in the **ADDRESSES** section earlier. Electronic mail, facsimile, or telephone requests will not be accepted. Requests for administrative review will be evaluated by the Secretary of the Interior, or his/her delegate, who will issue a notice of determination to proceed with, modify, or cancel this Initial Classification.

Before including your address, phone number, email address, or other personally identifiable information in any comment, be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. While you can ask the BLM in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

The selected lands/minerals affected by this classification are in Custer, Prairie, and Richland Counties, Montana, and described as follows:

Principal Meridian, Montana

T. 5 N., R. 46 E.,
sec. 24, E1/2.
T. 4 N., R. 47 E.,
sec. 6;
sec. 8, NW1/4NE1/4, SE1/4NE1/4, N1/2NW1/4, and NE1/4SE1/4.
T. 12 N., R. 50 E.,
sec. 14; lots 1 thru 4, S1/2SW1/4, and S1/2SE1/4.
T. 12 N., R. 52 E.,
sec. 3, lots 1, 2, and 3;
sec. 5;
sec. 6, lots 2 thru 7, S1/2NE1/4, SE1/4NW1/4, E1/2SW1/4, and SE1/4;
sec. 7, lots 1 thru 7, NW1/4NE1/4, and E1/2NW1/4;
sec. 8, lots 1, 2, and 3.
T. 13 N., R. 52 E.,
sec. 29, E1/2SE1/4SW1/4, E1/2NW1/4SE1/4SW1/4, E1/2SW1/4SE1/4SW1/4, and S1/2SE1/4;
sec. 30, S1/2SW1/4 and S1/2SE1/4;
sec. 33, lots 5, 6, and 7.
T. 26 N., R. 55 E.
sec. 1, lot 4;
sec. 2, lots 1 and 2, and SW1/4NE1/4.
T. 27 N., R. 56 E.,
sec. 7, lots 7 thru 12, SE1/4SW1/4, and S1/2SE1/4;
sec. 8, lot 12 and S1/2SW1/4;
sec. 9, lots 3, 4, and 5, SE1/4SW1/4, and SW1/4SE1/4;
sec. 17, E1/2, N1/2NW1/4, SW1/4NW1/4, and SW1/4;
sec. 18, lots 1 thru 4, NE1/4, E1/2NW1/4, SE1/4SW1/4, and SE1/4;
sec. 22, NE1/4NE1/4, SW1/4NW1/4, and W1/2SW1/4.

The areas described aggregate 5,816.63 acres.

The BLM has examined the lands described above for evidence of valid existing rights and any constraints that would prevent conveyance. No persons other than holders of leases, permits, and rights-of-way, asserted a claim to, or interest in, the lands proposed for classification.

When the selection is certified to the State, the document transferring title will contain the following reservation to the United States:

1. A right-of-way thereon for ditches and canals constructed by the authority of the United States, pursuant to the Act of August 30, 1890 (43 U.S.C. 945).

The title will also be taken subject to:

2. A right-of-way for County Road No. 152, administered by Richland County, pursuant to the provisions of Revised Statute 2477 (43 U.S.C. 932), lying over, across, and upon a strip of land located in lots 7, 8, and 12, Section 7, and lot 12, Section 8, T. 27 N., R. 56 E, Principal Meridian, Montana.

3. A railroad and telegraph and other appurtenant rights, granted under the Act of July 2, 1864 (13 Stat. 365) to the Northern Pacific Railroad Company, its successors or assigns, lying over, across, and upon a strip of land located in the S1/2SE1/4, Section 14, T. 12 N., R. 50 E., Principal Meridian, Montana.

4. Those rights for an underground telephone cable granted to Nemont Telephone Cooperative, Inc., its successors or assigns, by right-of-way MTM–54795, as to 1.35 acres in lots 7, 8, and 12 of Section 7 and lot 12 of Section 8, T. 27 N., R. 56 E, Principal Meridian, Montana, under the Act of October 21, 1976 (43 U.S.C. 1761).

5. Those rights for a road granted to Prairie County, its successors or assigns, by MTM–99059, as to 12.63 acres in lots 1 thru 4 of Section 5 and lots 2 thru 4 of Section 6, T. 12 N., R. 52 E., Principal Meridian, Montana, under the Act of October 21, 1976 (43 U.S.C. 1761).

6. Those rights for a fiber optic cable granted to Nemont Telephone Cooperative, Inc., its successors or assigns, by right-of-way MTM–105771, as to 1.45 acres in lots 7 and 12 of Section 7 and lot 12 of Section 8, T. 27 N., R. 56 E, Principal Meridian, Montana, under the Act of October 21, 1976 (43 U.S.C. 1761).

The right-of-way holders of MTM–54795, MTM–99059, and MTM–105771 have been afforded the opportunity to modify their existing authorization in accordance with 43 CFR 2807.15. Each of these rights-of-ways will be amended to a permanent easement prior to conveyance of the land to the State.

7. Those rights granted to the Laura Caldwell Irrevocable Trust by Grazing Allotment No. 01441 as to lots 1, 2, 5, and 7, S1/2NE1/4 and S1/2SE1/4 of Section 11 and SW1/4NE1/4, S1/2NW1/4, E1/2SW1/4, and SE1/4 of Section 12 and lots 1 and 2, NE1/4 and N1/2SE1/4 of Section 14, T. 27 N., R. 55 E., Principal Meridian Montana, until March 1, 2023.

8. Those rights granted to the Steppler Ranch by Grazing Allotment No. 01465 as to the W1/2 and S1/2SE1/4 of Section 14 and NE1/4NE1/4, W1/2NE1/4, W1/2, and SE1/4 of Section 23 and S1/2SE1/4 and SW1/4SW1/4 of Section 24 and N1/2 and N1/2SE1/4 of Section 25, T. 27 N., R. 55 E., Principal Meridian Montana, and lot 1 of Section 30, T. 27 N., R.56 E., Principal Meridian Montana, until March 1, 2023.

The subject lands contain grazing leases authorized under Section 15 of the Taylor Grazing Act. The holders of the BLM grazing use authorizations received the required 2-year notices as outlined in 43 CFR 4110.4–2(b) and have agreed to relinquish their authorizations when the land is conveyed. State of Montana procedures provide that upon Land Board Approval, the State will offer 10-year grazing leases to the current holders of BLM permits/leases on any transferred lands.

The subject lands hold permanent range improvements for which the permittees are due reasonable compensation as outlined in Section 402(g) of the Federal Land Policy and Management Act. The holders of these range improvements have been notified and agreed to the reasonable compensation determination and will receive payment once the land is conveyed.

The lands contain no oil and gas, geothermal, or other leases issued under the authority of the Mineral Leasing Act of 1920 (30 U.S.C. 181 *et seq.*) or the Geothermal Steam Act (30 U.S.C. 1001 *et seq.*). No mining claims are recorded with the BLM on these lands.

Unless a request for Secretarial review is received, this notice also terminates the proposed classification and segregation on the remaining 8,113.00 acres of the total 16,055.74 acres contained in the State's application, but

not needed to fulfill the in-lieu entitlement and described in the proposed classification dated October 17, 2016 (81 FR 71529), as extended by the notice dated November 15, 2017 (82 FR 52937). The lands will be opened to the operation of the public land laws, including location and entry under the United States mining laws, unless a request for review is received, in which case they shall remain classified and segregated. Appropriation of any of the lands prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38, shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The BLM will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

(Authority: 43 CFR parts 2400 and 2621)

Scott Haight,

District Manager, Eastern Montana/Dakotas District.

[FR Doc. 2021–01117 Filed 1–19–21; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM920000 L13100000.PP0000 212L1109AF]

Proposed Reinstatement of Terminated Oil and Gas Lease NMNM 119276, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of proposed reinstatement.

SUMMARY: In accordance with the Mineral Leasing Act of 1920, as amended, EOG Y Resources Inc., et al., timely filed a petition for reinstatement of competitive oil and gas lease NMNM 119276 in Lea County, New Mexico. The lessee paid the required rentals accruing from the date of termination. No lease was issued that affects these lands. The Bureau of Land Management (BLM) proposes to reinstate the lease.

FOR FURTHER INFORMATION CONTACT: Julieann Serrano, Supervisory Land Law Examiner, Branch of Adjudication, Bureau of Land Management New Mexico State Office, 301 Dinosaur Trail, Santa Fe, NM 87508, (505) 954–2149, *jserrano@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Ms. Serrano during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lessee agrees to new lease terms for rentals and royalties of $10 per acre, or fraction thereof, per year, and 16⅔ percent, respectively. The lessee agrees to additional or amended stipulations. The lessee paid the $500 administration fee for the reinstatement of the lease and the cost for publishing this notice.

The lessee met the requirements for reinstatement of the lease per Sec. 31(d) and (e) of the Mineral Leasing Act of 1920. The BLM is proposing to reinstate the lease, effective the date of termination subject to the:

- Original terms and conditions of the lease;
- Additional and amended stipulations;
- Increased rental of $10 per acre;
- Increased royalty of 16⅔ percent; and
- $151 cost of publishing this notice.

Authority: 43 CFR 3108.2–3.

Julieann Serrano,

Supervisory Land Law Examiner.

[FR Doc. 2021–01256 Filed 1–19–21; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–ARCH–DTS 31211; PPIMCANYA0 PPMPSAS1Z.Y00000 211]

Written Determination: Bicycle Use on Visitor Center Connector Trail at Arches National Park

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service determines that allowing bicycles on the newly constructed Visitor Center Connector Trail at Arches National Park is consistent with the protection of the Park's natural, scenic and aesthetic values, safety considerations and management objectives and will not disturb wildlife or Park resources.

DATES: Comments on this written determination must be received by 11:59 MST on February 22, 2021.

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

(1) *Electronically:* Visit *https://parkplanning.nps.gov/arch* and click on the link entitled ''Open for Comment''.

(2) *By hard copy:* Mail to Park Superintendent, Arches National Park, 2282 S West Resource Blvd., Moab, UT 84532.

Document Availability: The Visitor Center Connector Trail Environmental Assessment and Finding of No Significant Impact provide information and context for this written determination and are available at: *https://parkplanning.nps.gov/documentsList.cfm?projectID=92060.*

FOR FURTHER INFORMATION CONTACT: Patricia Trap, Superintendent, Arches National Park, (435) 719–2101, *patricia_trap@nps.gov.*

SUPPLEMENTARY INFORMATION:

Background

The National Park Service (NPS) developed an Environmental Assessment (EA) that analyzed the impacts of allowing bicycles on a newly constructed 0.26-mile-long paved path (Visitor Center Connector Trail) that connects a shared use path outside the Arches National Park (Park) boundary to the Arches Visitor Center. Published on January 13, 2020, the EA presented two alternatives for the Park and identified the alternative that would allow bicycle use on the path as the NPS preferred alternative. The Regional Director for Interior Regions 6, 7, and 8 signed a Finding of No Significant Impact (FONSI) on May 13, 2020 that identified the preferred alternative (Alternative 2) in the EA as the selected alternative.

Prior to designating an existing trail in a developed area for bicycle use, NPS regulations at 36 CFR 4.30 require a written determination that such use is consistent with the protection of the Park's natural, scenic, and aesthetic values, safety considerations and management objectives, and will not disturb wildlife or Park resources. After the 30-day public review period for this written determination and consideration of the comments submitted, the NPS Regional Director will evaluate whether to approve the written determination. If the written determination is approved by the Regional Director, the Superintendent may designate the trail for bicycle use and will provide notice of such designation under 36 CFR 1.7.

Written Determination

Park Significance, Purpose and Values

In 1929, Arches National Monument was established by Presidential Proclamation 1875 to protect extraordinary examples of wind erosion in the form of gigantic arches, natural bridges, windows, spires, balanced rocks, and other unique wind-worn sandstone formations. The Monument

was enlarged in 1938 by Presidential Proclamation to include protection of prehistoric structures of historic and scientific interest. The Monument was enlarged two more times in 1960 by Presidential Proclamation 3360 and in 1969 by Presidential Proclamation 3887 stating that it would be ''in the public interest to add to Arches certain contiguous lands on which outstanding geological features of great scientific interest are situated and certain other lands adjacent to the monument which are essential to the proper care, management, and protection of the objects of scientific interest situated on such lands and on lands now comprising a part of the monument.'' In 1971, an act of Congress (Pub. L. 92–155) changed the designation of the area from a National Monument to a National Park and slightly reduced the total acreage of the Park. More recently, in 1998, the Park was enlarged again by an act of Congress (Pub. L. 105–329). Today, the Park encompasses 76,679 acres in southeastern Utah and receives over 1.5 million annual visitors.

A formal statement of the purpose and significance of the Park is set forth in the 2013 Foundation Document. This document establishes the resources and values that warrant designation of the site as a unit of the National Park System. The purpose of the Park is to protect extraordinary examples of geologic features including arches, natural bridges, windows, spires, balanced rocks, as well as other features of geologic, historic, and scientific interest and to provide opportunities to experience these resources and their associated values in their majestic natural settings.

The Foundation Document also identifies the fundamental resources and values that warrant primary consideration during planning and management because they are critical to achieving the Park's purpose and maintaining its significance. The fundamental resources and values for the Park include geologic resources, clean air and scenic vistas, Colorado Plateau ecosystems, cultural features, and collaborative conservation, science, and scholarship.

Management Objectives

The Park's General Management Plan (GMP), completed in 1989, provides guidance for managing the Park during its development. It identifies recreational activities appropriate for different experience zones in the Park. Bicycle touring is listed as appropriate in the front country sightseeing zone; this zone encompasses the entrance road, visitor center, main scenic drive and associated pull-outs, and all paved parking areas. Additionally, the GMP outlines five interpretive themes, one of which includes safety. When the Park entrance road was expanded in 2017, it did not include a shoulder lane nor a separate lane for bicyclists or pedestrians. Bicyclists accessing the Park from the nearby town of Moab, Utah ride on a shared use path for two miles from the trail hub in town and then exit the path and enter the Park along the narrow and unsafe shoulder of the 0.625-mile-long entrance road. Allowing bicycle use on the newly constructed Visitor Center Connector Trail would meet the Park's management objective to provide safe and enjoyable recreational experiences for Park visitors as they access and leave the entrance area.

Wildlife and Park Resources

The location of the Visitor Center Connector Trail is adjacent to the Park boundary, park entrance road, and US Route 191. This area has high levels of disturbance due to its proximity to a busy state highway and to the entrance road. The EA evaluated the potential impacts to Park resources from allowing bicycles on the trail and determined that this would have no significant impacts nor impair Park resources or values. Given the moderate and highly mobile nature of the majority of wildlife species in the area, the already disturbed nature of the area, and the narrow footprint of the trail, NPS concluded that the use of bicycles on the trail would not disturb wildlife. The NPS expects that wildlife encountering bicycles on the trail would disperse into more protected areas within the Park where there is preferential habitat.

Natural, Scenic and Aesthetic Values

Bicycle use on the trail would not affect the Park's natural, scenic or aesthetic values because this activity would occur next to a busy road along an old transportation corridor (old entrance road) and directly adjacent to the existing Park entrance road. The area is already subject to visual impacts and noise from US Route 191 and Park operations. As a result, bicyclists would not substantially contribute to the existing impacts of human-caused sounds and sights in the area. Incremental effects would be negligible.

Safety Considerations

The trail was constructed in accordance with national guidelines for shared use paths and therefore is well suited for bicycle use. It has an asphalt running surface (2″ asphalt travel surface over 6″ of imported base), a minimum path width of ten feet with a two-foot shoulder, a five percent maximum running slope grade, and a safety railing adjacent to steep slopes. Signage will be installed to warn trail users of safety hazards. The trail would provide a much safer alternative for bicyclists who now must enter the Park on the narrow shoulder of the entrance road. The NPS will monitor activities on the trail and make safety-related adjustments, as needed.

Determination

Based upon the foregoing, the NPS determines that bicycle use on the Visitor Center Connector Trail is consistent with the protection of the Park's natural, scenic, and aesthetic values, safety considerations, and management objectives and will not disturb wildlife or Park resources.

Patricia S. Trap,

Superintendent.

[FR Doc. 2021–01358 Filed 1–19–21; 8:45 am]

BILLING CODE 4310–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–31341; 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 January 2, 2021, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by February 5, 2021.

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 January 2,

2021. 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:

HAWAII

Kauai County

Coco Palms Resort, 4–241 Kuhio Highway, Kapaa, SG100006139

MASSACHUSETTS

Plymouth County

Old Town Hall Historic District, 774, 842, 862, and 878 Tremont St., Duxbury, SG100006129

Suffolk County

Lawrence Avenue Historic District, Blue Hill Ave., Lawrence Ave., Coleus Park, Magnolia St., and Intervale St., Boston, SG100006127

Greenville Street Historic District, 2, 6–25 Greenville St., Boston, SG100006134

MICHIGAN

Wayne County

New Bethel Baptist Church, (The Civil Rights Movement in Detroit, Michigan, 1900–1976 MPS), 8430 Linwood St., Detroit, MP100006130

Parks, Rosa L. (McCauley) and Raymond, Flat

(The Civil Rights Movement in Detroit, Michigan, 1900–1976 MPS), 3201–3203 Virginia Park St., Detroit, MP100006131

Shrine of the Black Madonna of the Pan African Orthodox Christian Church

(The Civil Rights Movement in Detroit, Michigan, 1900–1976 MPS), 7625 Linwood St., Detroit, MP100006132

MISSISSIPPI

Hinds County

Wiener, Dr. Julian and Kathryn, House, 3858 Redbud Rd., Jackson, SG100006137

Marshall County

Old Philadelphia Church, Corner of Harris Ln. and North Red Banks Rd., Red Banks, SG100006142

NEW YORK

Herkimer County

Library Bureau-Remington Rand-Sperry UNIVAC Manufacturing Complex, 7 Spruce St., Ilion, SG100006144

Monroe County

Brockport West Side Historic District, Portions of Main, Holley, Utica, College, Maxon, Adams, Mercer, Allen, Chappell Sts., Centennial Ave., Brockway Pl., and Monroe Ave., Brockport, SG100006145

Westchester County

New York Central & Hudson River Railroad Power Station, 45 Water Grant St., Yonkers, SG100006146

OHIO

Perry County

Ludowici Roof Tile Company Historic District, 4757 Tile Plant Rd., New Lexington, SG100006136

Summit County

Oviatt, Orson Minot, House, 3758 Brecksville Rd., Richfield, SG100006141

Van Wert County

Downtown Van Wert Historic District, Roughly bounded by Jackson St., Town Creek, Central Ave., and Cherry St., Van Wert, SG100006140

OREGON

Multnomah County

Cook, Jacob H. and Etna M., House, 5631 SE Belmont St., Portland, SG100006123

Pallay Apartments

(Portland Eastside MPS), 631 SE Taylor St., Portland, MP100006124

Patton Home

4619 North Michigan Ave., Portland, SG100006125

Umatilla County

Rice, Gonzalez M. and Maude R., House, 503 North Main St., Pendleton, SG100006126

VERMONT

Windsor County

Eldredge, Wentworth and Diana, House, (Mid-Century Modern Residential Architecture in Norwich, Vermont MPS), Address Restricted, Norwich vicinity, MP100006133

Additional documentation has been received for the following resources:

SOUTH DAKOTA

Codington County

Olive Place (Additional Documentation), 223 14th Ave. NW, Watertown vicinity, AD78002547

UTAH

Cache County

Gardner, James, House (Additional Documentation), 173 North Main St., Mendon, AD82004111

Authority: Section 60.13 of 36 CFR part 60

Dated: January 5, 2021.

Sherry Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2021–01181 Filed 1–19–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–SER–CONG–30500; PS.SSELA0303.00.1]

Minor Boundary Revision at Congaree National Park

AGENCY: National Park Service, Interior.

ACTION: Notification of Boundary Revision.

SUMMARY: The boundary of Congaree National Park is modified to include approximately 216.13 acres of land located in Richland County, South Carolina, immediately adjacent to the boundary of Congaree National Park. Subsequent to the boundary revision, the National Park Service will acquire the land by donation from The Friends of Congaree, a nonprofit conservation organization.

DATES: The effective date of this boundary revision is January 21, 2021.

ADDRESSES: The map depicting this boundary revision is available for inspection at the following locations: National Park Service, Land Resources Program Center, Interior Region 2, Atlanta Office, 100 Alabama Street SW, Atlanta GA 30303, and National Park Service, Department of the Interior, 1849 C Street, NW, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Realty Officer John C. Danner, National Park Service, Land Resources Program Center, Interior Region 2, Atlanta Office, 100 Alabama Street SW, Atlanta GA 30303, telephone (470) 513–4301.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 54 U.S.C.

100506(c), the boundary of Congaree National Park is modified to include one adjoining tract containing a total of 216.13 acres of land, more or less. This boundary revision is depicted on Map No. 178/171,144, dated September 2020.

54 U.S.C. 100506(c) provides that, after notifying the House Committee on Natural Resources and the Senate Committee on Energy and Natural Resources, the Secretary of the Interior is authorized to make a boundary revision upon publication of notice in the **Federal Register**. The Committees have been notified of this boundary revision. This boundary revision and subsequent acquisition will ensure preservation and protection of the park's scenic and historic resources.

Lance Hatten,

Acting Regional Director, Interior Region 2.

[FR Doc. 2021–01162 Filed 1–19–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2021–0001]

Gulf of Mexico, Outer Continental Shelf (OCS), Oil and Gas Lease Sale 257

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of availability of a record of decision.

SUMMARY: The Bureau of Ocean Energy Management (BOEM) is announcing the availability of a Record of Decision for proposed Gulf of Mexico (GOM) regionwide oil and gas Lease Sale 257. This Record of Decision identifies BOEM's selected alternative for proposed Lease Sale 257, which is analyzed in the *Gulf of Mexico OCS Lease Sale: Final Supplemental Environmental Impact Statement 2018* (2018 GOM Supplemental EIS).

ADDRESSES: The Record of Decision is available on BOEM's website at *http://www.boem.gov/nepaprocess/.*

FOR FURTHER INFORMATION CONTACT: For more information on the Record of Decision, you may contact Ms. Helen Rucker, Chief, Environmental Assessment Section, Office of Environment, by telephone at 504–736–2421, or by email at *helen.rucker@boem.gov.*

SUPPLEMENTARY INFORMATION: In the 2018 GOM Supplemental EIS, BOEM evaluated five alternatives for proposed Lease Sale 257. We have summarized these alternatives below, noting some additional blocks that may be excluded due to their lease status at the time of this decision:

Alternative A—Regionwide Outer Continental Shelf (OCS) Lease Sale: This is BOEM's preferred alternative. This alternative would allow for a proposed GOM regionwide lease sale encompassing all three planning areas: Western Planning Area (WPA); Central Planning Area (CPA); and a small portion of the Eastern Planning Area (EPA) not under congressional moratorium. Under this alternative, BOEM would offer for lease all available, unleased blocks within the proposed regionwide lease sale area for oil and gas operations with the following exceptions: whole and portions of blocks deferred by the Gulf of Mexico Energy Security Act of 2006; blocks that are adjacent to or beyond the United States Exclusive Economic Zone in the area known as the northern portion of the Eastern Gap; whole and partial blocks within the boundary of the Flower Garden Banks National Marine Sanctuary as of the July 2008 *Memorandum on Withdrawal of Certain Areas of US OCS from Leasing Disposition*; depth-restricted, segregated portions of Block 299, Main Pass Area, South and East Addition (Louisiana Leasing Map LA10A); blocks where the lease status is currently under appeal; and whole or partial blocks that have received bids in previous lease sales, where the bidder has sought reconsideration of BOEM's rejection of their bid, unless the reconsideration request is fully resolved at least 30 days prior to the publication of the Final Notice of Sale. We have listed the unavailable blocks in Section I of the Final Notice of Sale for proposed Lease Sale 257 and at *www.boem.gov/Sale-257.* The proposed regionwide lease sale area encompasses about 91.93 million acres (ac), with approximately 79.7 million ac available for lease. As described in the 2018 GOM Supplemental EIS, the estimated amounts of resources projected to be leased, discovered, developed, and produced as a result of the proposed regionwide lease sale are between 0.211 and 1.118 billion barrels of oil (BBO) and 0.547 and 4.424 trillion cubic feet (Tcf) of natural gas.

Alternative B—*Regionwide OCS Lease Sale Excluding Available, Unleased Blocks in the WPA Portion of the Proposed Lease Sale Area:* This alternative would offer for lease all available, unleased blocks within the CPA and EPA portions of the proposed lease sale area for oil and gas operations, with the following exceptions: Whole and portions of blocks deferred by the Gulf of Mexico Energy Security Act of 2006; blocks that are adjacent to or beyond the United States Exclusive Economic Zone in the area known as the northern portion of the Eastern Gap; depth-restricted, segregated portions of Block 299, Main Pass Area, South and East Addition (Louisiana Leasing Map LA10A); blocks where the lease status is currently under appeal; and whole or partial blocks that have received bids in previous lease sales, where the bidder has sought reconsideration of BOEM's rejection of their bid, unless the reconsideration request is fully resolved at least 30 days prior to publication of the Final Notice of Sale. The proposed CPA/EPA lease sale area encompasses about 63.35 million ac, with approximately 53 million ac available for lease. The estimated amounts of resources projected to be leased, discovered, developed, and produced as a result of the proposed lease sale under Alternative B are 0.185–0.970 BBO and 0.441–3.672 Tcf of gas.

Alternative C—*Regionwide OCS Lease Sale Excluding Available, Unleased Blocks in the CPA and EPA Portions of the Proposed Lease Sale Area:* This alternative would offer for lease all available, unleased blocks within the WPA portion of the proposed lease sale area for oil and gas operations, with the following exceptions: Whole and partial blocks within the boundary of the Flower Garden Banks National Marine Sanctuary as of the July 2008 *Memorandum on Withdrawal of Certain Areas of US OCS from Leasing Disposition;* blocks where the lease status is currently under appeal; and whole or partial blocks that have received bids in previous lease sales, where the bidder has sought reconsideration of BOEM's rejection of their bid, unless the reconsideration request is fully resolved at least 30 days prior to publication of the Final Notice of Sale. The proposed WPA lease sale area encompasses about 28.58 million ac, with approximately 26.9 million ac available for lease. The estimated amounts of resources projected to be leased, discovered, developed, and produced as a result of the proposed lease sale under Alternative C are 0.026–0.148 BBO and 0.106–0.752 Tcf of gas.

Alternative D—Alternative A, B, or C, with the Option to Exclude Available, Unleased Blocks Subject to the Topographic Features, Live Bottom (Pinnacle Trend), and/or Blocks South of Baldwin County, Alabama, Stipulations: This alternative could be combined with any of the action alternatives above (*i.e.,* Alternative A, B, or C) and would allow the flexibility to offer leases under any alternative with

additional exclusions. Under Alternative D, the decisionmaker could exclude from leasing any available, unleased blocks in Alternative A subject to any one or a combination of the following stipulations: Topographic Features Stipulation; Live Bottom Stipulation; and Blocks South of Baldwin County, Alabama, Stipulation (not applicable to Alternative C). This alternative considered blocks subject to these stipulations because these areas have been emphasized in scoping, can be geographically defined, and adequate information exists regarding their ecological importance and sensitivity to OCS oil- and gas-related activities.

A total of 207 blocks within the CPA and 160 blocks in the WPA are affected by the Topographic Features Stipulation. There are currently no identified topographic features protected under this stipulation in the EPA. The Live Bottom Stipulation covers the pinnacle trend area of the CPA, affecting a total of 74 blocks. Under Alternative D, the number of blocks that would become unavailable for lease represents only a small percentage of the total number of blocks to be offered under Alternative A, B, or C (less than 4%, even if blocks subject to all three stipulations were excluded). Therefore, Alternative D could reduce offshore infrastructure and activities in these sensitive areas because Alternative D would most likely simply shift the location of offshore infrastructure and activities farther from these sensitive zones; it would not lead to a reduction in overall impacts. Moreover, the incremental negative impacts of the other alternatives compared with Alternative D would be largely mitigated by the application of the lease stipulations in Alternative A, as discussed below.

Alternative E—No Action: This alternative is not holding proposed regionwide Lease Sale 257 and is identified as the environmentally preferred alternative. Alternative E was not selected because, if it were, the needed domestic energy sources and the subsequent positive economic impacts from exploration and production, including employment, would not be realized. Not holding a single lease sale would also not significantly change the overall activity levels in the GOM (*i.e.,* on blocks leased in previous lease sales) and the associated environmental impacts in the near term; however, it would avoid the incremental contribution of the proposed regionwide lease sale to the cumulative effects of ongoing activity. Avoidance of this incremental contribution, however, is outweighed by the potential negative economic and socioeconomic impacts of choosing Alternative E.

Lease Stipulations—Eleven lease stipulations have been adopted for Lease Sale 257, including a new stipulation, related to the processing of certain post-lease permits, and described below. The 2018 GOM Supplemental EIS describes 10 of these 11 lease stipulations, which are included in the Final Notice of Sale Package.

In the Record of Decision for the *2017–2022 Outer Continental Shelf Oil and Gas Leasing: Proposed Final Program,* the Secretary of the Interior required the protection of biologically sensitive underwater features in all Gulf of Mexico oil and gas lease sales as programmatic mitigation; therefore, BOEM is adopting the Topographic Features Stipulation and Live Bottom Stipulation and applying them to designated lease blocks in proposed Lease Sale 257. Due to a proposed expansion of the Flower Garden Banks National Marine Sanctuary, this additional language notifies lessees that, should their lease block in the future be included in a national marine sanctuary, their operations may be subject to additional requirements and regulations from the National Oceanic and Atmospheric Administration and that a permit from that agency may be required in certain instances.

The additional nine lease stipulations considered for proposed regionwide Lease Sale 257 are the Military Areas Stipulation; the Evacuation Stipulation; the Coordination Stipulation; the Blocks South of Baldwin County, Alabama, Stipulation; the Protected Species Stipulation; the United Nations Convention on the Law of the Sea Royalty Payment Stipulation; the Below Seabed Operations Stipulation; the Stipulation on the Agreement between the United States of America and the United Mexican States Concerning Transboundary Hydrocarbon Reservoirs in the Gulf of Mexico; and the Timeframe for Decisions on an Application for Permit to Drill and an Application for Permit to Modify Stipulation. The Protected Species Stipulation has been recently updated due to the completion of the Endangered Species Act consultation with the National Marine Fisheries Service and the issuance of a Biological Opinion in March 2020, addressing OCS oil- and gas-related activities in the Gulf of Mexico, including this lease sale. The Timeframe for Decisions on an Application for Permit to Drill and an Application for Permit to Modify Stipulation was first adopted in Lease Sale 256. This stipulation is administrative in nature and addresses the processing and timing of decisions for Applications for Permit to Drill and Applications for Permit to Modify by the Bureau of Safety and Environmental Enforcement (BSEE). It does not alter any underlying requirements for those applications and therefore would not be expected to change any environmental effects reasonably foreseeable as a result of this lease sale and any related post-lease activities. As noted, BOEM is adopting these nine stipulations as lease terms where applicable and they are enforceable as part of the lease.

Further, Appendix B of the *Gulf of Mexico OCS Oil and Gas Lease Sales: 2017–2022; Gulf of Mexico Lease Sales 249, 250, 251, 252, 253, 254, 256, 257, 259, and 261—Final Multisale Environmental Impact Statement* provides a list and description of standard post-lease conditions of approval that BOEM or BSEE may require as a result of their plan and permit review processes for the Gulf of Mexico OCS region.

After careful consideration, BOEM selected the preferred alternative (Alternative A) from the 2018 GOM Supplemental EIS, with certain additional blocks excluded due to their status, for proposed Lease Sale 257. BOEM is also adopting 11 lease stipulations and all practicable means of mitigation at the lease sale stage. The preferred alternative meets the purpose of and need for the proposed action, as identified in the 2018 GOM Supplemental EIS, and provides for orderly resource development with protection of human, marine, and coastal environments while also ensuring that the public receives a fair market value for these resources and that free-market competition is maintained.

Authority: This Notice of Availability of a Record of Decision is published pursuant to the regulations (40 CFR part 1505) implementing the provisions of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*).

Michael A. Celata,

Regional Director, New Orleans Office, Department of the Interior Regions 1, 2, 4, and 6, Bureau of Ocean Energy Management.

[FR Doc. 2021–01251 Filed 1–19–21; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On January 14, 2021, the Department of Justice lodged a proposed Consent

Decree with the District Court of the Southern District of New York in a lawsuit entitled *United States* v. *Toyota Motor Corporation, et al.,* Civil Action No. 21–323.

In this action the United States seeks, as provided under the Clean Air Act (''CAA''), civil penalties and injunctive relief from defendants in connection with violation of emission-defect reporting regulations promulgated at 40 CFR part 85, subpart T. The proposed Consent Decree resolves the United States' claims, requires defendants to pay $180 million, and imposes injunctive relief.

The publication of this notice opens the public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Toyota Motor Corporation, et al.,* Civil Action No. 21–323, D.J. Ref. 90–5–2–1–11477. All comments must be submitted no later than 30 days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please email your request and payment to: Consent Decree Library, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $9.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021–01233 Filed 1–19–21; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[OMB Number 1100–NEW]

Agency Infromation Collection Activtices: Proposed eCollection eComments Requested; New Collection: Law Enforcement Agency Certifications for Department of Justice Funding

AGENCY: Office of Community Oriented Policing Services, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Community Oriented Policing Services (COPS Office) will be submitting the following emergency information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until February 22, 2021.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time please contact Shelley S. Hyland, Supervisory Program Specialist, Office of Community Oriented Policing Services, 145 N Street NE, Washington, DC 20503 (email: *shelley.hyland2@usdoj.gov*; telephone: 202–598–1826). If you are simply providing public comments, please forward them directly to Lashon M. Hilliard, COPS PRA Program Manager, 145 N Street NE, Washington, DC 20503 (email: *lashon.hilliard@usdoj.gov*; 202–305–5245).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Office of Community Oriented Policing Services, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Emergency request.

(2) *The Title of the Form/Collection:* Law Enforcement Agency Certifications for Department of Justice Funding

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* There will be no form number. The applicable component within the Department of Justice is the Office of Community Oriented Policing Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Respondents will be staff from designated independent credentialing bodies. On June 16, 2020, President Donald J. Trump issued E.O. 13929 on Safe Policing for Safe Communities, which requires local, state, and university/college law enforcement agencies seeking Department of Justice discretionary funding to meet two use of force requirements: (1) The applying agency maintains use of force policies that adhere to all applicable federal, state, and local laws; and (2) the applying agency maintains use of force policies that prohibit the use of choke holds, except in situations where the use of deadly force is allowed by law. Per guidance issued by the Attorney General on E.O. 13929, independent credentialing bodies are to submit a list of certified agencies to the Office of Community Oriented Policing Services by January 31st in the funding year. Respondents are asked to supply the following information for each certified agency: Originating Record Identifier (ORI), Employee Identification Number (EIN), Data Universal Number System (DUNS), name of law enforcement agency, city, state and zip code of where law enforcement agency is located, title of the law enforcement agency's chief executive (*e.g.,* sheriff, chief of police, commissioner), chief executive's name, and date law enforcement agency received certification for E.O. 13929.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The COPS Office estimates that 52 independent credentialing bodies will respond (49 state agencies and 3 national organizations). The COPS Office estimates compiling the lists of certified agencies will require

approximately 4 hours over three years for each of the independent credentialing bodies.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There is an estimated 217 total burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: January 14, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–01216 Filed 1–19–21; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2006–0028]

MET Laboratories, Inc.: Applications for Expansion of Recognition and Proposed Modification to the NRTL Program's List of Appropriate Test Standards

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the applications of MET Laboratories, Inc., for expansion of the recognition as a Nationally Recognized Testing Laboratory (NRTL) and presents the agency's preliminary finding to grant the applications. Additionally, OSHA proposes to add two new test standards to the NRTL Program's List of Appropriate Test Standards.

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before February 5, 2021.

ADDRESSES: Submit comments by any of the following methods:

Electronically: Submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

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–2006–0028, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries, (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET. *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 rulemaking record by express delivery, hand delivery, and messenger service.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA–2006–0028). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at *http://www.regulations.gov.* Therefore, the agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

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 through the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office.

Extension of comment period: Submit requests for an extension of the comment period on or before February 5, 2021 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N–3653, Washington, DC 20210, or by fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, phone: (202) 693–1999 or email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, phone: (202) 693–2110 or email: *robinson.kevin@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Notice of the Application for Expansion

OSHA is providing notice that MET Laboratories, Inc. (MET), is applying for expansion of the current recognition as a NRTL. MET requests the addition of four test standards to the NRTL scope of recognition.

OSHA recognition of a NRTL signifies that the organization meets the requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within the scope of recognition. Each NRTL's scope of recognition includes: (1) The type of products the NRTL may test, with each type specified by the applicable test standard; and (2) the recognized site(s) that has/have the technical capability to perform the product-testing and product-certification activities for test standards within the NRTL's scope. Recognition is not a delegation or grant of government authority; however, recognition enables employers to use products approved by the NRTL to meet OSHA standards that require product testing and certification.

The agency processes applications by a NRTL for initial recognition and for an expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides a preliminary finding. In the second notice, the agency provides a final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational web page for each NRTL, including MET, which details the NRTL's scope of recognition. These pages are available from the OSHA website at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

MET currently has one facility (site) recognized by OSHA for product testing

and certification, with the headquarters located at: MET Laboratories, Inc., 914 West Patapsco Avenue, Baltimore, Maryland 21230. A complete list of MET's scope of recognition is available at *https://www.osha.gov/dts/otpca/nrtl/met.html.*

II. General Background on the Application

MET submitted four applications, one dated November 6, 2017 (OSHA–2006–0028–0042), two dated April 4, 2018 (OSHA–2006–0028–0043 and OSHA–2006–0028–0044), and a fourth on January 14, 2019 (OSHA–2006–0028–0045) to expand the recognition to include four additional test standards. OSHA staff performed a detailed analysis of the application packets and reviewed other pertinent information. OSHA did not perform any on-site reviews in relation to these applications.

Table 1, below, lists the appropriate test standards found in MET's applications for expansion for testing and certification of products under the NRTL Program.

TABLE 1—PROPOSED APPROPRIATE TEST STANDARDS FOR INCLUSION IN MET'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 61010–2–201 *	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use—Part 2–201: Particular Requirements for Control Equipment.
UL 61010–2–030	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use—Part 2–030: Particular Requirements for Testing and Measuring Circuits.
UL 61010–031	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use—Part 031: Safety Requirements for Hand-Held and Hand-Manipulated Probe Assemblies for Electrical Measurement and Test.
UL 60335–2–72 *	Household and Similar Electrical Appliances—Safety—Part 2–72: Particular Requirements for Floor Treatment Machines With or Without Traction Drive, for Commercial Use.

* Represents the standards that OSHA proposes to add to the NRTL Program's List of Appropriate Test Standards.

III. Proposal To Add New Test Standards to the NRTL Program's List of Appropriate Test Standards

Periodically, OSHA will propose to add new test standards to the NRTL list of appropriate test standards following an evaluation of the test standard document. To qualify as an appropriate test standard, the agency evaluates the document to: (1) Verify it represents a product category for which OSHA requires certification by a NRTL, (2) verify the document represents an end product and not a component, and (3) verify the document defines safety test specifications (not installation or operational performance specifications). OSHA becomes aware of new test standards through various avenues. For example, OSHA may become aware of new test standards by: (1) Monitoring notifications issued by certain Standards Development Organizations; (2) reviewing applications by NRTLs or applicants seeking recognition to include new test standards in their scopes of recognition; and (3) obtaining notification from manufacturers, manufacturing organizations, government agencies, or other parties. OSHA may determine to include a new test standard in the list, for example, if the test standard is for a particular type of product that another test standard also covers or it covers a type of product that no standard previously covered.

In this notice, OSHA proposes to add two new test standards to the NRTL Program's List of Appropriate Test Standards. Table 2, below, lists the test standards that are new to the NRTL Program. OSHA preliminarily determined that these test standards are appropriate test standards and proposes to include them in the NRTL Program's List of Appropriate Test Standards. OSHA seeks public comment on this preliminary determination.

TABLE 2—TEST STANDARDS OSHA IS PROPOSING TO ADD TO THE NRTL PROGRAM'S LIST OF APPROPRIATE TEST STANDARDS

Test standard	Test standard title
UL 61010–2–201	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use—Part 2–201: Particular Requirements for Control Equipment.
UL 60335–2–72	Household and Similar Electrical Appliances—Safety—Part 2–72: Particular Requirements for Floor Treatment Machines With or Without Traction Drive, for Commercial Use.

III. Preliminary Findings on the Applications

MET submitted acceptable applications for expansion of the scope of recognition. OSHA's review of the application file, and pertinent documentation, indicate that MET has met the requirements prescribed by 29 CFR 1910.7 for expanding the recognition to include the addition of these four test standards for NRTL testing and certification listed in Table 2. This preliminary finding does not constitute an interim or temporary approval of MET's applications.

OSHA welcomes public comment as to whether MET meets the requirements of 29 CFR 1910.7 for expansion of the recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. Commenters must submit the written request for an extension by the due date for comments. OSHA will limit any extension to 10 days unless the requester justifies a longer period. OSHA may deny a request for an extension if the request is not adequately justified. To obtain or review copies of the exhibits identified in this notice, as well as comments submitted to the docket, contact the Docket Office at the above address. These materials also are available online at *http://www.regulations.gov* under Docket No. OSHA–2006–0028.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will make a recommendation to the Assistant Secretary for Occupational Safety and Health whether to grant MET's

applications for expansion of the scope of recognition. The Assistant Secretary will make the final decision on granting the application. In making this decision, the Assistant Secretary may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of the final decision in the **Federal Register**.

IV. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 8–2020 (85 FR 58393, Sept. 18, 2020)), and 29 CFR 1910.7.

Signed at Washington, DC, on January 14, 2021.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2021–01221 Filed 1–19–21; 8:45 am]

BILLING CODE 4510–26–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting

DATE AND TIME: The Legal Services Corporation's Board of Directors and its six committees will meet January 28–29, 2021. On Thursday, January 28, the first meeting will commence at 11:00 a.m., Eastern Daylight Time (EDT), with the next meeting commencing promptly upon adjournment of the immediately preceding meeting. On Friday, January 29, the first meeting will commence at 12:00 p.m., EDT, with the next meeting commencing promptly upon adjournment of the immediately preceding meeting. On Friday, January 29, the closed session meeting of the Board of Directors will commence at 5:15 p.m., EDT.

LOCATION: *PUBLIC NOTICE OF VIRTUAL REMOTE MEETING.*

Due to the COVID–19 public health crisis, Legal Services Corporation (LSC) will be conducting the January 28–29, 2021 meetings remotely via ZOOM.

PUBLIC OBSERVATION: Unless otherwise noted herein, the Board and all committee meetings will be open to public observation. Members of the public who wish to participate remotely in the public proceedings may do so by following the directions provided below.

DIRECTIONS FOR OPEN SESSIONS:

Thursday, January 28, 2021

- *To join the Zoom Meeting by computer: please click the below link. https://lsc-gov.zoom.us/j/98432856166?pwd=WENUMkxsZDcvczJGczQ4R1RFWmEwQT09*
- *Meeting ID:* 984 3285 6166
- *Passcode:* 768308
- To join the Zoom meeting with one touch from your mobile phone, click below:

+16468769923,,98432856166# US (New York)

+13017158592,,98432856166# US (Germantown)

- To join the Zoom meeting by phone, use this information:

Dial by Your Location

- *Find your local number: https://lsc-gov.zoom.us/u/a18q49yI6*

Friday, January 29, 2021

- *To join the Zoom Meeting by computer: please click the below link. https://lsc-gov.zoom.us/j/98502884283?pwd=eDBDdHlLSG9JV0FLbFZvWGNDSzhGUT09*
- *Meeting ID:* 985 0288 4283
- *Passcode:* 079447
- To join the Zoom meeting with one touch from your mobile phone, click below:

+13126266799,,9850288428# US (Germantown)

+16468769923,,9850288428# US (Chicago)

- To join the Zoom meeting by phone, use this information:

Dial by your location

- *Find your local number: https://lsc-gov.zoom.us/u/awDabt5DP*
- 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.
- To participate in the meeting during public comment you will be notified when your microphone is no longer ''MUTED'' and you may give your questions, and or comments.

MEETING SCHEDULE

	Time **
Thursday, January 28, 2021:	
1. Governance and Performance Review Committee	11:00 a.m.
2. Institutional Advancement Committee.	
3. Communications Subcommittee of the Institutional Advancement Committee.	
4. Operations & Regulations Committee.	
5. Delivery of Legal Services Committee.	
Friday, January 29, 2021:	
1. Finance Committee	12:00 p.m.
2. Combined Audit & Finance Committees.	
3. Audit Committee.	
4. Board of Directors.	

** Any portion of the closed session consisting solely of briefings does not fall within the Sunshine Act's definition of the term ''meeting'' and, therefore, the requirements of the Sunshine Act do not apply to such portion of the closed session. 5 U.S.C. 552b (a) (2) and (b). *See also* 45 CFR 1622.2 & 1622.3. Please note all meetings are Eastern Daylight Time (EDT).

STATUS OF MEETING: Open, except as noted below.

Board of Directors—Open, except that, upon a vote of the Board of Directors, a portion of the meeting may be closed to the public to hear briefings by management and LSC's Inspector General, and to consider and act on the General Counsel's report on potential and pending litigation involving LSC.**

Institutional Advancement Committee—Open, except that, upon a vote of the Board of Directors, the meeting may be closed to the public to consider and act on recommendation of new Leaders Council invitees and to receive a briefing on the Development activities.**

Audit Committee—Open, except that the meeting may be closed to the public to hear a briefing on the Office of

Compliance and Enforcement's active enforcement matters.**

Combined Audit and Finance Committees—Closed to hear a management briefing.**

A verbatim written transcript will be made of the closed session of the Board, Institutional Advancement Committee, Audit Committee, and Joint Audit and Finance Committees meetings. The transcript of any portions of the closed sessions falling within the relevant provisions of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(6) and (10), will not be available for public inspection. A copy of the General Counsel's Certification that, in his opinion, the closing is authorized by law will be available upon request.

MATTERS TO BE CONSIDERED:

January 28, 2021

Governance and Performance Review Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting on October 19, 2020
3. Report on briefing materials for Biden Transition team
   - Carol Bergman, Vice President for Government Relations & Public Affairs
4. Report on annual Board and Committee evaluations
   - Carol Bergman, Vice President for Government Relations & Public Affairs
5. Report on Governance and Performance Review Committee evaluation
   - Carol Bergman, Vice President for Government Relations & Public Affairs
6. Discussion of President's evaluation for 2020
7. Discussion of Inspector General's 2020 activities
   - Jeffrey Schanz, Inspector General
8. Consider and act on other business
9. Public comment
10. Consider and act on motion to adjourn the meeting

January 28, 2021

Institutional Advancement Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Institutional Advancement Committee's Open Session meeting of October 19, 2020
3. Discussion of Committee's evaluations for 2020 and the Committee's goals for 2021
4. Development report
   - Nadia Elguindy, Director of Institutional Advancement
   - Ron Flagg, President
5. Update on Leaders Council and Emerging Leaders Council
   - John G. Levi, Chairman of the Board
6. Update on Emerging Leaders Council Communications Committee
   - Kristen Sonday, Co-Chair of LSC's Emerging Leaders Council
7. Update on Disaster Task Force Implementation
   - Lynn Jennings, Vice President for Grants Management
   - David Bonebrake, Program Counsel, Office of Program Performance
8. Public Comment
9. Consider and act on other business
10. Consider and act on motion to adjourn the open session meeting and proceed to a closed session

Closed Session

1. Approval of minutes of the Committee's Closed Session meeting of October 19, 2020
2. Development activities report
   - Nadia Elguindy, Director of Institutional Advancement
   - Ron Flagg, President
3. Consider and act on motion to approve Leaders Council and Emerging Leaders Council invitees
4. Consider and act on other business
5. Consider and act on motion to adjourn the meeting

January 28, 2021

Communications Subcommittee of the Institutional Advancement Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Subcommittee's Open Session meeting of October 19, 2020
3. Discussion of Subcommittee's evaluations for 2020 and the Committee's goals for 2021
4. Communications and social media update
   - Carl Rauscher, Director of Communications and Media Relations
5. Public comment
6. Consider and act on other business
7. Consider and act on motion to adjourn the meeting

January 28, 2021

Operations & Regulations Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting of October 19, 2020
3. Discussion of Committee's evaluations for 2020 and the Committee's goals for 2021
4. Discussion of Management's report on implementation of the Strategic Plan 2017–2020
   - Ron Flagg, President
5. Public comment
6. Consider and act on other business
7. Consider and act on adjournment of meeting

January 28, 2021

Delivery of Legal Services Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting on October 19, 2020
3. Discussion of Committee's evaluations for 2020 and the Committee's goals for 2021
4. Update on revisions to LSC Performance Criteria
   - Lynn Jennings, Vice President for Grants Management
5. Briefing from the Office of Data Governance and Analysis
   - Carlos Manjarrez, Chief Data Officer, Office of Data Governance and Analysis
6. Panel Presentation on Intake Procedures
   - Joyce Akasaka, Senior Attorney, Legal Aid Society of San Diego
   - Ashley Lowe, Executive Director, Lakeshore Legal Aid
   - Lori Molloy, Executive Director, North Penn Legal Services
   - Leslie Powell-Boudreaux, Executive Director, Legal Services of North Florida
   - Alison Paul, Executive Director, Montana Legal Services
   - Moderator: Lynn Jennings, Vice President for Grants Management
7. Public comment
8. Consider and act on other business
9. Consider and act on motion to adjourn the meeting

January 29, 2021

Finance Committee

Open Session

1. Approval of agenda
2. Approval of the minutes of the Committee's Open Session meeting of October 20, 2020
3. Discussion of Committee's evaluations for 2020 and the Committee's goals for 2021
4. Discussion of LSC's FY 2021 appropriation
   - Carol Bergman, Vice President for Government Relations & Public Affairs
5. Presentation of FY 2021 Consolidated Operating Budget
   - Debbie Moore, Treasurer and Chief Financial Officer

6. Consider and Act on *Resolution 2021–XXX,* LSC's Consolidated Operating Budget for FY 2021
7. Presentation of LSC's Financial Report for the first three months of FY 2021
   - Debbie Moore, Treasurer and Chief Financial Officer
8. Discussion of LSC's FY 2022 appropriations request, additional COVID relief request, and emergency disaster supplemental appropriation request
   - Carol Bergman Vice President for Government Relations & Public Affairs
9. Public comment
10. Consider and act on other business
11. Consider and act on adjournment of meeting

January 29, 2021

Combined Audit & Finance Commitee

Closed Session

1. Approval of agenda
2. Management briefing
   - Ron Flagg, President
   - Rebecca Weir, Deputy General Counsel
   - Deborah Moore, Chief Financial Officer/Treasurer
   - Jada Breegle, Chief Information Officer
3. Consider and act on adjournment of meeting

January 29, 2021

Audit Committee

Open Session

4. Approval of agenda
5. Approval of minutes of the Committee's Open Session meeting on October 20, 2020
6. Discussion of Committee's evaluations for 2020 and the Committee's goals for 2021
7. Briefing of Office of Inspector General
   - Jeffrey Schanz, Inspector General
   - Roxanne Caruso, Assistant Inspector General for Audit
8. Pursuant to Section VIII(C)(5) of the Committee Charter, review LSC's and the Office of Inspector General's mechanisms for the submission of confidential complaints
   - Dan O'Rourke, Assistant Inspector General for Investigation
   - Lora Rath, Director, Office of Compliance and Enforcement
9. Management update regarding risk management
   - Ron Flagg, President
10. Briefing about follow-up by the Office of Compliance and Enforcement on referrals by the Office of Inspector General regarding audit reports and annual Independent Public audits of grantees
   - Jeffrey Schanz, Inspector General
   - Roxanne Caruso, Assistant Inspector General for Audit
   - Lora Rath, Director, Office of Compliance and Enforcement
11. Public comment
12. Consider and act on other business
13. Consider and act on motion to adjourn the open session meeting and proceed to a closed session

Closed Session

1. Approval of minutes of the Committee's Closed Session meeting of October 20, 2020
2. Briefing on Office of Compliance and Enforcement on active enforcement matter(s) and follow-up on open investigations referrals from the Office of Inspector General
   - Lora Rath, Director, Office of Compliance and Enforcement
3. Consider and act on adjournment of meeting

Jnuary 29, 2021

Board of Directors

Open Session—January 29, 2021

1. Pledge of Allegiance
2. Approval of agenda
3. Approval of minutes of the Board's Open Session meeting of October 20, 2020
4. Approval of minutes of the Board's Open Session telephonic meeting of November 16, 2020
5. Consider and act on nominations for the Chair of Board of Directors
6. Consider and act on nominations for the Vice Chair of Board of Directors
7. Chairman's Report
8. Members' Report
9. President's Report
10. Inspector General's Report
11. Consider and act on the report of the Operations and Regulations Committee
12. Consider and act on the report of the Governance and Performance Committee
13. Consider and act on the report of the Combined Audit and Finance Committees
14. Consider and act on the report of the Audit Committee
15. Consider and act on the report of the Finance Committee
16. Consider and act on the report of the Institutional Advancement Committee
17. Consider and act on the report of the Delivery of Legal Services Committee
18. Update on the Housing Task Force
19. Update on the Veterans Task Force and Opioid Task Force Implementation
   - Stefanie Davis, Senior Assistant General Counsel
20. Consider and act on the draft LSC Strategic Plan for 2021–2024
21. Public Comment
22. Consider and act on other business
23. Consider and act on whether to authorize a closed session of the Board to address items listed below

Closed Session

1. Approval of minutes of the Board's Closed Session meeting of October 20, 2020
2. Management briefing
3. Inspector General briefing
4. Consider and act on General Counsel's report on potential and pending litigation involving LSC
5. Consider and act on prospective Leaders Council and Emerging Leaders Council invitees
6. Consider and act on motion to adjourn meeting

CONTACT PERSON FOR INFORMATION: Rebecca Fertig Cohen, Chief of Staff & Corporate Secretary, at (202) 295–1576 and Caroline Shriver, Board Affairs Coordinator, at (202) 302–4335. Questions may be sent by electronic mail to *FR_NOTICE_QUESTIONS@lsc.gov.*

NON-CONFIDENTIAL MEETING MATERIALS: Non-confidential meeting materials will be made available in electronic format at least 24 hours in advance of the meeting on the LSC website, at *http://www.lsc.gov/board-directors/meetings/board-meeting-notices/non-confidential-materials-be-considered-open-session.*

Dated: January 14, 2021.

Stefanie Davis,

Senior Assistant General Counsel.

[FR Doc. 2021–01319 Filed 1–15–21; 11:15 am]

BILLING CODE 7050–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting

The National Science Board's Executive Committee (EC), pursuant to National Science Foundation regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

TIME AND DATE: Monday, January 25, 2021 from 1:00–2:00 p.m. EST.

PLACE: This meeting will be held by teleconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Open.

MATTERS TO BE CONSIDERED: Committee Chair's opening remarks; approval of Executive Committee minutes of November 12, 2020; and discuss issues and topics for an agenda of the NSB meeting scheduled for February 23–24, 2021.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Brad Gutierrez, 2415 Eisenhower Avenue, Alexandria, VA 22314. Telephone: 703/292–7000. To listen to this teleconference, members of the public must send an email to *nationalsciencebrd@nsf.gov* at least 24 hours prior to the teleconference. The National Science Board Office will send requesters a toll-free dial-in number. Meeting information and updates may be found at *http://www.nsf.gov/nsb/notices/.jsp#sunshine.* Please refer to the National Science Board website at *www.nsf.gov/nsb* for general information.

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2021–01412 Filed 1–15–21; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting

The National Science Board's Awards and Facilities Committee, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

TIME AND DATE: Tuesday, January 26, 2021, from 12:00–1:00 p.m. EST.

PLACE: This meeting will be held by teleconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Closed

MATTERS TO BE CONSIDERED: The agenda of the teleconference is: Chair's opening remarks, Discussion of Mid-scale Research Infrastructure Track 2 awards, and Chair's closing remarks.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Michelle McCrackin, *mmccrack@nsf.gov,* (703) 292–7000. Meeting information and updates may be found at *http://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.* Please refer to the National Science Board website *www.nsf.gov/nsb* for general information.

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2021–01408 Filed 1–15–21; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Open to the Public Meetings of the Networking and Information Technology Research and Development (NITRD) Program

AGENCY: Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO), National Science Foundation.

ACTION: Notice of public meetings.

SUMMARY: The NITRD Program holds meetings that are open to the public to attend. The Joint Engineering Team (JET) and Middleware And Grid Interagency Coordination (MAGIC) Team provide an opportunity for the public to engage and participate in information sharing with Federal agencies. The JET and MAGIC Teams report to the NITRD Large Scale Networking (LSN) Interagency Working Group (IWG).

DATES: January 2021–December 2021.

FOR FURTHER INFORMATION CONTACT: Paul Love for the JET and Mallory Hinks for the MAGIC Team at *nco@nitrd.gov* or (202) 459–9674. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Joint Engineering Team (JET), established in 1997, provides an opportunity for information sharing among Federal agencies and non-Federal participants who have an interest in high-performance research and engineering or research and education (REN) networking and networking to support science applications.

The MAGIC Team, established in 2002, provides for information sharing among Federal agencies and non-Federal participants with interests and responsibility for middleware, Grid, and cloud projects; individuals involved in middleware, Grid, and cloud research and infrastructure; individuals involved in implementing or operating Grids and clouds; and users of Grids, clouds and middleware. The JET and MAGIC Team meetings are hosted by the NITRD NCO with WebEx and/or teleconference participation available for each meeting.

Public Meetings Website: The JET and MAGIC Team meetings are scheduled 30 days in advance of the meeting date. Please reference the NITRD Public Meetings web page (*https://www.nitrd.gov/meetings/public/*) for each Team's upcoming meeting dates and times, in addition to the agendas, minutes, and other meeting materials and information.

Public Meetings Mailing Lists: Members of the public may be added to the mailing lists by sending their full name and email address to *jet-signup@nitrd.gov* for JET and *magic-signup@nitrd.gov* for MAGIC, with the subject line: ''Add to JET'' and/or ''Add to MAGIC.'' Meeting notifications and information are shared via the mailing lists.

Public Comments: The government seeks individual input; attendees/participants may provide individual advice only. Members of the public are welcome to submit their comments for JET to *jet-comments@nitrd.gov* and for MAGIC to *magic-comments@nitrd.gov* . Please note that under the provisions of the Federal Advisory Committee Act (FACA), all public comments and/or presentations will be treated as public documents and may be made available to the public via the JET and MAGIC web pages.

Reference Website: NITRD website at: *http://www.nitrd.gov/.*

Submitted by the National Science Foundation in support of the Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) on January 13, 2021.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2021–01074 Filed 1–19–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

TIME AND DATE: 9:30am, Tuesday, February 9, 2021.

PLACE: Virtual.

STATUS: The one item may be viewed by the public through webcast only.

MATTER TO BE CONSIDERED:

66515 Aviation Investigation Report: Rapid Descent into Terrain, Island Express Helicopters Inc., Sikorsky S–76B, N72EX, Calabasas, California, January 26, 2020

CONTACT PERSON FOR MORE INFORMATION: Candi Bing at (202) 590–8384 or by email at *bingc@ntsb.gov.*

Media Information Contact: Keith Holloway by email at *keith.holloway@ntsb.gov* or at (202) 314–6100 and Eric Weiss by email at *eric.weiss@ntsb.gov* or at (202) 314–6100.

This meeting will take place virtually. The public may view it through a live or archived webcast by accessing a link under ''Webcast of Events'' on the NTSB home page at *www.ntsb.gov*.

There may be changes to this event due to the evolving situation concerning the novel coronavirus (COVID–19). Schedule updates, including weather-related cancellations, are also available at *www.ntsb.gov*.

The National Transportation Safety Board is holding this meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b).

Dated: Friday, January 15, 2021.

Candi R. Bing,

Federal Register Liaison Officer.

[FR Doc. 2021–01362 Filed 1–15–21; 4:15 pm]

BILLING CODE 7533–01–P

NEIGHBORHOOD REINVESTMENT CORPORATION

Sunshine Act Meetings; Special Board of Directors Meeting

TIME & DATE: 1:00 p.m., Friday, January 29, 2021.

PLACE: Via Conference Call.

STATUS: Open (with the exception of Executive Session).

MATTERS TO BE CONSIDERED:

The General Counsel of the Corporation has certified that in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552 (b)(2) and (4) permit closure of the following portion(s) of this meeting:

- Executive Session

Agenda

I. CALL TO ORDER

II. Executive Session: NeighborWorks Compass Update

III. Action Item FY2021 Appropriation—Only Budget

IV. Action Item Authority for Monthly Health Insurance Invoices 2021

V. Adjournment

CONTACT PERSON FOR MORE INFORMATION: Lakeyia Thompson, Special Assistant, (202) 524–9940; *Lthompson@nw.org.*

Lakeyia Thompson,

Special Assistant.

[FR Doc. 2021–01378 Filed 1–15–21; 4:15 pm]

BILLING CODE 7570–02–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0102]

Information Collection: Domestic Licensing of Special Nuclear Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''Domestic Licensing of Special Nuclear Material.''

DATES: Submit comments by February 22, 2021. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0102 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0102.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The supporting statement and burden spreadsheet are available in ADAMS under Accession Nos. ML20336A188 and ML20192A094.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0102 in your comment submission.

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

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

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''Domestic Licensing of Special Nuclear Material.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is

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

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on October 8, 2020 (85 FR 63593).

1. *The title of the information collection:* Domestic Licensing of Special Nuclear Material.

2. *OMB approval number:* 3150–0009.

3. *Type of submission:* Extension.

4. *The form number if applicable:* Not applicable.

5. *How often the collection is required or requested:* Required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and amendments may be submitted at any time. Generally, renewal applications are submitted every 10 years, although the Commission has allowed longer periods for major fuel cycle facilities; updates of the Integrated Safety Analysis Summary are submitted annually.

6. *Who will be required or asked to respond:* Applicants for and holders of specific and general licenses to receive title to, own, acquire, deliver, receive, possess, use, or initially transfer special nuclear material.

7. *The estimated number of annual responses:* 1,214.

8. *The estimated number of annual respondents:* 200.

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 37,050 hours (31,557 hours reporting + 5,459 hours recordkeeping + 34 hours third-party disclosure).

10. *Abstract:* Part 70 of title 10 of the *Code of Federal Regulations* establishes requirements for licensees to own, acquire, receive, possess, use, and transfer special nuclear material. The information in the applications, reports, and records are used by the NRC to make licensing and or regulatory determinations concerning the use of special nuclear material.

Dated: January 14, 2021.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2021–01201 Filed 1–19–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0110]

An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 2 to Regulatory Guide (RG) 1.177, ''An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications.'' Revision 2 of RG 1.177 includes guidance to develop risk-informed applications for technical specification (TS) changes that considers engineering issues and applies risk insights. It provides guidance acceptable to the staff for using risk information to evaluate changes to nuclear power plant TS completion times (CTs), surveillance frequencies (SFs) and to assess the impact of such proposed changes on the risk associated with plant operation. In addition, it supplements RG 1.174, Revision 3, ''An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,''.

DATES: Revision 2 to RG 1.177 is available on January 21, 2021.

ADDRESSES: Please refer to Docket ID NRC–2012–0110 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2012–0110. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

Revision 2 to RG 1.177 and the regulatory analysis may be found in ADAMS under Accession Nos. ML20164A034 and ML19206A493, respectively.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Gary Wang, telephone: 301–415–1686, email: *Zeechung.Wang@nrc.gov;* or Harriet Karagiannis, telephone: 301–415–2493, email: *Harriet.Karagiannis@nrc.gov.* Both are staff of the Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a revision to an existing guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the NRC staff uses in evaluating specific issues or postulated events, and data that the NRC staff uses in its review of applications for permits and licenses.

Revision 2 of RG 1.177 was issued with a temporary identification of Draft Regulatory Guide, DG–1287. It updates the application of the defense-in-depth philosophy to be consistent with the philosophy described in RG 1.174, which was revised in 2018 to expand the meaning of, and the process for, assessing defense-in-depth considerations. Specifically, this revision of RG 1.177 references the defense-in-depth guidance in the revised RG 1.174 with respect to several staff regulatory positions. Additionally, the staff revised this guide to (1) adopt the terms ''PRA acceptability,'' and related phrasing variants, instead of terms such as ''PRA quality,'' and ''PRA technical adequacy,'' and ''technical adequacy'' to describe the appropriateness of the probabilistic risk analysis (PRA) used to support risk informed licensing submittals, (2) update Section 2.3, ''Evaluation of Risk Impact,'' of RG 1.177 by removing information that was repeated from RG 1.174 (*e.g.,* discussion of the ASME/ANS PRA standard) and, in its place,

incorporated a direct reference to RG 1.174, Revision 3, and (3) delineate the difference between temporary CT extensions and permanent CT extensions of TSs or maximum backstop CTs.

II. Additional Information

The NRC published a notice of the availability of DG–1287 (ADAMS under Accession No. ML19206A489), in the **Federal Register** on February 19, 2020 (85 FR 9484) for a 60-day public comment period. The public comment period closed on April 20, 2020, and the NRC received two comment documents. Public comments on DG–1287 and the staff responses to the public comments are available in ADAMS under Accession No. ML20191A231.

II. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

III. Backfitting, Forward Fitting, and Issue Finality

RG 1.177, Revision 2 provides updated guidance for power reactor applicants and licensees regarding the use of the defense-in-depth philosophy with other recently updated guidance and would make other conforming changes to the use of PRA and associated terminology. Issuance of this RG does not constitute backfitting or forward fitting or affect issue finality as further discussed in this notice.

Current or future applicants are not, with limited exceptions not applicable here, within the scope of the backfitting and issue finality regulations and forward fitting policy. Applicants are not, with certain exceptions, covered by either the backfit rule or any issue finality provisions under part 52 of title 10 of the *Code of Federal Regulations* (10 CFR). This is because neither the backfit rule nor the issue finality provisions under 10 CFR part 52, with certain exclusions further discussed, were intended to apply to every NRC action which substantially changes the expectations of current and future applicants.

The exceptions to the general principle are applicable whenever an applicant references a 10 CFR part 52 license (*e.g.,* an early site permit) and/or NRC regulatory approval (*e.g.,* a design certification rule) with specified issue finality provisions or a construction permit under 10 CFR part 50. The staff does not, at this time, intend to impose the positions represented in the RG in a manner that would constitute backfitting or affect the issue finality of a part 52 approval. If, in the future, the staff seeks to impose a position in the RG in a manner that constitutes backfitting or does not provide issue finality as described in the applicable issue finality provision, then the staff would need to address the backfit rule or the criteria for avoiding issue finality as described in the applicable issue finality provision.

The staff does not, at this time, intend to impose the positions represented in the RG in a manner that would constitute forward fitting. If, in the future, the staff seeks to impose a position in the RG in a manner that constitutes forward fitting, then the staff would need to address the forward fitting criteria in Management Directive 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests'' (ADAMS Accession No. ML18093B087).

Dated: January 13, 2020.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2021–01154 Filed 1–19–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0064]

Information Collection: Collection of Operator Simulator Training Data

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''Collection of Operator Simulator Training Data.''

DATES: Submit comments by February 22, 2021. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0064 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0064.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0064 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission.

The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

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

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''Collection of Operator Simulator Training Data.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on September 11, 2020, (85 FR 56277).

1. *The title of the information collection:* Collection of Operator Simulator Training Data.
2. *OMB approval number:* 3150–0234.
3. *Type of submission:* Extension.
4. *The form number if applicable:* Not applicable.
5. *How often the collection is required or requested:* Six per year.
6. *Who will be required or asked to respond:* All holders of, or applicants for, a power reactor operating license under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' except those that have certified that they have permanently ceased operations and have permanently removed all fuel from the reactor vessel. All holders of, or applicants for, a power reactor combined license under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.''
7. *The estimated number of annual responses:* 32.
8. *The estimated number of annual respondents:* 5.
9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 148.
10. *Abstract:* This information collection request is to the holders of, or applicants for, a power reactor operating license under 10 CFR part 50, ''Domestic Licensing of Production and Utilization Facilities,'' except those that have certified that they have permanently ceased operations and have permanently removed all fuel from the reactor vessel, and the holders of, or applicants for, a power reactor combined license under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.''

This information collection is for the specified licensees to use the NRC developed Scenario Authoring, Characterization and Debriefing Application (SACADA) software for their operator simulator training. The SACADA system was developed to collect licensed operator simulator training data to inform human reliability analysis (HRA) and to facilitate operator simulator training. The SACADA software can be used to author the simulation scenarios, facilitate the post simulation debriefing on crew performance, guide performance analysis, and generate various types of reports. The information entered into the SACADA database can be used to improve simulator training effectiveness and HRA.

The South Texas Project Nuclear Operating Company has used the software for its operator simulator training since 2012 and highly regards the software. The NRC welcomes more licensees to partner with the NRC to use the software. The licensees' participation in the information collection is voluntary. In the partnership, the NRC provides the SACADA software license, training, and technical support to the participating licensees, and the participating licensees grant NRC access to analyze the data to improve the NRC's HRA techniques. An agreement will be developed to specify the details. To participate in the information collection, the licensee will notify the NRC contact that it is interested in evaluating the software. Then the NRC will provide additional information including an onsite briefing. If the licensee thinks the SACADA software could be beneficial, the NRC will provide a training session, the software license, and technical support for the licensee to pilot the use of the software in its simulator training. After the pilot study, the licensee will decide whether or not to partner with the NRC on the information collection. Either party can terminate the agreement at any time.

Dated: January 14, 2021.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2021–01203 Filed 1–19–21; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Privacy Act of 1974; System of Records

AGENCY: U.S. Office of Personnel Management, Healthcare and Insurance.

ACTION: Notice of New System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Office of Personnel Management (OPM) proposes to establish a new system of records titled ''OPM/Central–23 FEHB Program Enrollment Records.'' This system of records will contain information about enrollees and their family members, who are or have been covered under the Federal Employees Health Benefits (FEHB) Program. This newly established system of records will be included in OPM's inventory of record systems.

DATES: Please submit comments on or before February 22, 2021. This new system is effective upon today's publication in the **Federal Register**, with the exception of the routine uses, which are effective February 25, 2021.

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

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.
- *Mail:* Padma Shah, Senior Policy Analyst, Healthcare and Insurance, Office of Personnel Management, Suite 3468, 1900 E Street NW, Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact Padma Shah, 202–606–2128. For privacy questions, please contact Kellie

Cosgrove Riley, Chief Privacy Officer, 202–606–2308.

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Office of Personnel Management proposes to establish a new system of records titled ''OPM/Central–23, FEHB Program Enrollment Records.'' This system of records is being established to support OPM's administration of the Federal Employees Health Benefits (FEHB) Program and will contain information about enrollees and their family members, who are or have been covered under the FEHB Program. The records are used for business processes related to eligibility verification, enrollment transactions, enrollment reconciliation, and premium collection; and to support the evaluation of the effectiveness of the FEHB Program through statistical analysis, policy planning, and reporting. To effectuate these purposes, OPM also uses contracts and interagency agreements.

Established in 1960 through the Federal Employees Health Benefits Act of 1959, 5 U.S.C. 8901 *et seq.,* the FEHB Program is the largest employer-sponsored group health insurance program in the world, covering over 8 million individuals. Covered individuals, as defined in 5 CFR 890.101, include employees of the Federal government, annuitants, members of their families, former spouses, and miscellaneous groups, enumerated in 5 U.S.C. 8901; United States Postal Service employees and annuitants, pursuant to 39 U.S.C. 1005; tribal employees, pursuant to 25 U.S.C. 1647b; and separated employees and former dependents who are eligible for Temporary Continuation of Coverage under 5 U.S.C. 8905a.

Eligible individuals may elect to enroll or change enrollment in the FEHB Program through a Health Benefits Election Form (*i.e.,* either the SF–2809 or OPM 2809 form) or an electronic alternative, which records information about themselves and their family members. Information is also collected through agencies via the Notice of Change in Health Benefits Enrollment (SF 2810). These paper or electronic instruments are submitted to the appropriate employing offices, as defined in 5 CFR 890.101 and then forwarded to FEHB Carriers; electronic transactions are processed through OPM's FEHB Data Hub (see below). Enrollees have opportunities to enroll or change enrollment upon entry on duty, other qualifying life events (QLEs) such as marriage or the birth of a child, and during the annual Federal Benefits Open Season.

Records about covered individuals under the FEHB Program are currently managed within four information technology systems. First, the Health Insurance Data Warehouse (HIDW), when fully developed, will host a Master Enrollment Index (MEI) of all covered individuals under the FEHB Program. Second, the FEHB Data Hub serves various purposes including receipt of electronic enrollment transactions from agencies, posting enrollment data to a server for secure distribution to the FEHB Carriers, and transferring quarterly enrollment data from the Carriers to the Centralized Enrollment Reconciliation Clearinghouse System (CLER). Third, OPM has an interagency agreement with the U.S. Department of Agriculture's National Finance Center (NFC) to develop and maintain CLER, which receives quarterly enrollment data from agencies and FEHB Carriers to facilitate reconciliation and reporting. Finally, OPM has another interagency agreement with NFC to develop and maintain the Tribal Insurance Processing System (TIPS), which collects enrollment data and premium payments from tribal employers.

While OPM is responsible for overall FEHB Program administration, the enrollment records in this system of records are obtained from a variety of sources, including other systems of records. For example, enrollment records may be maintained by employing agencies and in individuals' official personnel folders, where they are part of the OPM/Government–1 General Personnel Records system of records. Likewise, records concerning annuitants' FEHB enrollment may be maintained by OPM Retirement Services in individual annuitants' files as part of the currently titled OPM/Central–1 Civil Service Retirement and Insurance system of records (OPM/Central–1). A note has been added to the SORN to clarify that although some enrollment records continue to be maintained in other systems of records, Central–23 becomes the official, first line source for enrollment records.

The records contained in this new system of records to date have been included in OPM/Central–1. However, OPM's organizational structure and its retirement and insurance programs have evolved over time and OPM has determined that OPM/Central–1 no longer provides the public with the most informative notice regarding the system of records, nor adequately facilitates individuals' ability to exercise their rights under the Privacy Act and OPM's ability to respond effectively. Accordingly, OPM is in the process of regrouping the records currently contained in OPM/Central–1 and publishing corresponding systems of records notices. Additional systems of records notices related to other record sets currently encompassed in OPM/Central–1 will be published in the future.

FEHB Program enrollment records will now be maintained in the system of records known as OPM/Central–23 FEHB Program Enrollment Records. This newly established system of records will be included in OPM's inventory of records systems. In accordance with 5 U.S.C. 552a(r), OPM has provided a report of this system of records to the Office of Management and Budget and to Congress.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

SYSTEM NAME AND NUMBER:

FEHB Program Enrollment Records, OPM/Central–23

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Healthcare and Insurance, Office of Personnel Management, 1900 E Street NW, Washington, DC 20415, is responsible for this system of records. The records are maintained at OPM's data center in Macon, Georgia and through an interagency agreement with the U.S. Department of Agriculture's National Finance Center in New Orleans, Louisiana.

SYSTEM MANAGER:

Director, Healthcare and Insurance, Office of Personnel Management, 1900 E Street NW, Washington, DC 20415.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. Chapter 89, Health Insurance; 25 U.S.C. 1647b, (Tribal) Access to Federal Insurance; 39 U.S.C. 1005, Applicability of Laws Relating to Federal Employees; and 5 CFR part 890.

PURPOSES OF THE SYSTEM:

The purpose of this system of records is to support the administration of the Federal Employees Health Benefits (FEHB) Program, including business processes related to eligibility verification, enrollment transactions, enrollment reconciliation, and premium collection; and to support the evaluation of the effectiveness of the FEHB Program through auditing, statistical analysis, policy planning, and reporting. To effectuate these purposes, OPM also

uses contracts and interagency agreements.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Enrollees (defined in 5 CFR 890.101) and their family members, who are or have been covered under the FEHB Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

a. Full name, including any former names;
b. Social Security number, or other current or previous unique identification number(s);
c. Date of birth;
d. Date of death;
e. Sex;
f. Relationship code of any covered family member(s) to enrollee;
g. Mailing address;
h. Indicator for non-deliverable mailing address;
i. Date mailing address information was last processed;
j. Marital status;
k. Email address;
l. Enrollee's employment status;
m. Enrollee's employing office, including name and Personnel Office Identifier;
n. Enrollee's payroll office number;
o. Event code indicating the qualifying life event which permitted enrollment, a change in enrollment, or enrollment cancellation;
p. Transaction code indicating the most recent action that resulted in the creation or change of enrollment;
q. Date enrollment record was processed;
r. FEHB enrollment code, indicating plan, plan option, and enrollment type (Self Only, Self Plus One, or Self and Family);
s. Group insurance account identifier;
t. Effective date of FEHB coverage and any change in coverage;
u. Agency payroll office effective date;
v. Agency payroll office enrollment match code;
w. Code indicating the reason a family member's eligibility became effective;
x. End date of FEHB coverage, including possible 31-day extension;
y. Reason code for FEHB coverage termination;
z. Retirement claim number;
aa. Date employee retired;
bb. Date enrollee is reemployed by the Federal government;
cc. Medicare status, forms of Medicare coverage, and Medicare Beneficiary Identifier (formerly Medicare Claim Number);
dd. Other insurance, including name and policy number;
ee. Information related to tribal bank accounts in which FEHB premiums are maintained for monthly withdrawal; and
ff. Information necessary to verify family member eligibility, including but not limited to marriage certificates, birth certificates, and other information as set forth in OPM guidance.

RECORD SOURCE CATEGORIES:

Records are obtained from employing agencies and retirement systems, FEHB Carriers, shared service centers, the Centers for Medicare and Medicaid Services, Official Personnel Folders, retirement records and indirectly from individuals who participate in the FEHB Program. Note: With the establishment of this SORN, although enrollment records may continue to be maintained in other systems of records, Central–23 becomes the official, first line source for enrollment records.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside OPM as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

a. To the Department of Justice, including Offices of the U.S. Attorneys; another federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body; another party in litigation before a court, adjudicative, or administrative body; or to a court, adjudicative, or administrative body. Such disclosure is permitted only when it is relevant or necessary to the litigation or proceeding and one of the following is a party to the litigation or has an interest in such litigation:

(1) OPM, or any component thereof;
(2) Any employee or former employee of OPM in his or her official capacity;
(3) Any employee or former employee of OPM in his or her individual capacity where the Department of Justice or OPM has agreed to represent the employee;
(4) The United States, a Federal agency, or another party in litigation before a court, adjudicative, or administrative body, upon the OPM General Counsel's approval, pursuant to 5 CFR part 295 or otherwise.

b. To the appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates or is relevant to a violation or potential violation of civil or criminal law or regulation.

c. To a member of Congress from the record of an individual in response to an inquiry made at the request of the individual to whom the record pertains.

d. To the National Archives and Records Administration (NARA) for records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

e. To appropriate agencies, entities, and persons when (1) OPM suspects or has confirmed that there has been a breach of the system of records, (2) OPM has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, OPM (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with OPM's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

f. To another Federal agency or Federal entity, when OPM determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

g. To contractors, grantees, experts, consultants, or volunteers performing or working on a contract, service, grant, cooperative agreement, or other assignment for OPM when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to OPM employees.

h. To employing offices, shared service centers, and FEHB Carriers, information necessary to identify, reconcile, and audit enrollment in a plan; to verify eligibility for or coverage under the FEHB Program; to verify eligibility for payment of a claim for health benefits; and to carry out coordination of benefits.

i. To any source, including employing offices, from which additional information is requested relevant to OPM determination on an individual's eligibility for or enrollment in the FEHB Program, to the extent necessary to identify the individual and the type of information requested.

j. To an official of another Federal agency, information needed in the performance of official duties related to reconciling or reconstructing data files; compiling descriptive statistics; and/or making analytical studies to support the function for which the records were collected and maintained.

k. To a spouse or dependent child (or court-appointed guardian thereof) of an FEHB enrollee whether the enrollee has made enrollment changes, including changing FEHB plans; cancelling or suspending FEHB enrollment; and changing from a Self and Family to a Self Plus One or Self Only health benefits enrollment, or from a Self Plus One to Self Only health benefits enrollment.

l. To provide an official of another Federal agency information needed in the performance of official duties related to federal employee health benefits counseling, customer service, or operational readiness.

m. To the following recipients, information needed to conduct an analytical study of benefits being paid under the FEHB Program or the recipient's benefits program(s): Federal, State, or local agencies.

n. To the following recipients, information needed to adjudicate a claim for benefits under the FEHB Program or the recipient's benefits program(s): Federal, State, local, or agencies.

o. To another Federal or non-Federal entity, information needed to verify enrollment information through the use of computer matching agreements under the Privacy Act of 1974, as amended (5 U.S.C. 552a).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

These records in this system of records are stored electronically on OPM's servers hosted at an OPM data center and at the U.S. Department of Agriculture's National Finance Center. Access to the electronic systems is restricted to authorized users with a need to know.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

These records in this system of records are retrieved primarily by name and Social Security number, but may be retrieved by any personal identifier.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

A records retention schedule will be established with NARA for the records about covered individuals in this system of records and, until it is finalized, records will be treated as permanent. Once that schedule is established, the method(s) for disposing of records that are no longer be eligible for retention will be established.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in this system are protected from unauthorized access and misuse through various administrative, technical and physical security measures. OPM security measures are in compliance with the Federal Information Security Modernization Act of 2014 (Pub. L. 113–203), associated OMB policies, and applicable standards and guidance from the National Institute of Standards and Technology (NIST).

RECORD ACCESS PROCEDURES:

Individuals seeking notification of and access to their records in this system of records may do so by submitting a request in writing to the Office of Personnel Management, Office of Privacy and Information Management—FOIA, 1900 E Street NW, Washington, DC 20415–7900 or by emailing *foia@opm.gov*; ATTN: Healthcare and Insurance. Individuals must furnish the following information for their records to be located:

1. Full name, including any former name.
2. Date of birth.
3. Social Security Number.
4. Name and address of employing agency or retirement system.
5. Reasonable specification of the requested information.
6. The address to which the information should be sent.
7. Signature.

Individuals requesting access must also comply with OPM's Privacy Act regulations regarding verification of identity and access to records (5 CFR 297).

Enrollees who request access to their records will have access to the entirety of their record, to include information about all covered individuals who are part of their enrollment record. Family members of the enrollee who request access to their records may have access only to their own information and not to that of the enrollee or other covered family members.

CONTESTING RECORD PROCEDURES:

Individuals wishing to request amendment of records about them may do so by writing to the Office of Personnel Management, Office of Privacy and Information Management—FOIA, 1900 E Street NW, Washington, DC 20415–7900 or by emailing *foia@opm.gov*; ATTN: Healthcare and Insurance. Requests for amendment of records should include the words ''PRIVACY ACT AMENDMENT REQUEST'' in capital letters at the top of the request letter; if emailed include those words in the subject line. Individuals must furnish the following information for their records to be located:

1. Full name, including any former name, and address.
2. Date of birth.
3. Social Security Number.
4. Name and address of employing agency or retirement system.
5. Precise identification of the information to be amended.
6. Signature.

Individuals requesting amendment must also comply with OPM's Privacy Act regulations regarding verification of identity and access to records (5 CFR 297).

OPM may refer amendment requests to employing agencies, retirement systems, and FEHB Carriers because they may be the ultimate source of FEHB enrollment records.

NOTIFICATION PROCEDURES:

See ''Record Access Procedure.''

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

OPM/Central–1, ''Civil Service Retirement and Insurance Records'', 73 FR 15013 (March 20, 2008), 80 FR 74815 (November 30, 2015).

[FR Doc. 2021–01259 Filed 1–19–21; 8:45 am]

BILLING CODE 6325–XX–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0140, Representative Payee Application (RI 20–7) and Information Necessary for a Competency Determination (RI 30–3)

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on a revised information collection request (ICR), RI 20–7 *[Representative Payee Application]* and RI 30–3 *[Information for a Competency Determination]*.

DATES: Comments are encouraged and will be accepted until February 22, 2021.

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, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to: *oira_submission@omb.eop.gov* or faxed to (202) 395–6974..

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0140) was previously published in the **Federal Register** on April 13, 2020 at 85 FR 20532, allowing for a 60-day public comment period. No comments were received. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Form RI 20–7 is used by the Civil Service Retirement System (CSRS) and the Federal Employees Retirement System (FERS) to collect information from persons who apply to be fiduciaries for annuitants or survivor annuitants who appear to be incapable of handling their own funds or for minor children. RI 30–3 is an enclosure to RI 20–7 and is needed for adult annuitants who are alleged to be incompetent. RI 30–3 collects medical information regarding the annuitant's competency for OPM's use in evaluating the annuitant's condition.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Annuity Supplement Earnings Report.

OMB Number: 3206–0140.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 12,480 *[RI 20–7]* and 250 *[RI 30–3].*

Estimated Time per Respondent: 30 minutes *[RI 20–7]* and 1 hour *[RI 30–3].*

Total Burden Hours: 6,240 *[RI 20–7]* and 250 *[RI 30–3].*

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2021–01248 Filed 1–19–21; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0128, Application for Refund of Retirement Deductions (CSRS)—SF 2802 and Current/Former Spouse's Notification for Refund of Retirement Deductions Under CSRS—SF 2802A

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on a revised information collection request (ICR), SF 2802 *[Application for Refund of Retirement Deductions: CSRS]* and SF 2802A *[Notification of Application for Refund of Retirement Deductions Under CSRS].*

DATES: Comments are encouraged and will be accepted until February 22, 2021.

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, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to: *oira_submission@omb.eop.gov* or faxed to (202) 395–6974..

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0128) was previously published in the **Federal Register** on June 1, 2020 at 85 FR 33206, allowing for a 60-day public comment period. No comments were received. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Standard Form 2802 is used to support the payment of monies from the Retirement Fund. It identifies the applicant for refund of retirement deductions. Standard Form 2802A is used to comply with the legal requirement that any spouse or former spouse of the applicant has been notified that the former employee is applying for a refund.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Application for Refund of Retirement Deductions (CSRS) and Current/Former Spouse's Notification of Application for Refund of Retirement Deductions under CSRS.

OMB Number: 3206–0128.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 3,741 *[SF 2802]* and 3,389 *[SF 2802A].*

Estimated Time per Respondent: 60 minutes *[SF 2802]* and 15 minutes *[SF 2802A].*

Total Burden Hours: 4,588.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2021–01247 Filed 1–19–21; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0138, Reinstatement of Disability Annuity Previously Terminated Because of Restoration to Earning Capacity, RI 30–9

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on a revised information collection request (ICR), RI 30–9—Reinstatement of Disability Annuity Previously Terminated Because of Restoration to Earning Capacity.

DATES: Comments are encouraged and will be accepted until February 22, 2021.

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, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to: *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995, OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0138) was previously published in the **Federal Register** on April 7, 2020 at 85 FR 19517, allowing for a 60-day public comment period. No comments were received. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Form RI 30–9, Reinstatement of Disability Annuity Previously Terminated Because of Restoration to Earning Capacity, informs former annuitants of their right to request reconsideration. It also specifies the conditions to be met and the documentation that must be submitted with a request for reinstatement.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Reinstatement of Disability Annuity Previously Terminated Because of Restoration to Earning Capacity.

OMB Number: 3206–0138.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 200.

Estimated Time per Respondent: 60 minutes.

Total Burden Hours: 200.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2021–01249 Filed 1–19–21; 8:45 am]

BILLING CODE 6325–38–P

POSTAL SERVICE

Board of Governors; Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 86 FR 1122.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Thursday, January 14, 2021 at 3:00 p.m.

PLACE: Potomac, MD.

STATUS: Thursday, January 14, 2021—Closed.

CHANGES IN THE MEETING: Time of closed session changed.

REVISED TIME: Thursday, January 14, 2021, at 1:45 p.m.

CONTACT PERSON FOR MORE INFORMATION: Michael J. Elston, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–1000. Telephone: (202) 268–4800.

Michael J. Elston,

Secretary.

[FR Doc. 2021–01343 Filed 1–15–21; 11:15 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90916; SR–CBOE–2020–110]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Withdrawal of a Proposed Rule Change Amending Rule 5.52(d) in Connection With a Market-Maker's Electronic Volume Transacted on the Exchange

January 13, 2021.

On November 13, 2020, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe'') 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 change the electronic volume threshold trigger for continuous electronic quoting requirements for Market-Makers from one calendar quarter to two consecutive calendar quarters. The proposed rule change was published for comment in the **Federal Register** on November 30, 2020.[3] The Commission has received no comment letters on the proposed rule change.

On January 13, 2021, the Exchange withdrew the proposed rule change (SR–CBOE–2020–110).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[4]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–01134 Filed 1–19–21; 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. 90482 (November 23, 2020), 85 FR 76642 (November 30, 2020) (SR–CBOE–2020–110).

[4] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90918; File No. SR-Phlx-2021–01]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Pricing Schedule at Equity 7, Section 3

January 13, 2021.

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 January 4, 2021, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's pricing schedule at Equity 7, Section 3, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its pricing schedule, at Equity 7, Section 3, to make several changes to its Qualified Market Maker (''QMM'') Program. The QMM Program provides supplemental incentives to member organizations that meet certain quality standards in acting as market makers for securities on the Exchange.

Specifically, the Exchange proposes to adjust upward the average number of securities for which a member organization that qualifies as a QMM must quote at the national best bid and offer (''NBBO'') during a month to receive a supplemental credit of $0.0002 per share executed, as set forth in Equity 7, Section 3(c)(3). Currently, a member organization must quote at the NBBO at least 10% of the time for an average of at least 500 securities per day to qualify for the $0.0002 per share executed supplemental credit. The Exchange proposes to increase this number to 650 securities.

The Exchange proposes to increase the threshold number of securities in which a member organization must quote at the NBBO during a month to qualify for this supplemental credit as a means of encouraging QMMs to broaden the scope of their quoting activities on the Exchange. The Exchange believes that QMM activity on the Exchange is already robust enough to accommodate the establishment of a higher qualification threshold without compromising the ability of existing QMMs to maintain their current statuses in the program.

Second, the Exchange proposes to adjust downward the average number of securities for which a member organization must quote at the NBBO at least 10% of the time during market hours during a month to receive a supplemental credit of $0.0003 per share executed in Tape A securities or $0.0002 per share executed in Tape B and Tape C securities, as set forth in Equity 7, Section 3(c)(4). Currently, a member organization must quote at the NBBO at least 10% of the time for an average of at least 850 securities per day, and provide 0.12% or more of total Consolidated Volume during a month, to qualify for this supplemental credit. The Exchange proposes to reduce the threshold number of securities that must be quoted to 800 securities.

The Exchange proposes to lower the number of securities in which a member organization must quote at the NBBO during a month to qualify for this supplemental credit so as to render this credit more readily attainable for QMMs. The Exchange hopes that the proposal will lead to additional member organizations qualifying for the credit, which in turn would entail more QMMs quoting at the NBBO at least 10% of the time during the trading day in more securities than they do now, to the benefit of market quality.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[3] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[4] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Proposal is Reasonable

The Exchange's proposed changes to its schedule of credits and QMM Program are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for equity securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has 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'. . . .''[5]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, 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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(4) and (5).

[5] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (DC Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

broader forms that are most important to investors and listed companies.'' [6]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for equity security transaction services. The Exchange is only one of several equity venues to which market participants may direct their order flow. Competing equity exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon members achieving certain volume thresholds.[7]

Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules.[8] Within the foregoing context, the proposal represents a reasonable attempt by the Exchange to increase its market share relative to its competitors.

The Exchange's proposal to increase the threshold numbers of securities in which QMMs must quote at the NBBO during a month to qualify for the supplemental credit at Equity 7, Section 3(c)(2) [sic] will encourage QMMs to broaden the scope of their quoting activities on the Exchange. The Exchange believes that it is appropriate to periodically reassess and recalibrate the baselines for its pricing tiers when participant activity is adequate to support doing so. In this instance, QMM activity on the Exchange is robust enough to accommodate the establishment of a higher qualification threshold without compromising the ability of existing QMMs to maintain their current statuses in the program.

Additionally, the Exchange's proposal to ease one of its qualifications for the $0.0003/$0.0002 per share executed supplemental credit set forth in Equity 7, Section 3(c)(4) is also a reasonable attempt to improve the accessibility of that supplemental credit and will encourage member organizations to try to qualify for it.

The Proposals Are an Equitable Allocation of Credits

The Exchange believes its proposals will allocate its proposed credits fairly among its market participants.

The Exchange believes its proposal to raise the qualification criteria applicable its QMM supplemental credit, at Equity 7, Section 3(c)(2) [sic], is equitable because the proposal will encourage member organizations to quote significantly at the NBBO for a larger number of securities, which in turn will contribute to market quality in a meaningful way. At the same time, the proposed recalibrated qualification threshold will not compromise the ability of QMMs that currently qualify for this supplemental credit to continue to do so.

The Exchange also believes that it is equitable to lower a qualification threshold for its highest supplemental credit, at Equity 7, Section 3(c)(4), because the proposal will render the credit more readily attainable to member organizations. It is equitable for the Exchange to make it easier for member organizations to qualify for this supplemental credit because doing so may encourage member organizations to broaden the extent to which they quote securities at the NBBO, which in turn stands to improve the quality of the Exchange's equity market and increase its attractiveness to existing and prospective participants.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposals are not unfairly discriminatory. As an initial matter, the Exchange believes that nothing about its volume-based tiered pricing model is inherently unfair; instead, it is a rational pricing model that is well-established and ubiquitous in today's economy among firms in various industries—from co-branded credit cards to grocery stores to cellular telephone data plans—that use it to reward the loyalty of their best customers that provide high levels of business activity and incent other customers to increase the extent of their business activity. It is also a pricing model that the Exchange and its competitors have long employed with the assent of the Commission. It is fair because it incentivizes customer activity that increases liquidity, enhances price discovery, and improves the overall quality of the equity markets.

The Exchange intends for its proposals to increase participation and the extent of participation in its QMM program, which in turn would improve market quality for all member organizations on the Exchange.

The Exchange's proposal to raise the qualification requirements for its supplemental QMM credit, at Equity 7, Section 3(c)(2) [sic], is not unfairly discriminatory because no member organization that presently qualifies for this supplemental credit will fail to qualify for it upon raising the requirements. Although any member organization that newly qualifies for this credit will need to quote at the NBBO for a larger number of securities than they would need to do now, this is fair because meeting the heightened requirement will improve market quality. Meanwhile, the proposal to lower the qualification criteria for the highest supplemental QMM credit, at Equity 7, Section 3(c)(4), will improve the accessibility of that credit to member organizations. Again, if this proposal results in more member organizations meeting the requirements for this supplemental credit, then market quality will improve.

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.

Intramarket Competition

The Exchange does not believe that its proposals will place any category of Exchange participants at a competitive disadvantage. As noted above, all members of the Exchange will benefit from an increase in the addition of liquidity by those that choose to meet the criteria. Members may grow their businesses so that they have the capacity to receive credits for providing liquidity. Moreover, members are free to trade on other venues to the extent they believe that the credits provided are not attractive. As one can observe by looking at any market share chart, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes. The Exchange notes that the tier structure is consistent with broker-dealer fee practices as well as the other industries, as described above.

Moreover, the Exchange's proposal to modify its QMM program will not burden intramarket competition because the QMM Program, as modified, will continue to provide all member organizations with an opportunity to obtain supplemental credits for transactions if they improve the market by providing significant quoting at the

[6] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[7] *See* Cboe EDGX U.S. Equities Exchange Fee Schedule, available at *https://markets.cboe.com/us/equities/membership/fee_schedule/edgx/.*

[8] The Exchange perceives no regulatory, structural, or cost impediments to market participants shifting order flow away from it. In particular, the Exchange notes that such shifts in liquidity and market share occur within the context of market participants' existing duties of Best Execution and obligations under the Order Protection Rule under Regulation NMS.

NBBO in a large number of securities which the Exchange believes will improve market quality. By relaxing the qualification criteria, the modifications will make the Program more accessible to new member organizations and easier for existing QMMs to remain in the Program.

Intermarket Competition

Addressing whether the proposed fee could impose a burden on competition on other SROs that is not necessary or appropriate, the Exchange believes that its proposed modifications to its schedule of credits and charges will not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition both from the other live exchanges and from off-exchange venues, which include alternative trading systems that trade national market system stock. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

The proposed credit for adding liquidity and the proposed modifications to the QMM Program are reflective of this competition because, as a threshold issue, the Exchange is a relatively small market so its ability to burden intermarket competition is limited. In this regard, even the largest U.S. equities exchange by volume only has 17–18% market share, which in most markets could hardly be categorized as having enough market power to burden competition. Moreover, as noted above, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes. This is in addition to free flow of order flow to and among off-exchange venues which comprises more than 40% of industry volume in recent months.

In sum, the Exchange intends for the modified QMM Program to increase member organizations incentives to quote more securities at the NBBO for at least 10 percent of the day, which stands to improve the quality of the Exchange's market and its attractiveness to participants; however, if the proposals are unattractive to market participants, it is likely that the Exchange will either fail to increase its market share or even lose market share as a result. Accordingly, the Exchange does not believe that the proposed amended credits will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[9]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2021–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2021–01. 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–Phlx–2021–01 and should be submitted on or before February 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–01136 Filed 1–19–21; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90910; File No. SR–CboeBZX–2021–005]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend Its Fees Schedule

January 13, 2021.

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 January 4, 2021, 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 the 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 its 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 for its equity options platform (''BZX Options'') in connection with its Market Maker Penny Add Volume Tiers, effective January 4, 2021.

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 options venues to which market participants may direct their order flow. Based on publicly available information, no single options exchange has more than 17% of the market share and currently the Exchange represents only approximately 8% of the market share.[3] Thus, in such a low-concentrated and highly competitive market, no single options exchange, including the Exchange, possesses significant pricing power in the execution of option order flow. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange's fee schedule sets forth standard rebates and rates applied per contract, which varies depending on the Member's Capacity (Customer, Firm, Market Maker, etc.), whether the order adds or removes liquidity, and whether the order is in Penny or Non-Penny Pilot Securities. 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.

For example, the Exchange currently offers 12 Market Maker Penny Add Volume Tiers under footnote 6 of the Fee Schedule which provide additional rebates between $0.33 and $0.46 per contract for qualifying Market Maker orders (*i.e.,* that yield fee code PM or XM)[4] where a Member meets certain liquidity thresholds. For example, current Tier 12 offers an enhanced rebate of $0.46 per contract for qualifying orders where a Member has an ADAV[5] in Market Maker orders greater or equal to 0.75% of OCV.[6] The Exchange now proposes to amend the Market Maker Penny Add Volume Tiers by adding a new Tier 12 (and subsequently updating current Tier 12 to Tier 13). As proposed, new Tier 12 will provide an opportunity for a Member to receive an enhanced rebate of $0.44 per contract for qualifying orders where the Member (1) has a Step-Up ADAV in Market Maker orders from December 2020 ≥ 0.05% of overage [sic] OCV; and (2) is a Lead Market Maker (''LMM'') in at least 85 LMM Securities on BZX Equities.[7] The Exchange believes the proposed tier, along with the existing tiers, will continue to provide an incremental incentive for Members to strive for the highest tier levels, which provide increasingly higher rebates for such transactions. Additionally, the Exchange notes that the two prongs of the proposed criteria are similar to the criteria set forth in other Market Maker Penny Add Volume tiers. Many of the existing tiers provide criteria in which a Member must ''step up'' a percentage of ADAV or ADV[8] from a certain point in time over OCV or TCV,[9] and criteria which measures a Member's participation on the Exchange's equities platform (''BZX Equities''). Overall, the proposed enhanced rebate and corresponding criteria is designed to encourage Market Makers (including LMMs) to increase their order flow on BZX Options and Equities, which facilitates tighter spreads, signaling increased activity from other market participants, and thus ultimately contributes to deeper and more liquid markets and provides greater execution opportunities on the Exchange to the benefit of all market participants. The proposed change encourages Members to enroll as LMMs

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Cboe Global Markets U.S. Options Market Month-to-Date Volume Summary (December 31, 2020), available at *https://markets.cboe.com/us/options/market_statistics/.*

[4] Orders yielding fee code PM are Market Maker orders that add liquidity in Penny Program Securities and are offered a rebate of $0.29, and orders yielding fee code XM are Market Maker orders in XSP options that add liquidity and are offered a rebate of $0.29.

[5] ''ADAV'' means average daily added volume calculated as the number of contracts added, per day.

[6] ''OCC Customer Volume'' or ''OCV'' means the total equity and ETF options volume that clears in the Customer range at the Options Clearing Corporation (''OCC'') for the month for which the fees apply, excluding volume on any day that the Exchange experiences an Exchange System Disruption and on any day with a scheduled early market close.

[7] Pursuant to BZX Equities Rules, the term ''LMM'' means a Market Maker registered with the Exchange for a particular LMM Security that has committed to maintain Minimum Performance Standards in the LMM Security, and the term ''LMM Security'' means a Listed Security that has an LMM. *See* Cboe BZX Exchange, Inc. Rule 11.8(e)(1)(B) [sic] and (C) [sic].

[8] ''ADV'' means average daily volume calculated as the number of contracts added or removed, combined, per day.

[9] ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges to the consolidated transaction reporting plan for the month for which the fees apply, excluding volume on any day that the Exchange experiences an Exchange System Disruption and on any day with a scheduled early market close.

in LMM Securities on the Exchange's equities platform, which enhances market quality in securities listed on the Exchange's equity platform. The Exchange notes that LMMs serve a crucial role in providing quotes and trading opportunities for all market participants, which can lead to increased volume, enhanced price discovery and transparency, and more robust markets overall. As such, the proposed tier is designed to benefits all Members by contributing towards a robust and well-balanced market ecosystem across the Exchange's options and equities platforms, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency and improving investor protection.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[10] in general, and furthers the objectives of Section 6(b)(4),[11] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5) [12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As described above, 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 change reflects 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.

In particular, the Exchange believes the proposed tier is reasonable because it provides an additional opportunity for Members to receive an enhanced rebate on qualifying orders in a manner that incentivizes increased Market Maker order flow to the Exchange and LMM participation on the Exchange's equities platform. The Exchange notes that volume-based incentives and discounts have been widely adopted by exchanges,[13] including the Exchange,[14] 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 a highly competitive market. The Exchange is only one of several options venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. Competing options exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon Members achieving certain volume and/or growth thresholds.

Moreover, the Exchange believes the proposed additional Market Maker Penny Add Volume Tier is a reasonable means to encourage Market Makers to increase their order flow on the Exchange, as well as their participation in securities on the Exchange's equities platform. More specifically, the Exchange believes that adopting a tier with alternative criteria to the existing Market Maker Penny Add Volume Tiers may encourage those Members who could not previously achieve the criteria under existing Market Maker Volume Tiers 10 and 11 (which offer the same enhanced rebate as proposed for new Tier 12) or 12 (proposed to be renumbered to Tier 13) to increase their order flow on BZX Options and Equities. For example, the proposed tier would provide an additional rebate opportunity for Market Makers who increase their ADAV in Market Makers orders over OCV by at least 0.05% from December 2020 and participate as an LMM in at least 85 LMM Securities on BZX Equities, but do not meet the more stringent criteria under Tier 13 (*i.e.,* current Tier 12) of having an ADAV in Market Maker orders that is greater than or equal to 0.75% of average OCV (and thus, do not receive the slightly higher enhanced rebate of $0.46 per contract), or do not meet all three of the different, yet comparable, prongs of criteria under Tier 10 or Tier 11 (which provide the same enhanced rebate of $0.44 per contract). Overall, the proposed tier provides an alternative opportunity for Members to receive an enhanced rebate, as is thereby reasonably designed to incentivize Market Makers to grow their options volume and increase their participation on BZX Equities. The Exchange notes that increased Market Maker activity (including LMMs), particularly, facilitates tighter spreads and an increase in overall liquidity provider activity, both of which signal additional corresponding increase in order flow from other market participants, contributing towards a robust, well-balanced market ecosystem. Indeed, increased overall order flow benefits investors across both the Exchange's options and equities platforms by continuing to deepen the Exchange's liquidity pool, potentially providing even greater execution incentives and opportunities, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency and improving investor protection.

The Exchange also believes that proposed enhanced rebate is reasonably based on the difficulty of satisfying the proposed tier's criteria and ensures the proposed rebate and thresholds appropriately reflect the incremental difficulty in achieving the existing Market Maker Penny Add Volume Tiers. As indicated above, the Exchange does not believe that the proposed enhanced rebate amount represents a significant departure from the enhanced rebates currently offered under the Exchange's existing Market Maker Penny Add Volume Tiers. Indeed, the proposed enhanced rebate amount under new Tier 12 ($0.44) is incrementally lower than Tier 13 (current Tier 12) ($0.46), which, as described above, offers slightly more stringent criteria than proposed Tier 12, but is the same amount as the enhanced rebate offered under existing Tier 11 (*i.e.,* new Tier 11) ($0.44), the criteria for which the Exchange believes is comparable to the proposed criteria under proposed Tier 12.

The Exchange believes that the proposal represents an equitable allocation of fees and is not unfairly

[10] 15 U.S.C. 78f.

[11] 15 U.S.C. 78f(b)(4).

[12] 15 U.S.C. 78f.(b)(5).

[13] *See e.g.,* NYSE Arca Options Fee Schedule, Market Maker Penny and SPY Posting Credit Tiers. NYSE Arca also provides various discounts for its LMMs throughout its fee schedule.

[14] *See e.g.,* BZX Options Fee Schedule, Footnote 6, Market Maker Penny Add Volume Tiers, and Footnote 7, Market Maker Non-Penny Add Volume Tiers.

discriminatory because it applies uniformly to all Market Makers, in that all Market Makers have the opportunity to compete for and achieve the proposed tier and the proposed enhanced rebate will apply automatically and uniformly to all Market Makers that achieve the proposed tier's criteria. While the Exchange has no way of knowing whether this proposed rule change would definitively result in any particular Market Maker qualifying for the proposed tiers, the Exchange believes that at least two Market Makers will reasonably be able to compete for and achieve the proposed criteria in proposed Tier 12; however, the proposed tiers are open to any Market-Maker that satisfies the tier's criteria. The Exchange believes the proposed tier could provide an incentive for other Members to submit additional liquidity on BZX Options and Equities to qualify for the proposed additional enhanced rebate. To the extent a Member participates on the Exchange but not on BZX Equities, the Exchange believes that the proposal is still reasonable, equitably allocated and non-discriminatory with respect to such Member based on the overall benefit to the Exchange resulting from the success of BZX Equities. Particularly, the Exchange believes such success allows the Exchange to continue to provide and potentially expand its existing incentive programs to the benefit of all participants on the Exchange, whether they participate on BZX Equities or not. The proposed pricing program is also fair and equitable in that membership in BZX Equities and enrollment as an LMM is available to all market participants, which would provide them with access to the benefits on BZX Equities provided by the proposed change, even where a member of BZX Equities is not necessarily eligible for the proposed enhanced rebates on the Exchange.

The Exchange lastly notes that it does not believe the proposed tier will adversely impact any Member's pricing or ability to qualify for other tiers. Rather, should a Member not meet the proposed criteria, the Member will merely not receive the proposed enhanced rebate, and has 11 alternative choices (including only one with criteria the Exchange believes is more stringent) to aim to achieve under the Market Maker Penny Add Volume Tiers. Furthermore, the proposed enhanced rebate would apply to all Members that meet the required criteria under the proposed tier.

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 intramarket or intermarket 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 liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities 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.'' [15]

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 change applies uniformly to all Market Makers (including LMMs on BZX Equities). As described above, the Exchange believes that Market Makers (including LMMs) provide key liquidity to the Exchange's options and equities platforms, facilitating tighter spreads, signaling additional corresponding increase in order flow from other market participants, and ultimately contributing towards a robust, well-balanced market ecosystem. To the extent a Member participates on the Exchange but not on BZX Equities, the Exchange notes that the proposed change can provide an overall benefit to the Exchange resulting from the success of BZX Equities. Such success enables the Exchange to continue to provide and potentially expand its existing incentive programs to the benefit of all participants on the Exchange, whether they participate on BZX Equities or not. The proposed pricing program is also fair and equitable in that membership in BZX Equities is available to all market participants and registration as an LMM is available equally to all BZX Equities members.

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 director their order flow, including 15 other options exchanges and off-exchange venues. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single options exchange has more than 17% of the market share.[16] Therefore, no exchange possesses significant pricing power in the execution of option 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.'' [17] 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'. . . .''.[18] 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.

[15] Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

[16] *See supra* note 4.

[17] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[18] *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)).

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 [19] and paragraph (f) of Rule 19b–4 [20] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeBZX–2021–005 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–2021–005. 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–2021–005 and should be submitted on or before February 11, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–01131 Filed 1–19–21; 8:45 am]

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[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90909; File No. SR–Phlx–2021–02]

Self-Regulatory Organizations; Nasdaq Phlx LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify Phlx Options 8, Section 28, "Responsibilities of Floor Brokers" and Section 30, "Crossing, Facilitation and Solicited Orders"

January 13, 2021.

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 January 4, 2021, Nasdaq Phlx LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify Phlx Options 8, Section 28, "Responsibilities of Floor Brokers" and Section 30, "Crossing, Facilitation and Solicited Orders."

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Phlx proposes to amend its Trading Floor rules at Options 8, Section 28, "Responsibilities of Floor Brokers" and Section 30, "Crossing, Facilitation and Solicited Orders" to permit Floor Brokers [3] to utilize the Options Floor Based Management System ("FBMS"),[4] remotely,[5] to enter certain orders that do not require exposure in open outcry. This proposal is intended to provide greater accessibility to Floor Brokers for the portion of their business which does not require the physical infrastructure afforded by the Trading Floor and allow member organizations to more efficiently staff their operations.

Background

Today, Phlx Rules provide a Business Continuity and Disaster Recovery Plan for its Trading Floor ("BCP") which is

[3] The term "Floor Broker" means an individual who is registered with the Exchange for the purpose, while on the Options Floor, of accepting and handling options orders. *See* Options 8, Section 2(2).

[4] FBMS, an order management system, is the gateway for the electronic execution of equity, equity index and U.S. dollar-settled foreign currency option orders represented by Floor Brokers on the Exchange's Options Floor. Floor Brokers contemporaneously upon receipt of an order and prior to the representation of such an order in the trading crowd, record all options orders represented by such Floor Broker to FBMS, which creates an electronic audit trail. The execution of orders to Phlx's electronic trading system also occurs via FBMS. The FBMS application is available on hand-held tablets and stationary desktops.

[5] Utilizing FBMS while not physically present on the Trading Floor would be considered remote access.

described within Options 8, Section 26(g).[6] The Exchange may activate its business continuity and disaster recovery plans to maintain fair and orderly markets in the event of a System failure, disaster, or other unusual circumstance that may threaten the ability to conduct business on the Exchange. On March 17, 2019,[7] Phlx suspended open outcry trading as a result of precautions taken with respect to COVID–19. The Trading Floor re-opened on June 3, 2020.[8] During that period from March 17, 2019 to June 3, 2020, open outcry trading was unavailable.

At the time of the Phlx Trading Floor closure in March 2020, the Exchange permitted Floor Brokers, who otherwise had no means of trading on Phlx in an electronic environment, to utilize FBMS remotely, solely for the purpose of submitting limit orders to the electronic limit order book pursuant to Options 8, Section 28(g), or submitting a Floor Qualified Contingent Cross Order to the System pursuant to Options 8, Section 30(e).[9] Submitting a limit order to the electronic limit order book does not require exposure of that order in open outcry trading as the order is immediately exposed on the electronic limit order book. Similarly, a Floor Qualified Contingent Cross Order submitted to the System does not require exposure in open outcry as this order type is immediately executed upon entry to the System, provided the order complies with the provisions of Options 8, Section 30(e) and therefore a Floor Broker was not required to be present on the Trading Floor to transact these order types. Floor Brokers were not permitted to transact other order types within Options 3, Section 32 through FBMS during the floor closure. Phlx Surveillance staff surveilled Floor Qualified Contingent Cross Orders submitted through FBMS in real-time. Electronic limit orders must comply with automated System entry checks for compliance with Exchange rules.

When the Trading Floor reopened on June 3, 2020, the Exchange permitted each Trading Floor member organization to be represented on the Trading Floor. However, due to the social distancing measures that were put in place to comply with Commonwealth of Pennsylvania health standards as well as Nasdaq's safety measures designed to prevent the spread of COVID–19, not all members and employees associated with a Phlx member organization were able to return to the Trading Floor. Floor Brokers were permitted to continue remotely submitting the aforementioned orders through FBMS, due to the Exchange's inability to allow all Floor Members access to the physical Trading Floor.

Proposal

At this time, the Exchange proposes to amend Options 8, Section 28(g) and Options 8, Section 30(e) to continue to allow Floor Brokers the ability to submit limit orders to the electronic limit order book and Floor Qualified Contingent Cross Orders to the System via FBMS remotely, notwithstanding the existence of BCP measures. Floor Brokers may continue to submit limit orders to the electronic limit order book and Floor Qualified Contingent Cross Orders to the System while on the Trading Floor.

Prior to permitting Floor Brokers to access FBMS remotely for the limited purpose of submitting limit orders to the electronic limit order book and Floor Qualified Contingent Cross Orders to the System, the Exchange permitted Floor Brokers to submit limit orders to the electronic limit order book and Floor Qualified Contingent Cross Orders to the System utilizing FBMS while on the Trading Floor.[10] Phlx Options 8 Trading Rules apply to members and member organizations engaging in to transact options transactions while physically located on the Trading Floor, including trading crowds.[11] The Options 8 Trading Rules do not permit options transactions to be submitted to the Trading Floor through FBMS remotely by Floor Brokers.[12] Today, Phlx utilizes its Business Continuity Plan to permit Floor Brokers to access the Exchange's System remotely, through FBMS, for the limited purpose of submitting limit orders to the electronic limit order book and Floor Qualified Contingent Cross Orders to the System.

Due to the social distancing measures that were put in place to comply with Commonwealth of Pennsylvania health standards as well as Nasdaq's safety measures designed to prevent the spread of COVID–19, not all members and employees associated with a Phlx member organization were able to return to the Trading Floor. This proposal would create an exception to the Options 8 Rules for a limited purpose.

Today, Options 8, Section 28(g) permits a Floor Broker who wishes to place a limit order on the electronic limit order book to submit such a limit order electronically through FBMS. This capability exists to enable Floor Brokers to access electronic liquidity and/or to clear priority orders on the limit order book prior to transacting an order in the trading crowd through FBMS.[13] Placing limit orders on the order book does not require exposure in open outcry. The Exchange desires to permit Floor Brokers, by rule, the ability to continue to remotely submit limit orders to the electronic limit order book on a permanent basis. This would specifically allow Floor Brokers the ability to clear resting Customers orders from the limit order book for their customers in the event that a Customer order had priority on the limit order book that would otherwise prevent a Floor Qualified Contingent Cross Order from being entered in compliance with Options 8, Section 30(e).

Today, Options 8, Section 30(e) permits Floor Qualified Contingent Cross Orders to be submitted to the System by Floor Brokers on the Floor via FBMS. These orders are not required to be exposed in open outcry. In 2011, Phlx established a Floor Qualified

[6] Options 8, Section 26(g) provides:

(1) *Loss of Trading Floor.* If the physical location designated as the ''Trading Floor'' becomes unavailable, Phlx will enact its Business Continuity Plan and designate the Philadelphia Navy Yard as its ''Back-Up Trading Floor.''

(2) *Back-up Trading Floor Unavailable.* In the event that the Back-Up Trading Floor becomes inoperable, the Exchange will only operate its electronic market and will not operate a Trading Floor. The Exchange will operate only its electronic market until the Exchange's Trading Floor facility is operational. Open outcry trading will not be available in the interim.

(3) *Other Back-Up Trading Arrangements.* This Rule does not preclude the Exchange from conducting business, in the event the Trading Floor and Back-Up Trading Floor are rendered inoperable, pursuant to Options 4, Section 10.

[7] *See* Options Trader Alert #2020–07.

[8] *See* Options Trader Alert #2020–13.

[9] *See* Options Trader Alert #2020–8.

[10] *See* Options 8, Section 28(g) and 30(e).

[11] *See* Options 8, Section 1(a).

[12] *See* note 3 above, by definition Floor Brokers accept and handle options orders while on the Options Floor.

[13] *See* Securities Exchange Act Release No. 68960 (February 20, 2013), 78 FR 13132, 13134 (February 26, 2013) (SR–Phlx–2013–09) (Notice of Filing of Proposed Rule Change To Enhance the Functionality Offered on Its Options Floor Broker Management System (''FBMS'') by, Among Other Things, Automating Functions Currently Performed by Floor Brokers). This filing provided the following explanation, ''For example, if a Floor Broker enters a two-sided order through the new FBMS and there is an order on the book at a price that prevents the Floor Broker's order from executing, FBMS will indicate to the Floor Broker how many contracts need to be satisfied before the Floor Broker's order can execute at the agreed-upon price. If the Floor Broker agrees to satisfy that order, consistent with the order placed in his care, he can cause FBMS to send a portion of one of his orders to Phlx XL to trade against the order on the book, thereby clearing it and permitting the remainder of the Floor Broker's order to trade. This functionality is optional in the sense that the Floor Broker can decide not to trade against the book, consistent with order instructions he has been given, and therefore not execute his two-sided order at that particular price.'' Phlx XL refers to the electronic order book.

Contingent Cross Order.[14] The proposal specifically provided that ''. . . PHLX proposes to amend Rule 1064 to provide that a PHLX member effectuating a trade on the floor of the Exchange pursuant to the Regulation NMS Qualified Contingent Trade Exemption to Rule 611(a) (''QCT Exemption'') can cross the options legs of the trade on PHLX as a Floor QCC Order immediately upon entry and without order exposure if no Customer Orders exist on the Exchange's order book at the same price. Floor QCC Orders will be electronically entered by a Floor Broker on the floor of the Exchange using the Floor Broker Management System and the execution will then be executed electronically. Only Floor Brokers will be permitted to enter Floor QCC Orders.'' [15] The proposal specifically provided for a Floor Qualified Contingent Cross Order to be entered by Floor Brokers through FBMS while on the Trading Floor without order exposure. The filing further provides that ''. . . it would be incorrect to say that the Floor QCC Order differs from the electronic QCC Order due to the Options Floor Broker's presence on the Floor.'' [16]

The Exchange's proposal seeks to continue to permit Floor Brokers to enter both limit orders to the electronic limit order book and Floor Qualified Contingent Cross Orders to the System through FBMS, albeit remotely, without amending the manner in which these orders, which require no order exposure, are handled by FBMS or the System.

The Exchange believes that permitting Floor Brokers the ability to utilize FBMS remotely, for the limited purposes of submitting limit orders to the electronic limit order book and Floor Qualified Contingent Cross Order to the System, would allow Floor Brokers to conduct the portion of their business which does not require the infrastructure afforded by the Trading Floor remotely and, therefore, allow member organizations flexibility to more efficiently staff their operations. The ability to service certain orders, such as limit orders and Floor Qualified Contingent Cross Orders, which do not require open outcry exposure, is a relevant part of a Floor Broker's business. The Exchange is proposing to expand the ability of a member organization to conduct this limited portion of the Floor Broker business model to assist firms in being able to continuously operate this portion of their business, notwithstanding any closures or halts of the Trading Floor. Every Floor Broker must be registered with the Exchange pursuant to Options 8, Section 6 and would be assessed applicable fees provided for within Options 7. The Exchange notes that this proposal does not amend the manner in which fees or other pricing incentives, such as caps, apply to Floor Brokers. Any transaction originating from open outcry on the Trading Floor is considered a floor transaction. With offering FBMS remotely, the Exchange has not amended the manner in which fees are assessed or rebates are paid for purposes of Options 7 pricing to Floor Brokers. A limit order entered to the limit order book via FBMS was subject to electronic fees and rebates prior to the introduction of remote FBMS and that remains the case with the introduction of remote FBMS. These transactions are submitted to the electronic order book directly and are assessed the same fees and rebates as other limit orders submitted to the electronic order book. Also, the Exchange does not distinguish the manner in which it assesses pricing for Floor Qualified Contingent Cross Orders or electronic Qualified Contingent Cross Orders. The pricing is the same regardless of the manner in which the Qualified Contingent Cross Order was submitted. The Exchange proposes to add a sentence to Options 7, Section 1 to define a floor transaction to add clarity to the manner in which floor based pricing is assessed. The Exchange proposes to add the following definition to Options 7, Section 1, ''A 'floor transaction' is a transaction that is effected in open outcry on the Exchange's Trading Floor.''

Finally, the Exchange represents that it has the proper security infrastructure in place to offer FBMS remotely and securely to Floor Brokers.

Technical Amendment

The Exchange proposes a technical amendment to Options 8, Section 1(a) to add the word ''System'' to the end of ''Options Floor Based Management'' within the first sentence to conform the manner in which the Exchange utilizes this term within Options 8.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[17] in general, and furthers the objectives of Section 6(b)(5) of the Act,[18] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange's proposal to permit Floor Brokers the ability to utilize FBMS remotely, for the limited purposes of submitting limit orders to the electronic limit order book and Floor Qualified Contingent Cross Order to the System, is consistent with the Act. This proposal would allow member organizations to utilize their Floor Brokers, who may be located off the Trading Floor to conduct certain aspects of their business that do not require open outcry, remotely. Every Floor Broker would continue to be required to be registered with the Exchange pursuant to Options 8, Section 6 and would be assessed applicable fees provided for within Options 7.

Prior to permitting Floor Brokers to access FBMS remotely for the limited purpose of submitting limit orders to the electronic limit order book and Floor Qualified Contingent Cross Orders to the System, the Exchange permitted Floor Brokers to submit limit orders to the electronic limit order book and Floor Qualified Contingent Cross Order to the System utilizing FBMS while on the Trading Floor.[19] Phlx Options 8 Trading Rules require members and member organizations to transact options transactions while physically located on the Trading Floor, including trading crowds.[20] The Options 8 Trading Rules do not permit options transactions to be submitted to the Trading Floor through FBMS remotely by Floor Brokers.[21] This proposal would create an exception to the Options 8 Rules to allow Floor Brokers to submit limit orders and Floor Qualified Contingent Cross Orders remotely through FBMS.

Today, Options 8, Section 28(g) permits a Floor Broker who wishes to place a limit order on the electronic limit order book to submit such a limit order electronically through the FBMS. This capability exists to enable Floor Brokers to access electronic liquidity and/or to clear a priority orders on the limit order book prior to transacting an order in the trading crowd with the help of the FBMS.[22] Placing limit orders on

[14] *See* Securities Exchange Act Release No. 64415 (May 5, 2011), 76 FR 27732 (May 12, 2011) (SR–Phlx–2011–56) (Notice of Filing of Proposed Rule Change To Establish a Qualified Contingent Cross Order for Execution on the Floor of the Exchange).

[15] *Id* at 27732 and 27733.

[16] *Id* at 27733.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] *See* Options 8, Section 28(g) and 30(e).

[20] *See* Options 8, Section 1(a).

[21] *See* note 3 above, by definition Floor Brokers accept and handle options orders while on the Options Floor.

[22] *See* Securities Exchange Act Release No. 68960 (February 20, 2013), 78 FR 13132, 13134 (February 26, 2013) (SR–Phlx–2013–09) (Notice of Filing of

Continued

the Order Book does not require exposure in open outcry. The Exchange desires to continue to grant this capability remotely to allow Floor Brokers the ability to continue to clear Customer orders on the limit order book for their customers in the event that a Customer order had priority on the limit order book and prevents a Floor Qualified Contingent Cross Order from being entered.

Today, Options 8, Section 30(e) permits Floor Qualified Contingent Cross Orders to be submitted to the System by Floor Brokers on the Floor via FBMS. These orders are not required to be exposed in open outcry. In 2011, Phlx established a Floor Qualified Contingent Cross Order.[23] The proposal specifically provided for a Floor Qualified Contingent Cross Order to be entered by Floor Brokers through FBMS while on the Trading Floor without order exposure.

The Exchange's proposal seeks to continue to permit Floor Brokers to enter both limit orders to the electronic limit order book and Floor Qualified Contingent Cross Orders to the System through FBMS, albeit remotely, without amending the manner in which these orders, which require no order exposure, are handled by FBMS or the System.

Floor Brokers are an essential part of the Trading Floor and their business is largely dependent on access to the physical Trading Floor and the ability of market participants to expose orders in open outcry. Floor Brokers service multiple customer segments and several subsets of order flow. Their largest customers are bank trading desks, inter-dealer brokerage desks, liquidity providers, and hedge funds. Each of these client types direct certain orders to Floor Brokers. Banks and inter-dealers primarily utilize Floor Brokers for manual handling of stock-tied Floor Qualified Contingent Cross Orders, complicated order structures with abnormal ratios (beyond 3:1 allowable electronically) and ''cash spreads,'' where a notional trade value is negotiated and relayed to the trading crowd for participation. Banks also look to facilitate larger bank customer orders that exhibit considerable real-time risk. While Floor Brokers represent the bank side of these transactions, Floor Market Makers provide additional liquidity and efficiently perform the price discovery process through manual handling and exposure. Inter-dealers will also utilize Floor Brokers for price discovery and additional sourcing of liquidity for larger orders where they need assistance. Finally, complicated strategy transactions are often represented by Floor Brokers. End-users are more inclined to use their services due to their expertise in order handling and knowledge of the trading ecosystem.

Notwithstanding the importance of Floor Brokers on the Exchange's Trading Floor, the ability to service other orders, such as limit orders and Floor Qualified Contingent Cross Orders, which do not require open outcry exposure, is a relevant part of a Floor Broker's business. The Exchange is proposing to expand the ability of a member organization to conduct this limited portion of the Floor Broker business model to assist firms in being able to continuously operate this portion of their business, notwithstanding any closures or halts of the Trading Floor.

The Exchange notes that a closure of the Trading Floor renders the Floor Broker business, which is largely reliant on open outcry trading, inoperable. The Exchange believes that this proposal is designed to protect investors and the public interest as a form of risk mitigation as the proposal would allow the portion of the Floor Broker business, which is not dependent on open outcry, to continue regardless of the status of the Trading Floor. Further, the proposal would allow member organizations to more efficiently staff their operations. For example, member organizations may utilize staff in other locations as the remote access removes the dependency on physical presence on the Trading Floor.

This proposal does not amend the manner in which fees or other pricing incentives, such as caps, apply to Floor Brokers. Any transaction originating from open outcry on the Trading Floor is considered a floor transaction. With offering FBMS remotely, the Exchange has not amended the manner in which fees are assessed or rebates are paid for purposes of Options 7 pricing to Floor Brokers. A limit order entered to the limit order book via FBMS was subject to electronic fees and rebates prior to the introduction of remote FBMS and that remains the case with the introduction of remote FBMS. These transactions are submitted to the electronic order book directly and are assessed the same fees and rebates as other limit orders submitted to the electronic order book. Also, the Exchange does not distinguish the manner in which it assesses pricing for Floor Qualified Contingent Cross Orders or electronic Qualified Contingent Cross Orders. The pricing is the same regardless of the manner in which the Qualified Contingent Cross Order was submitted. Phlx Surveillance staff surveilled Floor Qualified Contingent Cross Orders submitted through FBMS in real-time. Electronic limit orders must comply with automated System entry checks for compliance with Exchange rules. Finally, the Exchange represents that it has the proper security infrastructure in place to offer FBMS remotely and securely to Floor Brokers.

Technical Amendment

The Exchange's proposal to amend Options 8, Section 1(a) to add the word ''System'' to the end of ''Options Floor Based Management'' within the first sentence is consistent with the Act as this term conforms the manner in which the Exchange utilizes the term ''Options Floor Based Management System'' throughout Options 8.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange's proposal to permit Floor Brokers the ability to utilize FBMS remotely, for the limited purposes of submitting limit orders to the electronic limit order book and Floor Qualified Contingent Cross Order to the System, does not impose an undue burden on competition. A Floor Broker, unlike a Market Maker, is mostly dependent on the infrastructure provided by a Trading Floor in order to operate its business model. Market Makers on the other hand may transact their business in either of the two models provide by Phlx, the Trading Floor or electronic model. Market Makers have the infrastructure to continue to conduct their business, even in the event of the closure of the Trading Floor, while Floor Brokers are mostly reliant on open

Proposed Rule Change To Enhance the Functionality Offered on Its Options Floor Broker Management System (''FBMS'') by, Among Other Things, Automating Functions Currently Performed by Floor Brokers). This filing provided, ''For example, if a Floor Broker enters a two-sided order through the new FBMS and there is an order on the book at a price that prevents the Floor Broker's order from executing, FBMS will indicate to the Floor Broker how many contracts need to be satisfied before the Floor Broker's order can execute at the agreed-upon price. If the Floor Broker agrees to satisfy that order, consistent with the order placed in his care, he can cause FBMS to send a portion of one of his orders to Phlx XL to trade against the order on the book, thereby clearing it and permitting the remainder of the Floor Broker's order to trade. This functionality is optional in the sense that the Floor Broker can decide not to trade against the book, consistent with order instructions he has been given, and therefore not execute his two-sided order at that particular price.''

[23] *See* Securities Exchange Act Release No. 64415 (May 5, 2011), 76 FR 27732 (May 12, 2011) (SR–Phlx–2011–56) (Notice of Filing of Proposed Rule Change To Establish a Qualified Contingent Cross Order for Execution on the Floor of the Exchange).

outcry trading and this portion of their business is inoperable if open outcry is unavailable.

The Exchange's proposal seeks to provide greater accessibility to Floor Brokers for the portion of their business which does not require the infrastructure afforded by the Trading Floor while not amending the manner in which those orders are handled by either FBMS or the System. This proposal is competitive in that it allows Floor Brokers the ability to participate more continuously and efficiently on Phlx. All Floor Brokers have access to FBMS and therefore would be able to remotely submit limit orders to the electronic limit order book and Floor Qualified Contingent Cross Orders to the System as well as continue to submit these types of orders while on the Trading Floor. Further, the Exchange believes that this proposal, which would allow member organizations to utilize their Floor Brokers, who may be located in other locations, to more efficiently staff their operations and also to conduct their business, even in the event of a closure of the Trading Floor.

Finally, this proposal does not amend the manner in which fees or other pricing incentives, such as caps, apply to Floor Brokers.

Technical Amendment

The Exchange's proposal to amend Options 8, Section 1(a) to add the word ''System'' to the end of ''Options Floor Based Management'' within the first sentence does not impose an undue burden on competition as this term conforms the manner in which the Exchange utilizes the term ''Options Floor Based Management System'' throughout Options 8.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [24] and Rule 19b–4(f)(6) thereunder.[25] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[26]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [27] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2021–02 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2021–02. 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–Phlx–2021–02 and should be submitted on or before February 11, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–01129 Filed 1–19–21; 8:45 am]

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[24] 15 U.S.C. 78s(b)(3)(A)(iii).

[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[27] 15 U.S.C. 78s(b)(2)(B).

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90914; File No. SR–CboeEDGX–2021–003]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fee Schedule To Expand the Existing Financial Product Distribution Program To Provide for a Derived Data Platform Service

January 13, 2021.

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 January 4, 2021, Cboe EDGX Exchange, Inc. (''Exchange'' or ''EDGX'') 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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (''EDGX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the Fee Schedule to expand the existing Financial Product Distribution Program (the ''Program'') to provide for a Derived Data Platform Service. Additionally, the proposal seeks to enhance the Program to provide for the distribution of data derived from the Cboe Aggregated Market (''Cboe One'') [3] Summary Feed. 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/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 purpose of the proposed rule change is to implement a pricing structure that would reduce fees charged to Distributors of ''Derived Data'', as defined below, through an Exchange approved Derived Data Platform Service. Additionally, the proposal seeks to enhance the Program to permit the distribution of data derived from Cboe One Summary through the existing White Label Service, Application Programming Interface (''API'') Service, and the proposed Platform Service.

[3] *See* Exchange Rule 13.8(b).

Derived Data Platform Service

''Derived Data'' is pricing data or other data that (i) is created in whole or in part from Exchange Data, (ii) is not an index or financial product, and (iii) cannot be readily reverse-engineered to recreate Exchange Data or used to create other data that is a reasonable facsimile or substitute for Exchange Data. Derived Data may be created by Distributors for a number of different purposes, as determined by the Distributor. Possible uses include the display of information or data, or the creation of derivative instruments, such as swaps,[4] swaptions,[5] or contracts for difference.[6] The specific use of the data is determined by the Distributor, as applicable fees do not depend on the purpose for placing the Derived Data under the Program.

The Exchange currently offers a White Label Service and an API Service that allow Distributors to benefit from discounted fees when distributing Derived Data taken from Exchange data.[7] Instead of the regular fee for external distribution [8] of Exchange data, Distributors of Derived Data under both the White Label Service and API Service are charged a tiered External Subscriber Fee based on the number of External Subscribers that receive Derived Data from the Distributor. Additionally, Distributors are charged a Professional User [9] Fee based on the number of Professional Users of the Derived Data. Non-Professional Users of Derived Data are not subject to a fee under either the White Label Service or the API Service.

The White Label Service is a type of hosted display solution in which a Distributor hosts, maintains, and controls a website or platform on behalf of a third-party entity. The service allows Distributors to make Derived Data available on a platform that is branded with a third-party brand, or co-branded with a third-party and a Distributor, while the Distributor maintains control of the applications data, entitlements and display. Alternatively, the API Service is a type of data feed distribution in which a Distributor delivers an API or similar distribution mechanism to a third-party entity for use within one or more platforms. The API Service allows Distributors to provide Derived Data to a third-party entity for use within one or more downstream platforms that are operated and maintained by the third-party entity. The Distributor maintains control of the entitlements, but does not maintain technical control of the usage or the display.

Now the Exchange is proposing to implement a third service under the Program, the Platform Service. The Platform Service would allow a Distributor to provide derivative products directly to users that are hosted within their infrastructure. The Platform Service would be strictly limited to derivative products based in whole or in part on Exchange data where only user remote access is permitted. Normally, distributors of Exchange market data may be subject to Distribution and User Fees including an: External Distribution Fee, Professional User Fee, and Non-Professional User Fee. Distributors would be liable for the fees normally applicable for external distribution except for the Non-Professional User fee,[10] which would be eliminated when participating in the Platform Service, further reducing costs for Distributors that provide access to such data to retail investors. In contrast to the existing White Label Service and API Service, the Platform Service provides a targeted discount to Distributors rather than to External Subscribers.

[4] A swap is a derivative contract in which two parties agree to exchange financial instruments.

[5] A swaption, or swap option, is an option to enter into a swap at a specified time.

[6] A contract for difference is an agreement to exchange the difference between the current value of an asset and its future value. If the price increases, the seller pays the buyer the amount of the increase. If the price decreases, the buyer pays the seller the amount of the decrease.

[7] Currently, EDGX Top data is the only Exchange data included in the Program; however, as discussed in further detail below, the Exchange is also proposing to include Cboe One Summary in the Program.

[8] External distribution occurs when a Distributor that receives an Exchange Market Data product distributes that data to a third-party or one or more users outside the Distributor's own entity.

[9] A ''Professional User'' of an Exchange Market Data product is any User other than a Non-Professional User. A ''Non-Professional User'' of an Exchange Market Data product is a natural person or qualifying trust that uses Data only for personal purposes and not for any commercial purpose and, for a natural person who works in the United States, is not: (i) Registered or qualified in any capacity with the Securities and Exchange Commission, the Commodities Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an ''investment adviser'' as that term is defined in Section 202(a)(11) of the Investment Advisors Act of 1940 (whether or not registered or qualified under that Act); or (iii) employed by a bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt; or, for a natural person who works outside of the United States, does not perform the same functions as would disqualify such person as a Non-Professional User if he or she worked in the United States.

[10] The Non-Professional User Fee for external distribution of EDGX Top is $0.10/month.

Like the existing White Label Service and API Service, the proposed Platform Service would be entirely optional, in that it would only apply to Distributors that opt to use Derived Data to create a Platform Service, as described herein. It would not impact or raise the cost of any other Exchange product, nor would it affect the cost of Exchange data, except in instances where Derived Data is made available on a Platform Service. A Distributor that provides a Platform Service for Exchange data that is not Derived Data or distributes Derived Data through a platform other than an approved White Label Service, API Service, or Platform Service would be liable for the fees normally applicable for the distribution of Exchange data.

Cboe One Summary

In addition to the above, the Exchange is proposing to adopt fees for the distribution of data derived from Cboe One Summary under the existing White Label Service and API Service, as well as the proposed Platform Service. Under the existing Fee Schedule, Distributors that participate in the Program may only create Derived Data from EDGX Top,[11] a proprietary data product that provides top of book quotations and execution information for all equity securities traded on the Exchange. The Exchange is now proposing a fee amendment to allow Distributors that participate in the Program to create Derived Data from Cboe One Summary in addition to EDGX Top. Cboe One Summary is a proprietary data product that provides the top of book quotations and execution information for all listed equity securities traded across the Exchange and its affiliated U.S. equities exchanges (the ''Cboe equity exchanges'').[12] Therefore, Distributors of Derived Data created from Cboe One Summary could display information or data or create derivative instruments based on top of book information across the four Cboe equity exchanges rather than just EDGX. The Exchange believes that the proposal will enhance the Program as the inclusion of Cboe One Summary will allow Distributors to create Derived Data that is based on a more comprehensive view of the U.S. equities market.

As discussed above, Distributors of Exchange data, including Cboe One Summary, may be subject to Distribution and User Fees including an: External Distribution Fee, Professional User Fee, and Non-Professional User Fee. As proposed, a Distributor that provides Derived Data from Cboe One Summary would be liable for the proposed fees discussed below instead of the fees normally applicable for the distribution of Cboe One Summary. Existing fees for EDGX Top Derived Data within a White Label Service or API Service are comprised of a tiered fee based on the number of External Subscribers, a monthly fee for each Professional User, and include no fee for Non-Professional Users. Similarly, the proposed fees for the Platform Service are comprised of the normal External Distribution and Professional User fees applicable for the distribution of EDGX Top except that they would not be subject to the Non-Professional Users fees normally applicable. The Exchange proposes to adopt a similar fee structure for Cboe One Summary Derived Data.

As proposed, Distributors would be charged the following fees for a White Label Service for Cboe One Summary Derived Data: (1) $1,000 Per month for each External Subscriber if the Distributor makes Derived Data available to 1–5 External Subscribers; (2) $750 per month for each External Subscriber if the Distributor makes Derived Data available to 6–10 External Subscribers; and (3) $500 per month for each External Subscriber if the Distributor makes Derived Data available to 11 or more External Subscribers. For example, a Distributor providing White Label Derived Data based on Cboe One Summary to six External Subscribers would be charged a monthly fee of $4,500 (*i.e.,* 6 External Subscribers x $750 each). Additionally, the Exchange would continue to charge a monthly Professional User fee of $10 per month for each Professional User. The Exchange proposes no Non-Professional User fee for the distribution of Cboe One Summary Derived Data under the White Label Service, which is consistent with the fee structure for the distribution of EDGX Top Derived Data under the White Label Service.

Alternatively, Distributors would be charged the following fees for an API Service for Cboe One Summary Derived Data: (1) $5,000 Per month for each External Subscriber if the Distributor makes Derived Data available to 1–5 External Subscribers; (2) $4,000 per month for each External Subscriber if the Distributor makes Derived Data available to 6–20 External Subscribers; and (3) $3,000 per month for each External Subscriber if the Distributor makes Derived Data available to 11 or more External Subscribers. For example, a Distributor providing API Service Derived Data based on Cboe One Summary to six External Subscribers would be charged a monthly fee of $24,000 (*i.e.,* 6 External Subscribers x $4,000 each). Additionally, the Exchange would continue to charge a monthly Professional User fee of $10 per month for each Professional User. The Exchange proposes no Non-Professional User fee for the distribution of Cboe One Summary Derived Data under the API Service, which is consistent with the fee structure for the distribution of EDGX Top Derived Data under the API Service.

Lastly, the Exchange proposes to adopt fees for the proposed Platform Service for Cboe One Summary data in addition to the proposed fees for EDGX Top discussed above. Like the proposed fee for EDGX Top Derived Data, Distributors of Cboe One Summary Derived Data would be liable for the fees normally applicable for the external distribution of Cboe One Summary, except for the Non-Professional User fee (*i.e.,* $0.25/month) which would be free under the Platform Service.

Corresponding Amendments to Fee Schedule

Based on the proposed amendments discussed above, the Exchange proposes several clarifying modifications to the Fee Schedule. First, the Exchange proposes to add a definition of ''Platform Service'' to the Market Data Fees definitions section of the Fee Schedule. The definition would provide that ''a Platform Service is a type of hosted display solution in which a Distributor provides derivative products to Platform Service Data Users within their infrastructure. The service allows Distributors to make Derived Data available as part of a platform, providing users remote access to derivative products based in whole or in part on Exchange Data.''

The Exchange also proposes to amend explanatory asterisks provided under the Program in the Fee Schedule. Specifically, the Exchange proposes to amend the paragraph following the first asterisk to reference the proposed Platform Service in addition to the existing references to the White Label Service and API Service. Additionally, the Exchange proposes to add references to Cboe One Summary after all references to EDGX Top in the paragraph following the first asterisk. Lastly, the Exchange proposes to add additional examples to asterisks two and three so as to explain the application of fees for Derived Data from Cboe One Summary. These proposed non-substantive changes would provide clarity in the Fee Schedule based on the addition of the Platform Service and Cboe One Summary proposed herein.

[11] *See* Exchange Rule 13.8(b).

[12] *Supra* note 3.

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 and other recipients of Exchange data.

The Exchange also believes that the proposed rule change is consistent with Section 11(A) of the Act.[15] Specifically, the proposed rule change supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets, and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. In addition, the proposed rule change is consistent with Rule 603 of Regulation NMS,[16] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory.

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed fee change would further broaden the availability of U.S. equity market data to investors, consistent with the principles of Regulation NMS.

The Exchange operates in a highly competitive environment. Indeed, there are 16 registered national securities exchanges that trade U.S. equities and have the capability to offer associated top of book market data products to their customers. The national securities exchanges also compete with the Securities Information Processors (''SIPs'') for market data customers. 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.'' [17] The proposed fee change is a result of the competitive environment, as the Exchange seeks to amend its fees to attract additional subscribers for its proprietary top of book data offerings through the introduction of a Derived Data Platform Service and the expansion of top of book data offerings to include Cboe One Summary under the Program.

The Exchange believes that it is reasonable to introduce reduced fees for the use of Derived Data on Platform Services as the proposed fee reduction would facilitate cost effective access to market information that is used primarily to create and display certain derivative instruments rather than to display the underlying U.S. equity securities. The proposed Platform Service fees are constrained by competition, and it is this competition that is driving the proposed fee change. Indeed, the Program is designed to allow the Exchange to compete more effectively for market data distributors that purchase market information to offer Derived Data to investors.

Similarly, the Exchange believes that it is reasonable to enhance the Program by expanding Exchange data offered under the Program to include Cboe One Summary as doing so will allow Distributors to create Derived Data that is based on a more comprehensive view of the U.S. equities market. Because Exchange data in this context is primarily purchased for the creation of Derived Data encompassing certain derivative instruments, Distributors do not require a consolidated view of the market across multiple exchanges, and will generally purchase such data from a single or select few exchange(s) for their purposes. As noted above, Cboe One Summary includes top of book quotation and transaction data across all four Cboe equity exchanges, which would allow Distributors to create more meaningful Derived Data than that available from a single exchange's market data at a potentially reduced price.

The existence of alternatives to the Program ensures that the Exchange cannot set unreasonable or unfairly discriminatory fees, as subscribers are free to elect such alternatives. That is, the Exchange competes with other exchanges that provide similar market data products and pricing programs. Expanding the availability of diverse competitive products actually promotes additional competition as it ensures that alternative products from different sources are readily available to Distributors and the broader market. The Exchange therefore believes that the introduction of pricing programs and the expansion of Exchange data are not only constrained by competition but also ensure continued competition that acts as a constraint on the pricing of services provided by other national securities exchanges and the SIPs. If a competing exchange were to charge less for a similar product than the Exchange charges under the proposed fee structure, prospective subscribers may choose not subscribe to, or cease subscribing to, the Program. The Exchange believes that lowering the cost of accessing Derived Data may make the Exchange's market information more attractive, and encourage additional Distributors to subscribe to Exchange market data instead of competitor products. The Exchange anticipates up to 10 Distributors to participate in the proposed Platform Service, and up to three Distributors to create Derived Data from Cboe One Summary. Distributors can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Further, firms have a wide variety of alternative market data products from which to choose, such as similar proprietary data products offered by other national securities exchanges, including those that choose to offer discounted fees for the distribution of Derived Data in an effort to compete for this business.

The proposed rule change would provide an optional fee structure for Distributors to use Exchange data to make Derived Data available to Non-Professional Users via an Exchange approved Platform Service at a reduced fee. As proposed, if a Distributor uses a Platform Service to distribute Derived Data, the Distributor would be charged the normal applicable External Distributor Fee excluding the Non-Professional User Fee. The Exchange believes that it is equitable and not unfairly discriminatory to charge a fee for Professional Users but no fee for Non-Professional Users. Non-Professional Users are already subject to a heavily discounted fee for EDGX Top market data relative to Professional Users. Differential fees for Professional and Non-Professional Users are widely used by the Exchange and other exchanges for their proprietary market data as this reduces costs for retail investors and makes market data more broadly available. The Exchange believes that eliminating fees for Non-

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78k–1.

[16] *See* 17 CFR 242.603.

[17] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

Professional Users that access Derived Data from Distributors pursuant to the Program is consistent with longstanding precedent indicating that it is consistent with the Act to provide reasonable incentives to retail investors that rely on the public markets for their investment needs.[18] Further, the proposed fee would only apply to Distributors that elect to participate in the Program by distributing Derived Data through a Platform Service. Exchange market data is distributed and purchased on a voluntary basis, in that neither the Exchange nor market data distributors are required by any rule or regulation to make this data available. Distributors of Exchange data are not required to participate in the proposed Program, which is merely an alternative option being proposed by the Exchange to potentially lower costs for market data that is Derived Data. As previously explained, the Exchange currently offers discounted fees for Distributors that distribute Derived Data on a White Label Service or an API Service. Expanding the universe of customers that can benefit from discounted fees for distributing Derived Data would serve to further increase the accessibility of the Exchange's market data products. Although the proposed pricing for the Platform Service differs from the pricing currently in place for the White Label and API Service Programs, it mirrors the normal External Distribution Fee for EDGX Top and Cboe One Summary except that there would be no fee for Non-Professional Users. The White Label Service provides an ''off-the-shelf'' solution to display Derived Data as it is ultimately designed and controlled by the Distributor. Alternatively, the API Service offers end clients of Distributors to use Derived Data in one or more of their own customized applications. The Exchange believes that the proposed pricing reflects the relative benefits provided to Distributors that offer a Platform Service that allows Users remote access to derivative products via a hosted display solution within the Distributors fully managed infrastructure.

The proposed rule change would also provide Distributors the option to create Derived Data from Cboe One Summary, and benefit from reduced fees for that product under the Financial Product Distribution Program, in addition to the currently available EDGX Top. The proposed fees would only apply to Distributors that elect to create Derived Data from Cboe One Summary. Similar to the fee structure for EDGX Top under the Program, no fee would be assessed for Non-Professional Users of Derived Data from Cboe One Summary. For the same reasons discussed above, the Exchange believes it is equitable and not unfairly discriminatory to charge a fee for Professional Users but no fee for Non-Professional Users. Further, the proposed fee would only apply to Distributors that elect to participate in the Program by distributing Derived Data from Cboe One Summary. Exchange market data is distributed and purchased on a voluntary basis, in that neither the Exchange nor market data distributors are required by any rule or regulation to make this data available. Although the proposed pricing for Cboe One Summary differs from the pricing currently in place for EDGX Top, the Exchange also believes that its pricing reflects the relative benefits provided to Distributors that provide Derived Data based on market information from all four Cboe equities exchanges. For example, the proposed fee for one to five External Subscribers of Derived Data based on Cboe One Summary using the API Service is equal to the aggregate standard External Distribution Fee across the Cboe equities exchange Top feeds, and is also equal to the standard External Distribution Fee for Cboe One Summary (*i.e.,* $5,000 per External Subscriber) on the Exchange. The proposed fee under the White Label Service is less than the proposed fee for API Service as Derived Data is provided on an ''off-the-shelf'' basis, and thus reflects the relative benefits provided to Distributors. Further, the proposed fee for Cboe One Summary under the proposed Platform Service is identical to the standard External Distributor fee for Cboe One Summary with the exception that there would be no fee associated with Non-Professional Users.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment, and its ability to price these data products is constrained by: (i) Competition among exchanges that offer similar data products, and pricing options, to their customers; and (ii) the existence of inexpensive real-time consolidated data disseminated by the SIPs. Top of book data is disseminated by both the SIPs and all 16 equities exchanges have the capability to disseminate such data. There are therefore a number of alternative products available to market participants and investors. In this competitive environment potential subscribers are free to choose which competing product to purchase to satisfy their need for market information. Often, the choice comes down to price, as broker-dealers or vendors look to purchase the lowest priced top of book data product, or quality, as market participants seek to purchase data that represents significant market liquidity. In order to better compete for this segment of the market, the Exchange is proposing to reduce fees charged to Distributors that distribute Derived Data through an Exchange approved Platform and enhance the existing program to offer Distributors the option to create Derived Data based on Cboe One Summary. The Exchange believes that this would facilitate greater access to Exchange data, ultimately benefiting investors that are provided access to such data. The proposed Platform Service fees would apply to data derived from EDGX Top and Cboe One Summary, which are subject to competition from both the SIPs and exchanges that offer similar products, including but not limited to those that choose to provide similar pricing options for Derived Data. A number of national securities exchanges, including the Exchange, its affiliated Cboe U.S. equities exchanges, and the Nasdaq Stock Market, LLC (''Nasdaq'') offer pricing discounts for Derived Data today. These pricing programs reduce the cost of accessing top of book market information that is used, among other things, to create derivative instruments rather than to trade U.S. equity securities. In order to better compete for this segment of the market, the Exchange is proposing to expand the Program to include a Derived Data Platform Service, which would allow additional market data customers to benefit from discounted pricing. Additionally, the Exchange is proposing to enhance the Program by providing a fee structure for Cboe One Summary, which would allow Distributors to create Derived Data that is based on a more comprehensive view of the U.S. equities market. The Exchange does not believe that the proposal would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges and data vendors are free to lower their prices to better

[18] As discussed previously, the Exchange does not fees [*sic*] to Non-Professional Users pursuant to the White Label Service and API Service. *See* Securities Exchange Act No. 84002 (August 30, 2018) 83 FR 45149 (September 5, 2018) (SR–CboeEDGX–2018–065) (Proposed fee amendment for White Label Service). *See also* Securities Exchange Act No. 87306 (October 15, 2019) 84 FR 56258 (October 21, 2019) (SR–CboeEDGX–2019–087) (Proposed fee amendment for API Service).

compete with the Exchange's offering. The Exchange believes that the proposed rule change is pro-competitive as it seeks to offer pricing incentives to customers to better position the Exchange as it competes to attract additional market data subscribers.

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 [19] and paragraph (f) of Rule 19b–4 [20] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeEDGX–2021–003 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–2021–003. 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–2021–003 and should be submitted on or before February 11, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–01133 Filed 1–19–21; 8:45 am]

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[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90912; File No. SR–CboeBZX–2021–003]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fee Schedule To Expand the Existing Financial Product Distribution Program To Provide for a Derived Data Platform Service

January 13, 2021.

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 January 4, 2021, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (''BZX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to amend the Fee Schedule to expand the existing Financial Product Distribution Program (the ''Program'') to provide for a Derived Data Platform Service. Additionally, the proposal seeks to enhance the Program to provide for the distribution of data derived from the Cboe Aggregated Market (''Cboe One'') [3] Summary Feed. 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 purpose of the proposed rule change is to implement a pricing structure that would reduce fees charged to Distributors of ''Derived Data'', as defined below, through an Exchange approved Derived Data Platform Service. Additionally, the proposal seeks to enhance the Program to permit the distribution of data derived from Cboe One Summary

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Rule 11.22(j).

through the existing White Label Service, Application Programming Interface (''API'') Service, and the proposed Platform Service.

Derived Data Platform Service

''Derived Data'' is pricing data or other data that (i) is created in whole or in part from Exchange Data, (ii) is not an index or financial product, and (iii) cannot be readily reverse-engineered to recreate Exchange Data or used to create other data that is a reasonable facsimile or substitute for Exchange Data. Derived Data may be created by Distributors for a number of different purposes, as determined by the Distributor. Possible uses include the display of information or data, or the creation of derivative instruments, such as swaps,[4] swaptions,[5] or contracts for difference.[6] The specific use of the data is determined by the Distributor, as applicable fees do not depend on the purpose for placing the Derived Data under the Program.

The Exchange currently offers a White Label Service and an API Service that allow Distributors to benefit from discounted fees when distributing Derived Data taken from Exchange data.[7] Instead of the regular fee for external distribution [8] of Exchange data, Distributors of Derived Data under both the White Label Service and API Service are charged a tiered External Subscriber Fee based on the number of External Subscribers that receive Derived Data from the Distributor. Additionally, Distributors are charged a Professional User [9] Fee based on the number of Professional Users of the Derived Data. Non-Professional Users of Derived Data are not subject to a fee under either the White Label Service or the API Service.

The White Label Service is a type of hosted display solution in which a Distributor hosts, maintains, and controls a website or platform on behalf of a third-party entity. The service allows Distributors to make Derived Data available on a platform that is branded with a third-party brand, or co-branded with a third-party and a Distributor, while the Distributor maintains control of the applications data, entitlements and display. Alternatively, the API Service is a type of data feed distribution in which a Distributor delivers an API or similar distribution mechanism to a third-party entity for use within one or more platforms. The API Service allows Distributors to provide Derived Data to a third-party entity for use within one or more downstream platforms that are operated and maintained by the third-party entity. The Distributor maintains control of the entitlements, but does not maintain technical control of the usage or the display.

Now the Exchange is proposing to implement a third service under the Program, the Platform Service. The Platform Service would allow a Distributor to provide derivative products directly to users that are hosted within their infrastructure. The Platform Service would be strictly limited to derivative products based in whole or in part on Exchange data where only user remote access is permitted. Normally, distributors of Exchange market data may be subject to Distribution and User Fees including an: External Distribution Fee, Professional User Fee, and Non-Professional User Fee. Distributors would be liable for the fees normally applicable for external distribution except for the Non-Professional User fee,[10] which would be eliminated when participating in the Platform Service, further reducing costs for Distributors that provide access to such data to retail investors. In contrast to the existing White Label Service and API Service, the Platform Service provides a targeted discount to Distributors rather than to External Subscribers.

Like the existing White Label Service and API Service, the proposed Platform Service would be entirely optional, in that it would only apply to Distributors that opt to use Derived Data to create a Platform Service, as described herein. It would not impact or raise the cost of any other Exchange product, nor would it affect the cost of Exchange data, except in instances where Derived Data is made available on a Platform Service. A Distributor that provides a Platform Service for Exchange data that is not Derived Data or distributes Derived Data through a platform other than an approved White Label Service, API Service, or Platform Service would be liable for the fees normally applicable for the distribution of Exchange data.

Cboe One Summary

In addition to the above, the Exchange is proposing to adopt fees for the distribution of data derived from Cboe One Summary under the existing White Label Service and API Service, as well as the proposed Platform Service. Under the existing Fee Schedule, Distributors that participate in the Program may only create Derived Data from BZX Top,[11] a proprietary data product that provides top of book quotations and execution information for all equity securities traded on the Exchange. The Exchange is now proposing a fee amendment to allow Distributors that participate in the Program to create Derived Data from Cboe One Summary in addition to BZX Top. Cboe One Summary is a proprietary data product that provides the top of book quotations and execution information for all listed equity securities traded across the Exchange and its affiliated U.S. equities exchanges (the ''Cboe equity exchanges'').[12] Therefore, Distributors of Derived Data created from Cboe One Summary could display information or data or create derivative instruments based on top of book information across the four Cboe equity exchanges rather than just BZX. The Exchange believes that the proposal will enhance the Program as the inclusion of Cboe One Summary will allow Distributors to create Derived Data that is based on a more comprehensive view of the U.S. equities market.

As discussed above, Distributors of Exchange data, including Cboe One Summary, may be subject to Distribution and User Fees including an: External Distribution Fee, Professional

[4] A swap is a derivative contract in which two parties agree to exchange financial instruments.

[5] A swaption, or swap option, is an option to enter into a swap at a specified time.

[6] A contract for difference is an agreement to exchange the difference between the current value of an asset and its future value. If the price increases, the seller pays the buyer the amount of the increase. If the price decreases, the buyer pays the seller the amount of the decrease.

[7] Currently, BZX Top data is the only Exchange data included in the Program; however, as discussed in further detail below, the Exchange is also proposing to include Cboe One Summary in the Program.

[8] External distribution occurs when a Distributor that receives an Exchange Market Data product distributes that data to a third-party or one or more users outside the Distributor's own entity.

[9] A ''Professional User'' of an Exchange Market Data product is any User other than a Non-Professional User. A ''Non-Professional User'' of an Exchange Market Data product is a natural person or qualifying trust that uses Data only for personal purposes and not for any commercial purpose and, for a natural person who works in the United States, is not: (i) Registered or qualified in any capacity with the Securities and Exchange Commission, the Commodities Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an ''investment adviser'' as that term is defined in Section 202(a)(11) of the Investment Advisors Act of 1940 (whether or not registered or qualified under that Act); or (iii) employed by a bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt; or, for a natural person who works outside of the United States, does not perform the same functions as would disqualify such person as a Non-Professional User if he or she worked in the United States.

[10] The Non-Professional User Fee for external distribution of BZX Top is $0.10/month.

[11] *See* Exchange Rule 11.22(d).

[12] *Supra* note 3.

User Fee, and Non-Professional User Fee. As proposed, a Distributor that provides Derived Data from Cboe One Summary would be liable for the proposed fees discussed below instead of the fees normally applicable for the distribution of Cboe One Summary. Existing fees for BZX Top Derived Data within a White Label Service or API Service are comprised of a tiered fee based on the number of External Subscribers, a monthly fee for each Professional User, and include no fee for Non-Professional Users. Similarly, the proposed fees for the Platform Service are comprised of the normal External Distribution and Professional User fees applicable for the distribution of BZX Top except that they would not be subject to the Non-Professional Users fees normally applicable. The Exchange proposes to adopt a similar fee structure for Cboe One Summary Derived Data.

As proposed, Distributors would be charged the following fees for a White Label Service for Cboe One Summary Derived Data: (1) $1,000 Per month for each External Subscriber if the Distributor makes Derived Data available to 1–5 External Subscribers; (2) $750 per month for each External Subscriber if the Distributor makes Derived Data available to 6–10 External Subscribers; and (3) $500 per month for each External Subscriber if the Distributor makes Derived Data available to 11 or more External Subscribers. For example, a Distributor providing White Label Derived Data based on Cboe One Summary to six External Subscribers would be charged a monthly fee of $4,500 (*i.e.,* 6 External Subscribers × $750 each). Additionally, the Exchange would continue to charge a monthly Professional User fee of $10 per month for each Professional User. The Exchange proposes no Non-Professional User fee for the distribution of Cboe One Summary Derived Data under the White Label Service, which is consistent with the fee structure for the distribution of BZX Top Derived Data under the White Label Service.

Alternatively, Distributors would be charged the following fees for an API Service for Cboe One Summary Derived Data: (1) $5,000 per month for each External Subscriber if the Distributor makes Derived Data available to 1–5 External Subscribers; (2) $4,000 per month for each External Subscriber if the Distributor makes Derived Data available to 6–20 External Subscribers; and (3) $3,000 per month for each External Subscriber if the Distributor makes Derived Data available to 11 or more External Subscribers. For example, a Distributor providing API Service Derived Data based on Cboe One Summary to six External Subscribers would be charged a monthly fee of $24,000 (*i.e.,* 6 External Subscribers × $4,000 each). Additionally, the Exchange would continue to charge a monthly Professional User fee of $10 per month for each Professional User. The Exchange proposes no Non-Professional User fee for the distribution of Cboe One Summary Derived Data under the API Service, which is consistent with the fee structure for the distribution of BZX Top Derived Data under the API Service.

Lastly, the Exchange proposes to adopt fees for the proposed Platform Service for Cboe One Summary data in addition to the proposed fees for BZX Top discussed above. Like the proposed fee for BZX Top Derived Data, Distributors of Cboe One Summary Derived Data would be liable for the fees normally applicable for the external distribution of Cboe One Summary, except for the Non-Professional User fee (*i.e.,* $0.25/month) which would be free under the Platform Service.

Corresponding Amendments to Fee Schedule

Based on the proposed amendments discussed above, the Exchange proposes several clarifying modifications to the Fee Schedule. First, the Exchange proposes to add a definition of ''Platform Service'' to the Market Data Fees definitions section of the Fee Schedule. The definition would provide that ''a Platform Service is a type of hosted display solution in which a Distributor provides derivative products to Platform Service Data Users within their infrastructure. The service allows Distributors to make Derived Data available as part of a platform, providing users remote access to derivative products based in whole or in part on Exchange Data.''

The Exchange also proposes to amend explanatory asterisks provided under the Program in the Fee Schedule. Specifically, the Exchange proposes to amend the paragraph following the first asterisk to reference the proposed Platform Service in addition to the existing references to the White Label Service and API Service. Additionally, the Exchange proposes to add references to Cboe One Summary after all references to BZX Top in the paragraph following the first asterisk. Lastly, the Exchange proposes to add additional examples to asterisks two and three so as to explain the application of fees for Derived Data from Cboe One Summary. These proposed non-substantive changes would provide clarity in the Fee Schedule based on the addition of the Platform Service and Cboe One Summary proposed herein.

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 and other recipients of Exchange data.

The Exchange also believes that the proposed rule change is consistent with Section 11(A) of the Act.[15] Specifically, the proposed rule change supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets, and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. In addition, the proposed rule change is consistent with Rule 603 of Regulation NMS,[16] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory.

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed fee change would further broaden the availability of U.S. equity market data to investors, consistent with the principles of Regulation NMS.

The Exchange operates in a highly competitive environment. Indeed, there are 16 registered national securities exchanges that trade U.S. equities and have the capability to offer associated top of book market data products to their customers. The national securities exchanges also compete with the Securities Information Processors (''SIPs'') for market data customers. 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

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78k–1.

[16] *See* 17 CFR 242.603.

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.'' [17] The proposed fee change is a result of the competitive environment, as the Exchange seeks to amend its fees to attract additional subscribers for its proprietary top of book data offerings through the introduction of a Derived Data Platform Service and the expansion of top of book data offerings to include Cboe One Summary under the Program.

The Exchange believes that it is reasonable to introduce reduced fees for the use of Derived Data on Platform Services as the proposed fee reduction would facilitate cost effective access to market information that is used primarily to create and display certain derivative instruments rather than to display the underlying U.S. equity securities. The proposed Platform Service fees are constrained by competition, and it is this competition that is driving the proposed fee change. Indeed, the Program is designed to allow the Exchange to compete more effectively for market data distributors that purchase market information to offer Derived Data to investors.

Similarly, the Exchange believes that it is reasonable to enhance the Program by expanding Exchange data offered under the Program to include Cboe One Summary as doing so will allow Distributors to create Derived Data that is based on a more comprehensive view of the U.S. equities market. Because Exchange data in this context is primarily purchased for the creation of Derived Data encompassing certain derivative instruments, Distributors do not require a consolidated view of the market across multiple exchanges, and will generally purchase such data from a single or select few exchange(s) for their purposes. As noted above, Cboe One Summary includes top of book quotation and transaction data across all four Cboe equity exchanges, which would allow Distributors to create more meaningful Derived Data than that available from a single exchange's market data at a potentially reduced price.

The existence of alternatives to the Program ensures that the Exchange cannot set unreasonable or unfairly discriminatory fees, as subscribers are free to elect such alternatives. That is, the Exchange competes with other exchanges that provide similar market data products and pricing programs. Expanding the availability of diverse competitive products actually promotes additional competition as it ensures that alternative products from different sources are readily available to Distributors and the broader market. The Exchange therefore believes that the introduction of pricing programs and the expansion of Exchange data are not only constrained by competition but also ensure continued competition that acts as a constraint on the pricing of services provided by other national securities exchanges and the SIPs. If a competing exchange were to charge less for a similar product than the Exchange charges under the proposed fee structure, prospective subscribers may choose not subscribe to, or cease subscribing to, the Program. The Exchange believes that lowering the cost of accessing Derived Data may make the Exchange's market information more attractive, and encourage additional Distributors to subscribe to Exchange market data instead of competitor products. The Exchange anticipates up to 10 Distributors to participate in the proposed Platform Service, and up to three Distributors to create Derived Data from Cboe One Summary. Distributors can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Further, firms have a wide variety of alternative market data products from which to choose, such as similar proprietary data products offered by other national securities exchanges, including those that choose to offer discounted fees for the distribution of Derived Data in an effort to compete for this business.

The proposed rule change would provide an optional fee structure for Distributors to use Exchange data to make Derived Data available to Non-Professional Users via an Exchange approved Platform Service at a reduced fee. As proposed, if a Distributor uses a Platform Service to distribute Derived Data, the Distributor would be charged the normal applicable External Distributor Fee excluding the Non-Professional User Fee. The Exchange believes that it is equitable and not unfairly discriminatory to charge a fee for Professional Users but no fee for Non-Professional Users. Non-Professional Users are already subject to a heavily discounted fee for BZX Top market data relative to Professional Users. Differential fees for Professional and Non-Professional Users are widely used by the Exchange and other exchanges for their proprietary market data as this reduces costs for retail investors and makes market data more broadly available. The Exchange believes that eliminating fees for Non-Professional Users that access Derived Data from Distributors pursuant to the Program is consistent with longstanding precedent indicating that it is consistent with the Act to provide reasonable incentives to retail investors that rely on the public markets for their investment needs.[18] Further, the proposed fee would only apply to Distributors that elect to participate in the Program by distributing Derived Data through a Platform Service. Exchange market data is distributed and purchased on a voluntary basis, in that neither the Exchange nor market data distributors are required by any rule or regulation to make this data available. Distributors of Exchange data are not required to participate in the proposed Program, which is merely an alternative option being proposed by the Exchange to potentially lower costs for market data that is Derived Data. As previously explained, the Exchange currently offers discounted fees for Distributors that distribute Derived Data on a White Label Service or an API Service. Expanding the universe of customers that can benefit from discounted fees for distributing Derived Data would serve to further increase the accessibility of the Exchange's market data products. Although the proposed pricing for the Platform Service differs from the pricing currently in place for the White Label and API Service Programs, it mirrors the normal External Distribution Fee for BZX Top and Cboe One Summary except that there would be no fee for Non-Professional Users. The White Label Service provides an ''off-the-shelf'' solution to display Derived Data as it is ultimately designed and controlled by the Distributor. Alternatively, the API Service offers end clients of Distributors to use Derived Data in one or more of their own customized applications. The Exchange believes that the proposed pricing reflects the relative benefits provided to Distributors that offer a Platform Service that allows Users remote access to derivative products via a hosted display solution within the Distributors fully managed infrastructure.

[17] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[18] As discussed previously, the Exchange does not fees [*sic*] to Non-Professional Users pursuant to the White Label Service and API Service. *See* Securities Exchange Act No. 84002 (August 30, 2018) 83 FR 45149 (September 5, 2018) (SR–CboeBZX–2018–065) (Proposed fee amendment for White Label Service). *See also* Securities Exchange Act No. 87306 (October 15, 2019) 84 FR 56258 (October 21, 2019) (SR–CboeBZX–2019–087) (Proposed fee amendment for API Service).

The proposed rule change would also provide Distributors the option to create Derived Data from Cboe One Summary, and benefit from reduced fees for that product under the Financial Product Distribution Program, in addition to the currently available BZX Top. The proposed fees would only apply to Distributors that elect to create Derived Data from Cboe One Summary. Similar to the fee structure for BZX Top under the Program, no fee would be assessed for Non-Professional Users of Derived Data from Cboe One Summary. For the same reasons discussed above, the Exchange believes it is equitable and not unfairly discriminatory to charge a fee for Professional Users but no fee for Non-Professional Users. Further, the proposed fee would only apply to Distributors that elect to participate in the Program by distributing Derived Data from Cboe One Summary. Exchange market data is distributed and purchased on a voluntary basis, in that neither the Exchange nor market data distributors are required by any rule or regulation to make this data available. Although the proposed pricing for Cboe One Summary differs from the pricing currently in place for BZX Top, the Exchange also believes that its pricing reflects the relative benefits provided to Distributors that provide Derived Data based on market information from all four Cboe equities exchanges. For example, the proposed fee for one to five External Subscribers of Derived Data based on Cboe One Summary using the API Service is equal to the aggregate standard External Distribution Fee across the Cboe equities exchange Top feeds, and is also equal to the standard External Distribution Fee for Cboe One Summary (*i.e.,* $5,000 per External Subscriber) on the Exchange. The proposed fee under the White Label Service is less than the proposed fee for API Service as Derived Data is provided on an ''off-the-shelf'' basis, and thus reflects the relative benefits provided to Distributors. Further, the proposed fee for Cboe One Summary under the proposed Platform Service is identical to the standard External Distributor fee for Cboe One Summary with the exception that there would be no fee associated with Non-Professional Users.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment, and its ability to price these data products is constrained by: (i) Competition among exchanges that offer similar data products, and pricing options, to their customers; and (ii) the existence of inexpensive real-time consolidated data disseminated by the SIPs. Top of book data is disseminated by both the SIPs and all 16 equities exchanges have the capability to disseminate such data. There are therefore a number of alternative products available to market participants and investors. In this competitive environment potential subscribers are free to choose which competing product to purchase to satisfy their need for market information. Often, the choice comes down to price, as broker-dealers or vendors look to purchase the lowest priced top of book data product, or quality, as market participants seek to purchase data that represents significant market liquidity. In order to better compete for this segment of the market, the Exchange is proposing to reduce fees charged to Distributors that distribute Derived Data through an Exchange approved Platform and enhance the existing program to offer Distributors the option to create Derived Data based on Cboe One Summary. The Exchange believes that this would facilitate greater access to Exchange data, ultimately benefiting investors that are provided access to such data. The proposed Platform Service fees would apply to data derived from BZX Top and Cboe One Summary, which are subject to competition from both the SIPs and exchanges that offer similar products, including but not limited to those that choose to provide similar pricing options for Derived Data. A number of national securities exchanges, including the Exchange, its affiliated Cboe U.S. equities exchanges, and the Nasdaq Stock Market, LLC (''Nasdaq'') offer pricing discounts for Derived Data today. These pricing programs reduce the cost of accessing top of book market information that is used, among other things, to create derivative instruments rather than to trade U.S. equity securities. In order to better compete for this segment of the market, the Exchange is proposing to expand the Program to include a Derived Data Platform Service, which would allow additional market data customers to benefit from discounted pricing. Additionally, the Exchange is proposing to enhance the Program by providing a fee structure for Cboe One Summary, which would allow Distributors to create Derived Data that is based on a more comprehensive view of the U.S. equities market. The Exchange does not believe that the proposal would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges and data vendors are free to lower their prices to better compete with the Exchange's offering. The Exchange believes that the proposed rule change is pro-competitive as it seeks to offer pricing incentives to customers to better position the Exchange as it competes to attract additional market data subscribers.

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 [19] and paragraph (f) of Rule 19b–4 thereunder.[20] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission 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–2021–003 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–2021–003. This file number should be included on the

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f).

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–2021–003 and should be submitted on or before February 11, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–01132 Filed 1–19–21; 8:45 am]

BILLING CODE 8011–01–P

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90917; File No. SR–NYSE–2020–95]

Self-Regulatory Organizations; New York Stock Exchange LLC, Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Make Permanent Commentaries to Rule 7.35A and Commentaries to Rule 7.35B and Make Related Changes to Rules 7.32, 7.35C, 46B, and 47

January 13, 2021.

On November 13, 2020, New York Stock Exchange LLC (''NYSE'' or the ''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 make permanent Commentaries .01(a) and (b) and .06 to Rule 7.35A (DMM-Facilitated Core Open and Trading Halt Auctions) and Commentaries .01 and .03 to Rule 7.35B (DMM-Facilitated Closing Auctions) and make related changes to Rules 7.32 (Order Entry), 7.35C (Exchange-Facilitated Closing Auctions), 46B (Regulatory Trading Official), and 47 (Floor Officials—Unusual Situations). The proposed rule change was published for comment in the **Federal Register** on December 1, 2020.[3] The Commission has received no comment letters 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 propose 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 published 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 the proposed rule change is January 15, 2021. The Commission is extending this 45-day period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, pursuant to Section 19(b)(2) of the Act,[5] the Commission designates March 1, 2021, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change (File No. SR–NYSE–2020–95).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90495 (November 24, 2020), 85 FR 77304 (December 1, 2020) (SR–NYSE–2020–95).

[4] 15 U.S.C. 78s(b)(2).

[5] 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–01135 Filed 1–19–21; 8:45 am]

BILLING CODE 8011–01–P

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–139, OMB Control No. 3235–0128]

Proposed Collection; Comment Request

Upon Written Request, Copies Available from: U.S. Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Extension:
Rule 12f–1

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 12f–1 (17 CFR 240.12f–1), under the Securities Exchange Act of 1934 (''Act'') (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 12f–1 (''Rule''), originally adopted in 1979 pursuant to Sections 12(f) and 23(a) of the Act, and as further modified in 1995 and 2005, sets forth the requirements for filing an exchange application to reinstate unlisted trading privileges (''UTP'') in a security in which UTP has been suspended by the Commission pursuant to Section 12(f)(2)(A) of the Act. Under Rule 12f–1, an exchange must submit one copy of an application for reinstatement of UTP to the Commission that contains specified information, as set forth in the Rule. The application for reinstatement, pursuant to the Rule, must provide the name of the issuer, the title of the security, the name of each national securities exchange, if any, on which the security is listed or admitted to unlisted trading privileges, whether transaction information concerning the security is reported pursuant to an effective transaction reporting plan contemplated by Rule 601 of Regulation NMS, the date of the Commission's suspension of unlisted trading privileges in the security on the

exchange, and any other pertinent information related to whether the reinstatement of UTP in the subject security is consistent with the maintenance of fair and orderly markets and the protection of investors. Rule 12f–1 further requires a national securities exchange seeking to reinstate its ability to extend unlisted trading privileges in a security to indicate that it has provided a copy of such application to the issuer of the security, as well as to any other national securities exchange on which the security is listed or admitted to unlisted trading privileges.

The information required by Rule 12f–1 enables the Commission to make the necessary findings under the Act prior to granting applications to reinstate unlisted trading privileges. This information is also made available to members of the public who may wish to comment upon the applications. Without the Rule, the Commission would be unable to fulfill these statutory responsibilities.

There are currently 24 national securities exchanges subject to Rule 12f–1. The burden of complying with Rule 12f–1 arises when a potential respondent seeks to reinstate its ability to extend unlisted trading privileges to any security for which unlisted trading privileges have been suspended by the Commission, pursuant to Section 12(f)(2)(A) of the Act. The staff estimates that each application would require approximately one hour to complete. Thus each potential respondent would incur on average one burden hour in complying with the Rule.

The Commission staff estimates that there could be as many as 24 responses annually for an aggregate annual hour burden for all respondents of approximately 24 hours (24 responses × 1 hour per response). Each respondent's related internal cost of compliance for Rule 12f–1 would be approximately $221.00, or, the cost of one hour of professional work of a paralegal needed to complete the application. The total annual cost of compliance for all potential respondents, therefore, is approximately $5,304 (24 responses × $221.00 per response).

Compliance with Rule 12f–1 is mandatory. Rule 12f–1 does not have a record retention requirement *per se.* However, responses made pursuant to Rule 12f–1 are subject to the recordkeeping requirements of Rules 17a–3 and 17a–4 of the Act. Information received in response to Rule 12f–1 shall not be kept confidential; the information collected is public information.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: January 14, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–01245 Filed 1–19–21; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16846 and #16847; Georgia Disaster Number GA–00123]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Georgia

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Georgia (FEMA–4579–DR), dated 01/12/2021.

Incident: Tropical Storm Zeta.

Incident Period: 10/29/2020.

DATES: Issued on 01/12/2021.

Physical Loan Application Deadline Date: 03/15/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 10/12/2021.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 01/12/2021, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Banks, Carroll, Cherokee, Dawson, Douglas, Fannin, Forsyth, Franklin, Gilmer, Habersham, Hall, Haralson, Heard, Lumpkin, Paulding, Pickens, Rabun, Stephens, Towns, Union, White.

The Interest Rates are:

	Percent
For Physical Damge:	
Non-Profit Oganization With Credit Available Elsewhere ...	2.750
Non-Profit Oganization Without Credit Available Elsehere	2.750
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 168468 and for economic injury is 168470.

(Catalog of Federal Domestic Assistance Number 59008)

Cynthia Pitts,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2021–01183 Filed 1–19–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16842 and #16843; Louisiana Disaster Number LA–00106]

Presidential Declaration of a Major Disaster for the State of Louisiana

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Louisiana (FEMA–4577–DR), dated 1/12/2021.

Incident: Hurricane Zeta.

Incident Period: 10/26/2020 through 10/29/2020.

DATES: Issued on 01/12/2021.

Physical Loan Application Deadline Date: 03/15/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 10/12/2021.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 01/12/2021, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Parishes (Physical Damage and Economic Injury Loans): Jefferson, Lafourche, Orleans, Plaquemines, Saint Bernard, Terrebonne.

Contiguous Parishes (Economic Injury Loans Only):

Louisiana: Assumption, Saint Charles, Saint James, Saint Mary, Saint Tammany, St John The Baptist, Tangipahoa.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	2.375
Homeowners Without Credit Available Elsewhere	1.188
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	3.000
Non-Profit Organizations With Credit Available Elsewhere	2.750
Non-Profit Organizations Without Credit Available Elsewhere	2.750
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	3.000
Non-Profit Organizations Without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 168428 and for economic injury is 168430.

(Catalog of Federal Domestic Assistance Number 59008)

Cynthia Pitts,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2021–01177 Filed 1–19–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16844 and #16845; Utah Disaster Number UT–00080]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Utah

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Utah (FEMA–4578–DR), dated 01/12/2021.

Incident: Straight-line Winds.

Incident Period: 09/07/2020 through 09/08/2020.

DATES: Issued on 01/12/2021.

Physical Loan Application Deadline Date: 03/15/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 10/12/2021.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 01/12/2021, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Davis, Morgan, Salt Lake, Weber.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere	2.750
Non-Profit Organizations Without Credit Available Elsewhere	2.750
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 16844B and for economic injury is 168450.

(Catalog of Federal Domestic Assistance Number 59008)

Cynthia Pitts,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2021–01178 Filed 1–19–21; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice: 11318]

Notice of Department of State Sanctions Blocking Property and Suspending Entry of Certain Persons Contributing to the Situation in Syria

SUMMARY: The Secretary of State has imposed sanctions on three individuals.

DATES: The Secretary of State's determination and selection of certain sanctions to be imposed upon the two persons identified in the **SUPPLEMENTARY INFORMATION** section were effective on November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Taylor Ruggles, Director, Office of Economic Sanctions Policy and Implementation, Bureau of Economic and Business Affairs, Department of State, Washington, DC 20520, tel.: (202) 647–7677, email: *RugglesTV@state.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 2(a) of E.O. 13894 of October 14, 2019, the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of Commerce, the Secretary of Homeland Security, and the United States Trade Representative, and with the President of the Export-Import Bank, the Chairman of the Board

of Governors of the Federal Reserve System, and other agencies and officials as appropriate, is authorized to impose on a person any of the sanctions described in section 2(c) of E.O. 13894 upon determining that the person met any criteria set forth in section 2(a)(i) or section 2(a)(ii) of E.O. 13894.

The Secretary of State has determined, pursuant to Section 2(a)(i)(A) of E.O. 13894, that Saqr Rustom and the National Defense Forces are responsible for or complicit in, have directly or indirectly engaged in, attempted to engage in, or financed, the obstruction, disruption, or prevention of a ceasefire in northern Syria.

Pursuant to Sections 2(b) and 2(c) of E.O. 13894, the Secretary of State has selected the following sanctions to be imposed upon Saqr Rustom and the National Defense Forces:

• Block all property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person of Saqr Rustom and the National Defense Forces, and provide that such property and interests in property may not be transferred, paid, exported, withdrawn, or otherwise dealt in (Section 2(c)(iv) of E.O. 13894).

Peter D. Haas,

Principal Deputy Assistant Secretary, Bureau of Economic and Business Affairs, Department of State.

[FR Doc. 2021–00951 Filed 1–19–21; 8:45 am]

BILLING CODE 4710–AE–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Determination Pursuant to Section 301: Austria's Digital Services Tax

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice.

SUMMARY: The U.S. Trade Representative has determined that Austria's Digital Services Tax (DST) is unreasonable or discriminatory and burdens or restricts U.S. commerce and thus is actionable under Section 301.

FOR FURTHER INFORMATION CONTACT: For questions concerning the investigation, please contact Thomas Au or Patrick Childress, Assistant General Counsels at (202) 395–0380 and (202) 395–9531, respectively, Robert Tanner, Director, Services and Investment at (202) 395–6125, or Michael Rogers, Director, Europe and the Middle East at (202) 395–2684.

SUPPLEMENTARY INFORMATION:

I. Austria's DST

Based on information obtained during the investigation, USTR has prepared a comprehensive report on Austria's DST (Austria DST Report). The Austria DST Report, which is posted on the USTR website at *https://ustr.gov/issue-areas/enforcement/section-301-investigations/section-301-digital-services-taxes,* includes a full description of Austria's DST. To summarize, Austria's DST imposes a 5% tax on gross revenues from digital advertising services provided in Austria. The DST applies only to companies with annual global revenues of €750 million or more, and annual revenues from digital advertising services in Austria of €25 million or more.

II. Proceedings in the Investigation

On June 2, 2020, the U.S. Trade Representative initiated an investigation of Austria's DST pursuant to section 302(b)(1)(A) of the Trade Act of 1974, as amended (Trade Act). *See* 85 FR 34709 (June 5, 2020) (notice of initiation). The notice of initiation solicited written comments on, *inter alia,* the following aspects of Austria's DST: Discrimination against U.S. companies, retroactivity, and possibly unreasonable tax policy. With respect to tax policy, USTR solicited comments on, *inter alia,* whether the DST diverged from principles reflected in the U.S. and international tax systems including extraterritoriality, taxing revenue not income, and a purpose of penalizing particular technology companies for their commercial success.

Interested persons filed over 380 written submissions in response to the notice of initiation. The public submissions are available on *www.regulations.gov* in docket number USTR–2020–0022.

Under Section 303 of the Trade Act, the U.S. Trade Representative requested consultations with the Government of Austria regarding the issues involved in the investigation. Consultations were held on December 21, 2020.

As noted, based on information obtained during the investigation, USTR has prepared and published the Austria DST Report, which includes a comprehensive discussion on whether the acts, policies, and practices under investigation are actionable under Section 301(b) of the Trade Act. The Austria DST Report supports findings that Austria's DST is unreasonable or discriminatory and burdens or restricts U.S. commerce.

III. Determination on the Act, Policy, or Practice Under Investigation

Based on the information obtained during the investigation, and taking account of public comments and the advice of the Section 301 Committee and advisory committees, the U.S. Trade Representative has made the following determination under sections 301(b) and 304(a) of the Trade Act (19 U.S.C. 2411(b) and 2414(a)): the act, policy, or practice covered in the investigation, namely Austria's DST, is unreasonable or discriminatory and burdens or restricts U.S. commerce, and thus is actionable under section 301(b) of the Trade Act. In particular:

1. Austria's DST, by its structure and operation, discriminates against U.S. digital companies.
2. Austria's DST is unreasonable because it is inconsistent with principles of international taxation.
3. Austria's DST burdens or restricts U.S. commerce.

IV. Further Proceedings

Sections 301(b) and 304(a)(1)(B) of the Trade Act provide that if the U.S. Trade Representative determines that an act, policy, or practice of a foreign country is unreasonable or discriminatory and burdens or restricts United States commerce, the U.S. Trade Representative shall determine what action, if any, to take under Section 301(b). These matters will be addressed in subsequent proceedings under Section 301.

Joseph Barloon,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2021–01173 Filed 1–19–21; 8:45 am]

BILLING CODE 3290–F0–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Determination Pursuant to Section 301: The United Kingdom's Digital Services Tax

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice.

SUMMARY: The U.S. Trade Representative has determined that the United Kingdom's Digital Services Tax (DST) is unreasonable or discriminatory and burdens or restricts U.S. commerce and thus is actionable under Section 301.

FOR FURTHER INFORMATION CONTACT: For questions concerning the investigation, please contact Thomas Au or Patrick Childress, Assistant General Counsels at

(202) 395–0380 and (202) 395–9531, respectively, Robert Tanner, Director, Services and Investment at (202) 395–6125, or Michael Rogers, Director, Europe and the Middle East at (202) 395–2684.

SUPPLEMENTARY INFORMATION:

I. The United Kingdom's DST

Based on information obtained during the investigation, USTR has prepared a comprehensive report on the United Kingdom's DST (UK DST Report). The UK DST Report, which is posted on the USTR website at *https://ustr.gov/issue-areas/enforcement/section-301-investigations/section-301-digital-services-taxes,* includes a full description of the United Kingdom's DST. To summarize, the United Kingdom's DST was introduced as part of the Finance Bill 2020 and adopted on July 22, 2020. The United Kingdom's DST applies a two percent tax on the revenues of certain search engines, social medial platforms and online marketplaces. The United Kingdom's DST applies only to companies with digital services revenues exceeding £500 million and United Kingdom digital services revenues exceeding £25 million. Companies became liable for the DST on April 1, 2020.

II. Proceedings in the Investigation

On June 2, 2020, the U.S. Trade Representative initiated an investigation of the United Kingdom's DST pursuant to section 302(b)(1)(A) of the Trade Act of 1974, as amended (Trade Act). 85 FR 34709 (June 5, 2020) (notice of initiation). The notice of initiation solicited written comments on, *inter alia,* the following aspects of the United Kingdom's DST: discrimination against U.S. companies; retroactivity; and possibly unreasonable tax policy. With respect to tax policy, USTR solicited comments on, *inter alia,* whether the DST diverged from principles reflected in the U.S. and international tax systems including extraterritoriality; taxing revenue not income; and a purpose of penalizing particular technology companies for their commercial success.

Interested persons filed over 380 written submissions in response to the notice of initiation. The public submissions are available on *www.regulations.gov* in docket number USTR–2020–0022.

Under Section 303 of the Trade Act, the U.S. Trade Representative requested consultations with the Government of the United Kingdom regarding the issues involved in the investigation. Consultations were held on December 4, 2020.

As noted, based on information obtained during the investigation, USTR has prepared and published the UK DST Report, which includes a comprehensive discussion on whether the acts, policies, and practices under investigation are actionable under Section 301(b) of the Trade Act. The UK DST Report supports findings that the United Kingdom's DST is unreasonable or discriminatory and burdens or restricts U.S. commerce.

III. Determination on the Act, Policy, or Practice Under Investigation

Based on the information obtained during the investigation, and taking account of public comments and the advice of the Section 301 Committee and advisory committees, the U.S. Trade Representative has made the following determination under sections 301(b) and 304(a) of the Trade Act (19 U.S.C. 2411(b) and 2414(a)): the act, policy, or practice covered in the investigation, namely the United Kingdom's DST, is unreasonable or discriminatory and burdens or restricts U.S. commerce, and thus is actionable under section 301(b) of the Trade Act. In particular:

1. The United Kingdom's DST, by its structure and operation, discriminates against U.S. digital companies, including due to the selection of covered services and the revenue thresholds.

2. The United Kingdom's DST is unreasonable because it is inconsistent with principles of international taxation, including due to application to revenue rather than income, extraterritoriality, and retroactivity.

3. The United Kingdom's DST burdens or restricts U.S. commerce.

IV. Further Proceedings

Sections 301(b) and 304(a)(1)(B) of the Trade Act provides that if the U.S. Trade Representative determines that an act, policy, or practice of a foreign country is unreasonable or discriminatory and burdens or restricts United States commerce, the U.S. Trade Representative shall determine what action, if any, to take under Section 301(b). These matters will be addressed in subsequent proceedings under Section 301.

Joseph Barloon,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2021–01174 Filed 1–19–21; 8:45 am]

BILLING CODE 3290–F0–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Determination Pursuant to Section 301: Spain's Digital Services Tax

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice.

SUMMARY: The U.S. Trade Representative has determined that Spain's Digital Services Tax (DST) is unreasonable or discriminatory and burdens or restricts U.S. commerce and thus is actionable under Section 301.

FOR FURTHER INFORMATION CONTACT: For questions concerning the investigation, please contact Thomas Au or Patrick Childress, Assistant General Counsels at (202) 395–0380 and (202) 395–9531, respectively, Robert Tanner, Director, Services and Investment at (202) 395–6125, or Michael Rogers, Director, Europe and the Middle East at (202) 395–2684.

SUPPLEMENTARY INFORMATION:

I. Spain's DST

Based on information obtained during the investigation, USTR has prepared a comprehensive report on Spain's DST (Spain DST Report). The Spain DST Report, which is posted on the USTR website at *https://ustr.gov/issue-areas/enforcement/section-301-investigations/section-301-digital-services-taxes,* includes a full description of Spain's DST. To summarize, Spain introduced a legislative proposal to establish a DST on February 28, 2020 and adopted the DST on October 7, 2020. The DST applies a three percent tax on certain digital services revenues related to online advertising services, online intermediary services, and data transmission services. Companies with worldwide revenues of €750 million or more and €3 million in certain digital services revenues are subject to the tax. The tax is expected to take effect on January 15, 2021.

II. Proceedings in the Investigation

On June 2, 2020, the U.S. Trade Representative initiated an investigation of Spain's DST pursuant to section 302(b)(1)(A) of the Trade Act of 1974, as amended (Trade Act). *See* 85 FR 34709 (June 5, 2020) (notice of initiation). The notice of initiation solicited written comments on, *inter alia,* the following aspects of Spain's DST: discrimination against U.S. companies, retroactivity, and possibly unreasonable tax policy. With respect to tax policy, USTR solicited comments on, *inter alia,* whether the DST diverged from

principles reflected in the U.S. and international tax systems including extraterritoriality, taxing revenue not income, and a purpose of penalizing particular technology companies for their commercial success.

Interested persons filed over 380 written submissions in response to the notice of initiation. The public submissions are available on *www.regulations.gov* in docket number USTR–2020–0022.

Under Section 303 of the Trade Act, the U.S. Trade Representative requested consultations with the Government of Spain regarding the issues involved in the investigation. Consultations were held on December 17, 2020.

As noted, based on information obtained during the investigation, USTR has prepared and published the Spain DST Report, which includes a comprehensive discussion on whether the acts, policies, and practices under investigation are actionable under Section 301(b) of the Trade Act. The Spain DST Report supports findings that Spain's DST is unreasonable or discriminatory and burdens or restricts U.S. commerce.

III. Determination on the Act, Policy, or Practice Under Investigation

Based on the information obtained during the investigation, and taking account of public comments and the advice of the Section 301 Committee and advisory committees, the U.S. Trade Representative has made the following determination under sections 301(b) and 304(a) of the Trade Act (19 U.S.C. 2411(b) and 2414(a)): the act, policy, or practice covered in the investigation, namely Spain's DST, is unreasonable or discriminatory and burdens or restricts U.S. commerce, and thus is actionable under section 301(b) of the Trade Act. In particular:

1. Spain's DST, by its structure and operation, discriminates against U.S. digital companies, including due to the selection of covered services and the revenue thresholds.
2. Spain's DST is unreasonable because it is inconsistent with principles of international taxation.
3. Spain's DST burdens or restricts U.S. commerce.

IV. Further Proceedings

Sections 301(b) and 304(a)(1)(B) of the Trade Act provide that if the U.S. Trade Representative determines that an act, policy, or practice of a foreign country is unreasonable or discriminatory and burdens or restricts United States commerce, the U.S. Trade Representative shall determine what action, if any, to take under Section 301(b). These matters will be addressed in subsequent proceedings under Section 301.

Joseph Barloon,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2021–01171 Filed 1–19–21; 8:45 am]

BILLING CODE 3290–F0–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–XXXX]

Petition for Exemption; Summary of Petition Received; Southern Seaplane, Inc.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before February 10, 2021.

ADDRESSES: Send comments identified by docket number FAA–2020–1043 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Brittany Newton, 202–267–6691, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Timothy R. Adams,

Deputy Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2020–1043.

Petitioner: Southern Seaplane, Inc.

Section(s) of 14 CFR Affected: Part 141, appendix I, paragraph 4(j)(2)(iii) and (iv).

Description of Relief Sought: Southern Seaplane, Inc., seeks relief from Appendix I, paragraph 4(j)(2)(iii) and (iv) of Title 14 of the Code of Federal Regulations which requires one 2-hour cross country flight during daytime conditions and one 2-hour cross country flight during nighttime conditions. Southern Seaplane, Inc., wishes to omit these requirements because they are a prerequisite for enrollment into its course.

[FR Doc. 2021–01223 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0616]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Certification Procedures for Products and Parts

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the FAA invites public comments about our

intention to request 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 June 19, 2020. The collection involves FAA regulations that prescribe certification standards for aircraft, aircraft engines, propellers, appliances, and parts. The information collected is used to determine compliance and applicant eligibility. The respondents are aircraft parts designers, manufacturers, and aircraft owners.

DATES: Written comments should be submitted by February 22, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Brian Cable by email at: *Brian.Cable@faa.gov;* phone: (202) 267–1579.

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.

OMB Control Number: 2120–0018.

Title: Certification Procedures for Products and Parts.

Form Numbers: FAA Forms 8110–12, 8130–1, 8130–6, 8130–9, 8130–12.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 19, 2020 (85 FR 37149). The FAA received one comment that is unrelated to the information collection.

Title 14, Code of Federal Regulations (14 CFR) part 21 prescribes certification standards for aircraft, aircraft engines, propellers, appliances, and parts. The information collected is used to determine compliance and applicant eligibility. FAA airworthiness inspectors, designated inspectors, engineers, and designated engineers review the required data submittals to determine that aviation products and articles and their manufacturing facilities comply with the applicable requirements, and that the products and articles have no unsafe features.

Respondents: Approximately 50,700 aircraft parts designers, manufacturers, and aircraft owners.

Frequency: On occasion.

Estimated Average Burden per Response: 30 minutes.

Estimated Total Annual Burden: 18,785 hours.

Issued in Washington, DC, on January 13, 2021.

Daniel J. Elgas,

Manager, Strategic Policy Management Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2021–01152 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2020–0421]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Anti-Drug Program for Personnel Engaged in Specific Aviation Activities

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 May 19, 2020. The information collected is used to determine program compliance or non-compliance of regulated aviation employers, conduct oversight planning, determine employers required to provide annual Management Information System testing information, and communicate with entities subject to the program regulations.

DATES: Written comments should be submitted by February 22, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Vicky Dunne by email at: *Vicky.Dunne@faa.gov;* phone: 202–267–8442.

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.

OMB Control Number: 2120–0535.

Title: Anti-Drug Program for Personnel Engaged in Specific Aviation Activities.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 19, 2020 (FR 30000). The name of the Information Collection Request was changed from 'Antidrug and Alcohol Misuse Prevention Program' to reflect the current regulation and program title (Drug and Alcohol Testing Program for Personnel Engaged in Specified Aviation Activities). We also removed the word 'Reinstatement' used in the 2018 submission, which was used because the 2014 renewal was not published.

The FAA mandates specified aviation entities to conduct drug and alcohol testing under its regulations, Drug and Alcohol Testing Program (14 CFR part 120), 49 U.S.C. 31306 (Alcohol and controlled substances testing), and the Omnibus Transportation Employee Testing Act of 1991 (the Act). The FAA uses information collected for determining program compliance or non-compliance of regulated aviation employers, oversight planning, determining who must provide annual MIS testing information, and communicating with entities subject to the program regulations.

Respondents: Approximately 6,700 affected entities annually.

Frequency: On occasion.

Estimated Average Burden per Response: 5 minutes.

Estimated Total Annual Burden: 22,902 hours.

Nancy Rodriguez Brown,

Acting Deputy Director, Drug Abatement Division, Aviation Safety.

[FR Doc. 2021–01220 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by the California Department of Transportation (Caltrans).

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final. The actions relate to a proposed highway project, I–10 Pavement Rehabilitation Project in the County of Riverside, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before June 21, 2021. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Antonia Toledo, Senior Environmental Planner, California Department of Transportation-District 8, 464 W 4th Street, MS–820, San Bernardino, CA 92401. Office Hours: 8:00 a.m.–5:00 p.m., Pacific Standard Time, telephone, (909) 501–5741 or email *Antonia.Toledo@dot.ca.gov.* For FHWA: David Tedrick at (916) 498–5024 or email *david.tedrick@dot.gov.*

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the FHWA assigned, and Caltrans assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that Caltrans has taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: Rehabilitation of the existing asphalt concrete (AC) pavement on the Interstate 10 from Post Mile (PM) R60.7 to PM R74.3. Rehabilitation activities include removal and replacement of existing inside and outside shoulders, guardrails, rumble strips, drainage inlets, dikes, and oversized drains. The project also includes widening of bridges and placement, repair, and installation of permanent desert tortoise fence. Grading will be limited to five feet outside the edge of shoulder, except at bridge locations. The project would also include the installation of electric vehicle charging stations at Cactus City Rest Area. The proposed project will also include the installation of a two-lane temporary detour in the existing median. Following construction, the eastbound detour lane would be converted to a general-purpose lane, and the eastbound outside lane would be designated as a truck climbing lane.

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (EA)/Finding of No Significant Impact (FONSI) for the project, approved on September 10, 2020, and in other documents in Caltrans' project records. The Final EA, FONSI and other project records are available by contacting Caltrans at the addresses provided above.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4331(b)(2)
2. Federal Highway Act of 1970, U.S.C. 772
3. Federal Clean Air Act, as amended
4. Clean Water Act of 1977 and 1987
5. Federal Water Pollution Control Act of 1972
6. Safe Drinking Water Act of 1944, as amended
7. Endangered Species Act of 1973
8. Executive Order 11990, Protection of Wetlands
9. Executive Order 13112, Invasive Species
10. Fish and Wildlife Coordination Act of 1934, as amended
11. Migratory Bird Treaty Act
12. Title VI of the Civil Rights Act of 1964, as amended
13. Executive Order 12898, Federal Actions to Address Environmental Justice in Minority and Low-Income Populations
14. National Historic Preservation Act of 1966, as amended

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1)

Issued on: January 13, 2021.

Rodney Whitfield,

Director, Financial Services, Federal Highway Administration, California Division.

[FR Doc. 2021–01143 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

[Docket No. DOT–OST–2021–0005]

Automated Vehicles Comprehensive Plan; Request for Comments

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT).

ACTION: Notice of request for comments (RFC).

SUMMARY: The Office of the Secretary of Transportation (OST) invites public comment on the document, *Automated Vehicles Comprehensive Plan (Comprehensive Plan).* The *Comprehensive Plan* describes how the United States Department of Transportation (U.S. DOT) is working towards the safe and full integration of Automated Driving Systems (ADS) into the surface transportation system. It explains Departmental goals related to ADS, identifies actions being taken to meet those goals, and provides real-world examples of how these Departmental actions relate to emerging ADS applications.

DATES: You should submit your comments within 60 days after the date of publication in the **Federal Register**.

Written Comments: Comments should refer to the docket number above and be submitted by one of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of

the **SUPPLEMENTARY INFORMATION** section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

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 at *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or to the street address listed above. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT:

Please contact us at *automation@dot.gov*.

SUPPLEMENTARY INFORMATION:

The *Comprehensive Plan* document is available at: *www.transportation.gov/av.*

Development of ADS technology is occurring along multiple paths and significant uncertainty still exists around what form ADS applications and vehicles will take in the future. Even with the progress the industry has made over the last decade, no vehicle equipped with an ADS is available for purchase in the U.S., to date. Technologies are still under development, and the deployment of ADS-equipped vehicles—outside of small-scale pilots—remains years away.

The *Comprehensive Plan* addresses clear near-term needs while laying the groundwork for longer-term changes. This plan does not attempt to predict the future forms of ADS-equipped vehicles or the services they may provide. U.S. DOT will periodically review its activities and plans to reflect new technology and industry developments and stakeholder feedback, eliminate unnecessary or redundant initiatives, and align investments with emerging focus areas. Comments received to this Comprehensive Plan will assist the Department in planning and prioritizing its future activities, but comments directed at any particular action contained in the Plan, including the ongoing rulemakings, are outside of the scope of this request and should, instead, be provided in the relevant docket for that action during its open comment period.

Public Participation

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are filed correctly in the docket, please include the docket number of this document in your comments.

Please submit one copy (two copies if submitting by mail or hand delivery) of your comments, including the attachments, to the docket following the instructions given above under **ADDRESSES**. Please note, if you are submitting comments electronically as a PDF (Adobe) file, we ask that the documents submitted be scanned using an Optical Character Recognition (OCR) process, thus allowing the agency to search and copy certain portions of your submissions.

How do I submit confidential business information?

Any submissions containing Confidential Information must be delivered to OST in the following manner:

- Submitted in a sealed envelope marked ''confidential treatment requested'';
- Accompanied by an index listing the document(s) or information that the submitter would like the Department to withhold. The index should include information such as numbers used to identify the relevant document(s) or information, document title and description, and relevant page numbers and/or section numbers within a document; and
- Submitted with a statement explaining the submitter's grounds for objecting to disclosure of the information to the public.

OST also requests that submitters of Confidential Information include a non-confidential version (either redacted or summarized) of those confidential submissions in the public docket. In the event that the submitter cannot provide a non-confidential version of its submission, OST requests that the submitter post a notice in the docket stating that it has provided OST with Confidential Information. Should a submitter fail to docket either a non-confidential version of its submission or to post a notice that Confidential Information has been provided, we will note the receipt of the submission on the docket, with the submitter's organization or name (to the degree permitted by law) and the date of submission.

Will the agency consider late comments?

The U.S. DOT will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent practicable, the agency will also consider comments received after that date.

How can I read the comments submitted by other people?

You may read the comments received at the address given above under COMMENTS. The hours of the docket are indicated above in the same location. You may also see the comments on the internet, identified by the docket number at the heading of this notice, at *http://www.regulations.gov.*

Issued in Washington, DC, on January 13, 2021 under authority delegated at 49 U.S.C. 1.25a.

Thomas Finch Flton,

Deputy Assistant Secretary for Transportation Policy.

[FR Doc. 2021–01115 Filed 1–19–21; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Agency Information Collection Activities; Proposed Renewal; Comment Request; Renewal Without Change of Purchases of Bank Checks and Drafts, Cashier's Checks, Money Orders, and Traveler's Checks

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, FinCEN invites comments on the proposed renewal, without change, of a currently approved information collection found in existing Bank Secrecy Act regulations. Specifically, the regulations require recordkeeping for the issuance or sale of bank checks and drafts, cashier's checks, money orders, and traveler's checks when the issuance or sale involves the use of currency in an amount between $3,000 and $10,000, inclusive. Although no changes are proposed to the information collection itself, this request for comments covers a future expansion of the scope of the annual hourly burden and cost estimate associated with these regulations. This request for comments is made pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments are welcome, and must be received on or before March 22, 2021.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal E-rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Refer to Docket Number FINCEN–2021–0001 and the specific Office of Management and Budget (OMB) control number 1506–0057.
- *Mail:* Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINCEN–2021–0001 and OMB control number 1506–0057.

Please submit comments by one method only. Comments will also be taken into account in FinCEN's review of existing regulations, consistent with Treasury's 2011 Plan for Retrospective Analysis of Existing Rules. All comments submitted in response to this notice will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory Support Section at 1–800–767–2825 or electronically at *frc@fincen.gov.*

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Provisions

The legislative framework generally referred to as the Bank Secrecy Act (BSA) consists of the Currency and Financial Transactions Reporting Act of 1970, as amended by the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act) (Public Law 107–56) and other legislation. The BSA is codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, 31 U.S.C. 5311–5314 and 5316–5332, and notes thereto, with implementing regulations at 31 CFR Chapter X.

The BSA authorizes the Secretary of the Treasury, *inter alia,* to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or counter-intelligence activities to protect against international terrorism, and to implement anti-money laundering (AML) programs and compliance procedures.[1] Regulations implementing the BSA appear at 31 CFR Chapter X. The authority of the Secretary to administer the BSA has been delegated to the Director of FinCEN.[2]

The BSA prohibits financial institutions from issuing any ''bank check, cashier's check, traveler's check, or money order to any individual in connection with a transaction or group of such contemporaneous transactions which involves United States coins or currency (or such other monetary instruments as the Secretary may prescribe) in amounts or denominations of $3,000 or more'' unless the individual either has a verified transaction account with the financial institution or furnishes the financial institution with the information required by regulations and that information is verified and recorded by the financial institution; financial institutions must record the method of account verification or the information required to be furnished.[3] To implement these requirements, FinCEN issued a regulation requiring financial institutions to maintain records of the issuance or sale of bank checks and drafts, cashier's checks, money orders, and traveler's checks.[4] The regulation on its face applies to all financial institutions as defined in 31 CFR 1010.100(t). However, as a practical matter banks and money services businesses (MSBs) are the types of financial institutions most likely to be issuing or selling bank checks and drafts, cashier's checks, money orders, and traveler's checks.

Under 31 CFR 1010.415, financial institutions are required to maintain records of certain information related to the issuance or sale of bank checks and drafts, cashier's checks, money orders, and traveler's checks when the issuance or sale involves currency between $3,000-$10,000, inclusive, to any individual purchaser of one or more of these instruments. Under 31 CFR 1010.415(a)(1)(i), if the purchaser has a deposit account with the financial institution, the financial institution is required to maintain records of: (A) The name of the purchaser; (B) the date of purchase; (C) the type(s) of instrument(s) purchased; (D) the serial number(s) of each of the instrument(s) purchased; and (E) the amount in dollars of each of the instrument(s) purchased. Under 31 CFR 1010.415(a)(1)(ii), the financial institution must also verify that the individual is a deposit accountholder or must verify the individual's identity.[5]

Under 31 CFR 1010.415(a)(2)(i), if the purchaser does not have a deposit account with the financial institution, the financial institution must maintain a record of: (A) The name and address of the purchaser; (B) the social security number of the purchaser, or if the purchaser is an alien and does not have a social security number, the alien identification number; (C) the date of birth of the purchaser; (D) the date of the purchase; (E) the type(s) of instrument(s) purchased; (F) the serial number(s) of the instrument(s) purchased; and (G) the amount in dollars of each of the instrument(s) purchased. Under 31 CFR 1010.415(a)(2)(ii), the financial institution must also verify the purchaser's name and address by examination of a document which is normally acceptable as a means of identification when cashing checks for nondepositors and which contains the name and address of the purchaser, and must record the specific identifying information.

[1] Section 358 of the USA PATRIOT Act added language expanding the scope of the BSA to intelligence or counter-intelligence activities to protect against international terrorism. Section 6101 of the Anti-Money Laundering Act of 2020 (''the AML Act'') added language further expanding the scope of the BSA but did not disturb these longstanding purposes. The AML Act is Division F of Pub. L. 116–283 (January 1, 2021).

[2] Treasury Order 180–01 (re-affirmed Jan. 14, 2020).

[3] 31 U.S.C. 5325.

[4] 31 CFR 1010.415. This regulation was originally published in 1990 as 31 CFR 103.29. *See* Amendment to the Bank Secrecy Act Regulations Relating to Identification Required to Purchase Bank Checks and Drafts, Cashier's Checks, Money Orders and Traveler's Checks, 55 FR 20139 (May 15, 1990). It was modified slightly in 1994. *See* Amendments to the Bank Secrecy Act Regulations Relating to Identification Required to Purchase Bank Checks and Drafts, Cashier's Checks, Money Orders, and Traveler's Checks, 59 FR 52250 (October 17, 1994).

[5] Verification may be either through a signature card or other file or record at the financial institution provided the deposit accountholder's name and address were verified previously and that information was recorded on the signature card or other file or record; or by examination of a document which is normally acceptable as a means of identification when cashing checks for nondepositors and which contains the name and address of the purchaser. If the deposit accountholder's identity has not been verified previously, the financial institution may only verify the deposit accountholder's identity by examination of a document which is normally acceptable within the banking community as a means of identification when cashing checks for nondepositors and which contains the name and address of the purchaser, and must also record the specific identifying information (*e.g.,* State of issuance and number of driver's license).

Under 31 CFR 1010.415(b), financial institutions must treat contemporaneous purchases of the same or different types of instruments totaling $3,000 or more as one purchase. Multiple purchases during one business day totaling $3,000 or more must be treated as one purchase if an individual employee, director, officer, or partner of the financial institution has knowledge that these purchases have occurred.

Under 31 CFR 1010.415(c), financial institutions must retain all required records for a period of five years and make those records available to the Secretary upon request at any time.

II. Paperwork Reduction Act of 1995 (PRA) [6]

Title: Purchases of bank checks and drafts, cashier's checks, money orders, and traveler's checks (31 CFR 1010.415).

OMB Control Number: 1506–0057.

Report Number: Not applicable.

Abstract: FinCEN is issuing this notice to renew the OMB control number for the recordkeeping requirement for the issuance or sale of bank checks and drafts, cashier's checks, money orders, and traveler's checks when the issuance or sale involves the use currency in an amount between $3,000 and 10,000, inclusive.

Affected Public: Businesses or other for-profit institutions, and non-profit institutions.

Type of Review:

- Renewal without change of a currently approved information collection.
- Propose for review and comment a renewal of the portion of the PRA burden that has been subject to notice and comment in the past (the ''traditional annual PRA burden'').
- Propose for review and comment a future expansion of the scope of the PRA burden (the ''future annual PRA burden'').

Frequency: As required.

Estimated Number of Respondents: 15,677 financial institutions.[7]

Estimated Recordkeeping Burden: 117,579 burden hours.

Part 1 of this notice describes the breakdown of the estimated number of financial institutions, by type. Part 2 proposes for review and comment a renewal of the estimate of the traditional annual PRA hourly burden, which includes a scope and methodology similar to the estimate used in the past, with the incorporation of a more robust cost estimate. The scope and methodology used in the past was limited to an estimate of the burden of the overall regulation and did not assign or categorize burden estimates according to the specific steps to create and maintain records for issuances or sales of bank checks and drafts, cashier's checks, money orders, and traveler's checks between $3,000–$10,000, inclusive, to deposit accountholders or other customers. Part 3 of this notice proposes for review and comment a methodology for a future estimate of an annual PRA burden. The estimate would include the PRA hourly burden and cost of creating and maintaining records related to issuances or sales of bank checks and drafts, cashier's checks, money orders, and traveler's checks between $3,000 and 10,000, based on estimates of the volume of these instruments issued or sold, the number of depository accountholder or other customers purchasing these instruments per year, and the average time to verify the identity of depository accountholder and other customers. Finally, Part 4 solicits input from the public about: (a) The accuracy of the traditional annual PRA burden estimate; (b) the more granular calculation needed to establish a future annual PRA burden; (c) the criteria, metrics, and most appropriate questions FinCEN should consider when conducting research to obtain the information on which to base an estimate of the future annual PRA burden; and (d) any other comments about the regulations and the current and proposed future hourly burden and cost estimates of these requirements.

Part 1. Breakdown of the Financial Institutions Covered by This Notice

The breakdown of financial institutions, by type, covered by this notice is reflected in Table 1 below:

TABLE 1—BREAKDOWN OF FINANCIAL INSTITUTIONS COVERED BY THIS NOTICE, BY TYPE OF FINANCIAL INSTITUTION

Type of financial institution	Number of financial institutions
Banks	[8] 11,161
Issuers/Sellers of Money Orders	[9] 4,353
Issuers/Sellers of Traveler's Checks	[10] 163
Total Number of Financial Institutions	15,677

Part 2. Traditional Annual PRA Burden and Cost

The scope of the traditional annual PRA burden and cost estimates in this renewal encompasses all of the recordkeeping requirements for the issuance or sale of bank checks and drafts, cashier's checks, money orders, and traveler's checks between $3,000–$10,000, inclusive. FinCEN continues to estimate the annual hourly burden of creating and maintaining records for the issuance or sale of bank checks and drafts, cashier's checks, money orders, or traveler's checks to individual purchasers when the sale involves currency between $3,000–$10,000, inclusive, at seven and a half hours per covered financial institution, irrespective of the volume of such transactions. This estimate covers the burden of (i) verifying the identity of depository accountholder and other

[6] Public Law 104–13, 44 U.S.C. 3506(c)(2)(A).

[7] Table 1 below sets forth a breakdown of the types of financial institutions covered by this notice.

[8] According to the Federal Deposit Insurance Corporation (FDIC) there were 5,103 FDIC-insured banks as of March 31, 2020. According to the Federal Reserve Board (FRB), there were 203 other entities supervised by the FRB, as of June 16, 2020, that fall within the definition of bank (20 Edge Act institutions, 15 agreement corporations (as defined in 12 CFR 28.2) and 168 foreign banking organizations). According to the National Credit Union Administration there were 5,236 federally regulated credit unions as of December 31, 2019. Approximately 297 state-chartered non-depository trust companies, 228 non-federally insured credit unions, 12 non-federally insured state-chartered banks and savings and loan or building and loan associations, 1 private bank, 52 international financial entities, and 29 international banking entities—all of which are required to implement written AML program as a result of a final rule issued on September 15, 2020 (85 FR 57129)—are also required to keep the records described in this notice.

[9] This number is derived from self-reported information in MSB registrations submitted to FinCEN. FinCEN's MSB registration database available at *https://www.fincen.gov/msb-state-selector.*

[10] *Id.*

customers purchasing bank checks and drafts, cashier's checks, money orders, or traveler's checks when the issuance or sale involves currency between $3,000-$10,000, inclusive, and (ii) creating and maintaining records of certain information for a minimum of five years to be made available to the Secretary upon request.[11]

The estimated burden associated with each portion of the traditional annual PRA estimate is as follows:

TABLE 2—BURDEN ASSOCIATED WITH MAINTAINING RECORDKEEPING REQUIREMENTS FOR ISSUANCE/SALE OF BANK CHECKS AND DRAFTS, CASHIER'S CHECKS, MONEY ORDERS, OR TRAVELER'S CHECKS

Type of financial institution	Number of financial institutions	Time per financial institution	Total burden hours
Banks	11,161	7.5 hour	83,708
Issuers/Sellers of Money Orders	4,353	7.5 hour	32,648
Issuers/Sellers of Travel Checks	163	7.5 hour	1,223
Total Burden Hours			117,579

To calculate the hourly costs of the burden estimate, FinCEN identified two roles and corresponding staff positions involved in verifying documentation and maintaining records for the issuance or sale of bank checks and drafts, cashier's checks, money orders and traveler's checks between $3,000-$10,000, inclusive: (i) Direct supervision (reviewing operational-level work and cross-checking all or a sample of the work product against supporting documentation) and (ii) clerical work (engaging in verification and recordkeeping).

FinCEN calculated the fully-loaded hourly wage for each of these two roles by using the median wage estimated by the U.S. Bureau of Labor Statistics (BLS),[12] and computing an additional benefits cost as follows:

TABLE 3—FULLY-LOADED HOURLY WAGE BY ROLE AND BLS JOB POSITION FOR ALL FINANCIAL INSTITUTIONS COVERED BY THIS NOTICE

Role	BLS-Code	BLS-Name	Median hourly wage	Benefit factor	Fully-loaded hourly wage
Direct supervision	13–1041	Compliance Officer	$33.20	1.50	$49.80
Clerical work (research, review, and recordkeeping).	43–3099	Financial Clerk	20.40	1.50	30.60

FinCEN estimates that, *in general and on average,*[13] each role would spend different amounts of time on each portion of the traditional annual PRA burden. For verifying the identity of the purchaser and maintaining the recordkeeping requirement, the estimated cost of the hourly burden is $33.00, per the calculations in Table 4 below:

TABLE 4—WEIGHTED AVERAGE HOURLY COST OF MAINTAINING RECORDKEEPING REQUIREMENTS

Direct supervision		Clerical work		Weighted average hourly cost
% time	Hourly cost	% time	Hourly cost	
10%	$4.98	90%	$27.54	* $33.00

(*) $32.52 rounded to $33.00.

The total estimated cost of the traditional annual PRA burden is $3,880,107 as reflected in Table 5 below:

[11] Some of this estimated burden, particularly with respect to depository customers of a bank, may duplicate burden estimated in connection with a bank's compliance with its ordinary customer identification program obligations under 31 CFR 1020.220. FinCEN plans to take this other burden into account in future estimates.

[12] The U.S. Bureau of Labor Statistics, Occupational Employment Statistics-National, May 2019, available at *https://www.bls.gov/oes/tables.htm.* The most recent data from the BLS corresponds to May 2019. For the benefits component of total compensation, see U.S. Bureau of Labor Statistics, Employer's Cost per Employee Compensation as of December 2019, available at *https://www.bls.gov/news.release/ecec.nr0.htm.* The ratio between benefits and wages for financial activities is $15.95 (hourly benefits)/$32.05 (hourly wages) = 0.50. The benefit factor is 1 plus the benefit/wages ratio, or 1.50. Multiplying each hourly wage by the benefit factor produces the fully-loaded hourly wage per position.

[13] By ''in general,'' FinCEN means without regard to outliers. By ''on average,'' FinCEN means the mean of the distribution of each subset of the population.

[14] See Table 2.

[15] See Table 4.

TABLE 5—TOTAL COST OF TRADITIONAL ANNUAL PRA BURDEN

Steps	Hourly burden	Hourly cost	Total cost
Verifying and maintaining records (divided between the roles listed in Table 4)	[14] 117,579	[15] $33	$3,880,107
Total Cost			$3,880,107

Part 3. Future Annual PRA Burden

In the future, FinCEN intends to be more granular in estimating the annual PRA burden, by including the estimated hourly burden and cost behind the individual steps required to maintain records for the issuance or sale of bank checks and drafts, cashier's checks, money orders, and traveler's checks between $3,000-$10,000, inclusive, to depository accountholder and other customers. In particular, FinCEN seeks to include in this calculation the number of these instruments issued or sold per financial institution annually, the number of depository accountholder and other customers purchasing these instruments per year, and the average time per financial institution to verify the identity of depository accountholder and other customers. FinCEN does not have the information to estimate the annual number of instruments issued or sold to depository accountholder and other customers that trigger the recordkeeping requirements being renewed in this notice. For that reason, FinCEN is relying on estimates used in prior renewals of this OMB control number and the applicable regulations. FinCEN further recognizes that after receiving public comments as a result of this notice, future traditional annual PRA hourly burden and cost estimates may vary significantly from those contained in this document. FinCEN intends to conduct more granular studies of the actions included in the proposed scope of the annual PRA burden in the near future, to arrive at more accurate estimates of net BSA hourly burden and cost.[16] The data obtained in these studies also may result in a significant change from the estimated traditional annual PRA burden.

Estimated Recordkeeping Burden: The average estimated annual PRA burden, measured in hours per respondent, is seven and a half hours.

Estimated Number of Respondents: 15,677, as set out in Table 1.

Estimated Total Annual Recordkeeping Burden: The estimated total annual PRA burden is 117,579 hours, as set out in Table 2.

Estimated Total Annual Recordkeeping Cost: The estimated total annual PRA cost is $3,880,107, as set out in Table 5.

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. Records required to be retained under the BSA must be retained for five years.

Part 4. Request for Comments

(a) Specific Request for Comments on the Traditional Annual PRA Hourly Burden and Cost

FinCEN invites comments on any aspect of the traditional annual PRA burden, as set out in Part 2 of this notice. In particular, FinCEN seeks comments on the adequacy of: (i) FinCEN's assumptions underlying its burden estimate; (ii) the estimated number of hours required by each portion of the burden; and (iii) the organizational roles of the financial institution engaged in each portion of the burden, the roles' estimated hourly remuneration, and the estimated proportion of time spent by each role on the requirements. FinCEN encourages commenters to include any publicly available sources for alternative estimates or methodologies.

(b) Specific Request for Comments on the Proposed Criteria for Determining the Scope of a Future Annual PRA Hourly Burden and Cost Estimate

FinCEN invites comments on any aspect of the criteria for an estimate of the future annual PRA burden, as set out in Part 3 of this notice.

(c) Specific Request for Comments on the Appropriate Criteria, Methodology, and Questionnaire Required To Obtain Information to More Precisely Estimate the Future Annual PRA Hourly Burden and Cost

FinCEN invites comments on the most appropriate and comprehensive means to question financial institutions about the annual hourly burden and cost attributable solely to creating and maintaining records for the issuance or sale of bank checks and drafts, cashier's checks, money orders and traveler's checks between $3,000-$10,000, inclusive (*i.e.,* the hourly burden and cost of complying with the recordkeeping requirements imposed exclusively by the BSA; the volume of these instruments issued or sold; the number of depository accountholder and other customers purchasing these instruments per year; and the average time to verify the identity of depository accountholder and other customers).

The future annual PRA hourly burden and cost estimate of the recordkeeping necessary to comply with maintaining records for issuance or sale of bank checks and drafts, cashier's checks, money orders and traveler's checks between $3,000-$10,000, inclusive, to any individual purchaser must take into consideration only the effort involved in obtaining those data elements that are used exclusively for complying with requirements under 31 CFR 1010.415. FinCEN seeks comments from the public regarding any questions we should consider posing in future notices, in addition to the specific questions for comment outlined directly below. Also, due to the evident difficulty involved in estimating the volume of bank checks and drafts, cashier's checks, money orders and traveler's checks issued or sold that involve currency between $3,000-$10,000, inclusive, the annual number of depository accountholder and other customers purchasing these instruments, and the average time to verify the identity of depository accountholder and other customers, FinCEN welcomes any suggestions as to how to derive these estimates by using publicly available financial information.

[16] Net hourly burden and cost are the burden and cost a financial institution incurs to comply with requirements that are unique to the BSA, and that do not support any other business purpose or regulatory obligation of the financial institution. Burden for purposes of the PRA does not include the time and financial resources needed to comply with an information collection, if the time and resources are for things a business (or other person) does in the ordinary course of its activities if the agency demonstrates that the reporting activities needed to comply are usual and customary. 5 CFR 1320.3(b)(2).

(d) Specific Questions for Comment Associated With Recordkeeping Requirements for Issuance or Sale of Bank Checks and Drafts, Cashier's Checks, Money Orders and Traveler's Checks That Involve Currency Between $3,000-$10,000, Inclusive, by Depository Accountholder and Other Customers

- Annually, on average, how often does your financial institution issue or sell bank checks and drafts, cashier's checks, money orders, or traveler's checks that involve currency between $3,000-$10,000, inclusive?
- On average, how long does it take your institution to create a record for the issuance or sale of bank checks and drafts, cashier's checks, money orders, or traveler's checks that involve currency between $3,000-$10,000, inclusive?
- On average, what is the cost to maintain records of the issuance or sale of bank checks and drafts, cashier's checks, money orders, or traveler's checks that involve currency between $3,000-$10,000, inclusive?
- On average, what is the amount of time and cost to verify and maintain a record for depository customers that purchase bank checks and drafts, cashier's checks, money orders, or traveler's checks that involve currency between $3,000-$10,000, inclusive, for a period of five years?
- On average, what is the amount of time and cost to verify and maintain a record for customers who do not hold depository accounts that purchase bank checks and drafts, cashier's checks, money orders, or traveler's checks that involve currency between $3,000-$10,000, inclusive, for a period of five years?

(e) General 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: (i) 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; (ii) the accuracy of the agency's estimate of the burden of the collection of information; (iii) ways to enhance the quality, utility, and clarity of the information to be collected; (iv) 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 (v) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Kenneth A. Blanco,

Director, Financial Crimes Enforcement Network.

[FR Doc. 2021–01187 Filed 1–19–21; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more individuals that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these individuals blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2480; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; or Assistant Director for Regulatory Affairs, tel.: 202–622–4855.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On December 30, 2020 OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following individuals are blocked under the relevant sanctions authority listed below.

Individuals

1. CORNIELLES RUIZ, Lorena Carolina, Coche Miguel Otero Silva Vereda 80, Casa 3, Caracas, Venezuela; DOB 03 Jul 1988; nationality Venezuela; Gender Female; Cedula No. V–18967792 (Venezuela) (individual) [VENEZUELA]. Designated pursuant to section 1(a)(ii)(C) of E.O. 13692, as amended by E.O. 13857, for being a current or former official of the Government of Venezuela.

2. TORRES ESPINOZA, Ramon Antonio, Castillejo Principal del Portico 0301, Guatire, Venezuela; DOB 13 Sep 1968; nationality Venezuela; Gender Male; Cedula No. V–6303894 (Venezuela) (individual) [VENEZUELA]. Designated pursuant to section 1(a)(ii)(C) of E.O. 13692, as amended by E.O. 13857, for being a current or former official of the Government of Venezuela.

Dated: December 30, 2020.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control, Department of the Treasury.

[FR Doc. 2020–29153 Filed 1–19–21; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), 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 information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Diesel Fuel and Kerosene Excise Tax; Dye Injection.

DATES: Written comments should be received on or before March 22, 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 regulations should be directed to Sara Covington, at (737) 800–6149 or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Diesel Fuel and Kerosene Excise Tax; Dye Injection.

OMB Number: 1545–1418.

Regulation Project Number: T.D. 9199.

Abstract: In order for diesel fuel and kerosene that is used in a nontaxable

use to be exempt from tax under section 4082(a), it must be indelibly dyed by use of a mechanical dye injection system that satisfies the requirements in the regulations. These regulations affect certain enterers, refiners, terminal operators, and throughputters.

Current Actions: There is no changes in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 200.

Estimated Time per Response: 7 hrs.

Estimated Total Burden Hours: 1,400.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained 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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 13, 2021.

Sara L. Covington,

IRS Tax Analyst.

[FR Doc. 2021–01168 Filed 1–19–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1099–A

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 information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 1099–A, Acquisition or Abandonment of Secured Property.

DATES: Written comments should be received on or before March 22, 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. Requests for additional information or copies of the forms and instructions should be directed to Sara Covington, at (737) 800–6149, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Sara.L.Covington@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Acquisition or Abandonment of Secured Property.

OMB Number: 1545–0877.

Form Number: 1099–A.

Abstract: Form 1099–A is used by persons who lend money in connection with a trade or business, and who acquire an interest in the property that is security for the loan or who have reason to know that the property has been abandoned, to report the acquisition or abandonment.

Current Actions: There are no changes being made to the form approved under this collection. However, changes to the estimated number of filers (563,000 to 466,000), will result in a total burden decrease of 15520 (90080 minus 74560).

Type of Review: Revision of a current OMB approval.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Responses: 466,000.

Estimated Time per Response: 9 min.

Estimated Total Annual Burden Hours: 74,560.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained 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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 13, 2021.

Sara L. Covington,

IRS Tax Analyst.

[FR Doc. 2021–01169 Filed 1–19–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Multiemployer Pension Plan Application To Reduce Benefits

AGENCY: Department of the Treasury.

ACTION: Notice of availability; Request for comments.

SUMMARY: The Board of Trustees of the American Federation of Musicians & Employers Pension Fund, a multiemployer pension plan, has submitted an application to reduce benefits under the plan in accordance with the Multiemployer Pension Reform Act of 2014 (MPRA). The purpose of this notice is to announce that the application submitted by the Board of Trustees of the American Federation of Musicians & Employers Pension Fund has been published on the website of the Department of the Treasury (Treasury), and to request public comments on the application from

interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the American Federation of Musicians & Employers Pension Fund.

DATES: Comments must be received by March 8, 2021.

ADDRESSES: You may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov,* in accordance with the instructions on that site. Commenters are strongly encouraged to submit public comments electronically. Treasury expects to have limited personnel available to process public comments that are submitted on paper through mail. Until further notice, any comments submitted on paper will be considered to the extent practicable.

Comments may be mailed to the Department of the Treasury, MPRA Office, 1500 Pennsylvania Avenue NW, Room 1224, Washington, DC 20220, Attn: Danielle Norris. Comments sent via facsimile, telephone, or email will not be accepted.

Additional Instructions. All comments received, including attachments and other supporting materials, will be made available to the public. Do not include any personally identifiable information (such as your Social Security number, name, address, or other contact information) or any other information in your comment or supporting materials that you do not want publicly disclosed. Treasury will make comments available for public inspection and copying on *www.regulations.gov* or upon request. Comments posted on the internet can be retrieved by most internet search engines.

FOR FURTHER INFORMATION CONTACT: For information regarding the application from the American Federation of Musicians & Employers Pension Fund, please contact Treasury at (202) 622–1534 (not a toll-free number).

SUPPLEMENTARY INFORMATION: MPRA amended the Internal Revenue Code to permit a multiemployer plan that is projected to have insufficient funds to reduce pension benefits payable to participants and beneficiaries if certain conditions are satisfied. In order to reduce benefits, the plan sponsor is required to submit an application to the Secretary of the Treasury, which must be approved or denied in consultation with the Pension Benefit Guaranty Corporation (PBGC) and the Department of Labor.

On December 30, 2020, the American Federation of Musicians & Employers Pension Fund's Board of Trustees submitted an application for approval to reduce benefits under the plan. As required by MPRA, that application has been published on Treasury's website at *https://home.treasury.gov/services/the-multiemployer-pension-reform-act-of-2014/applications-for-benefit-suspension.* Treasury is publishing this notice in the **Federal Register**, in consultation with PBGC and the Department of Labor, to solicit public comments on all aspects of the American Federation of Musicians & Employers Pension Fund's application.

Comments are requested from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the American Federation of Musicians & Employers Pension Fund. Consideration will be given to any comments that are timely received by Treasury.

David Kautter,

Assistant Secretary for Tax Policy.

[FR Doc. 2021–01121 Filed 1–19–21; 8:45 am]

BILLING CODE 4810–25–P

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Part II

Department of Energy

Federal Energy Regulatory Commission

18 CFR Part 35

Managing Transmission Line Ratings; Proposed Rule

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM20–16–000]

Managing Transmission Line Ratings

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) proposes to reform both the *pro forma* Open Access Transmission Tariff and the Commission's regulations under the Federal Power Act to improve the accuracy and transparency of transmission line ratings. Specifically, the proposal would require: Transmission providers to implement ambient-adjusted ratings on the transmission lines over which they provide transmission service; Regional Transmission Organizations (RTOs) and Independent System Operators (ISOs) to establish and implement the systems and procedures necessary to allow transmission owners to electronically update transmission line ratings at least hourly; and transmission owners to share transmission line ratings and transmission line rating methodologies with their respective transmission provider(s) and, in RTOs/ISOs, with their respective market monitor(s).

DATES: Comments are due March 22, 2021.

ADDRESSES: Comments, identified by docket number RM20–16, may be filed electronically at *http://www.ferc.gov* in acceptable native applications and print-to-PDF, but not in scanned or picture format. For those unable to file electronically, comments may be filed by mail or hand-delivery to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426. The Comment Procedures Section of this document contains more detailed filing procedures.

FOR FURTHER INFORMATION CONTACT:

Dillon Kolkmann (Technical Information), Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8650, *Dillon.kolkmann@ferc.gov*.

Mark Armamentos (Technical Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8103, *Mark.armamentos@ferc.gov*.

Ryan Stroschein (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8099, *Ryan.Stroschein@ferc.gov*.

SUPPLEMENTARY INFORMATION:

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I. Introduction

1. In this Notice of Proposed Rulemaking (NOPR), the Federal Energy Regulatory Commission (Commission) proposes, pursuant to section 206 of the Federal Power Act (FPA),[1] to reform the *pro forma* Open Access Transmission Tariff (OATT) and the Commission's regulations to improve the accuracy and transparency of transmission line ratings used by transmission providers. Transmission line ratings represent the maximum transfer capability of each transmission line. As explained below, transmission line ratings and the rules by which they are established are practices that directly affect the cost of wholesale energy, capacity and ancillary services, as well as the cost of delivering wholesale energy to transmission customers. Inaccurate transmission line ratings may result in Commission-

[1] 16 U.S.C. 824e.

jurisdictional rates that are unjust and unreasonable.

2. Transmission line ratings often are calculated based on assumptions about ambient conditions that do not accurately reflect the near-term transfer capability of the system.[2] For example, transmission line ratings currently based on seasonal or static assumptions may indicate less transmission system transfer capability than the transmission system can actually provide, leading to restricted flows and increased congestion costs. Alternatively, transmission line ratings currently based on seasonal or static assumptions may overstate the near-term transfer capability of the system, creating potential reliability and safety problems. In either case, the current use of seasonal and static assumptions results in transmission line ratings that do not accurately represent the transfer capability of the transmission system.

3. To address these issues with respect to shorter-term requests for transmission service, we propose two requirements for greater use of ambient-adjusted line ratings (AARs),[3] which are transmission line ratings that incorporate near-term forecasted ambient air temperatures. First, we propose to require that transmission providers use AARs as the basis for evaluation of transmission service requests that will end within ten days of the request. Second, we propose to require that transmission providers use AARs as the basis for determination of the necessity of certain curtailment, interruption, or redispatch of transmission service that is anticipated to occur within those ten days.

4. To address these issues with respect to longer-term requests for transmission service, we propose to require that transmission providers use seasonal line ratings as the basis for evaluation of such requests. We also propose to require that transmission providers use seasonal line ratings as the basis for the determination of the necessity of curtailment, interruption, or redispatch that is anticipated to occur more than ten days in the future.[4]

5. Moreover, in certain situations, use of dynamic line ratings (DLRs) presents opportunities for transmission line ratings that may be more accurate than those established with AARs.[5] DLRs are based not only on forecasted ambient air temperature, but also on other weather conditions such as wind, cloud cover, solar irradiance intensity, precipitation, and/or on transmission line conditions such as tension or sag. One factor that may contribute to the limited deployment of DLRs by transmission owners is that the regional transmission organizations (RTO) and independent system operators (ISO) that operate the transmission system and oversee organized wholesale electric markets may not be able to automatically incorporate frequently updated transmission line ratings such as DLRs into their operating and market models. To address this issue, we propose to require RTOs/ISOs to establish and implement the systems and procedures necessary to allow transmission owners to electronically update transmission line ratings on at least an hourly basis.

6. The proposed reforms noted above are intended to improve the accuracy of transmission line ratings used during normal (pre-contingency) operations.[6] We also seek comment on whether to require transmission providers to implement unique emergency ratings[7] that would be used during post-contingency operations.

7. Finally, we propose to require transmission owners to share transmission line ratings and methodologies with their transmission provider(s) and, in regions served by an RTO/ISO, also with the market monitor(s) of that RTO/ISO. We also seek comment on whether transmission line ratings and transmission line rating methodologies should be shared with other transmission providers, upon request.

8. We seek comment on these proposed reforms by 60 days after publication of this NOPR in the **Federal Register**.

II. Background

A. Order Nos. 888 and 889

9. In Order No. 888, the Commission required public utilities to unbundle their generation and transmission services and file open access non-discriminatory transmission tariffs (OATTs) to allow third parties equal access to their transmission system.[8] In Order No. 889, issued at the same time as Order No. 888, the Commission established part 37 of the Commission's regulations that require each public utility that owns, controls, or operates facilities used for the transmission of electric energy in interstate commerce to create or participate in an Open Access Same-time Information System (OASIS) that would provide transmission customers the same access to information to enable them to obtain open access non-discriminatory transmission service.[9] Among the new requirements, public utilities were directed to calculate their available transfer capability (ATC) as a way to give potential third party transmission customers information on transmission service availability. In Order No. 888, the Commission used the term ''Available Transmission Capability'' to describe the amount of additional

[2] Federal Energy Regulatory Commission, Staff Paper, *Managing Transmission Line Ratings,* Docket No. AD19–15–000 (Aug. 2019) (Commission Staff Paper), *https://www.ferc.gov/sites/default/files/2020-05/tran-line-ratings.pdf.*

[3] As discussed below, we propose to define an ambient-adjusted line rating, or AAR, as a transmission line rating that: (1) Applies to a time period of not greater than one hour; (2) reflects an up-to-date forecast of ambient air temperature across the time period to which the rating applies; and (3) is calculated at least each hour, if not more frequently. Proposed 18 CFR 35.28(b)(10).

[4] The use of seasonal transmission line ratings for long-term requests for transmission service and as the basis for the determination of curtailment, interruption, or redispatch is currently standard practice. However, as detailed later, the Commission proposes changes to seasonal transmission line rating implementation.

[5] As discussed below, the Commission proposes to define a dynamic line rating, or DLR, as a transmission line rating that: (1) Applies to a time period of not greater than one hour; (2) reflects up-to-date forecasts of inputs such as (but not limited to) ambient air temperature, wind, solar irradiance intensity, transmission line tension, or transmission line sag; and (3) is calculated at least each hour, if not more frequently. Proposed 18 CFR 35.28(b)(11).

[6] The NERC Glossary defines ''normal rating'' as: ''[t]he rating as defined by the equipment owner that specifies the level of electrical loading . . . that a system, facility, or element can support or withstand through the daily demand cycles without loss of equipment life.'' NERC, *Glossary of Terms Used in NERC Reliability Standards* (June 2, 2020), *https://www.nerc.com/pa/Stand/Glossary%20of%20Terms/Glossary_of_Terms.pdf.*

[7] The NERC Glossary defines ''emergency rating'' as: ''T[t]he rating as defined by the equipment owner that specifies the level of electrical loading or output . . . that a system, facility, or element can support, produce, or withstand for a finite period. The rating assumes acceptable loss of equipment life or other physical or safety limitations for the equipment involved.'' *Id.* For purposes of this NOPR, the phrase ''unique emergency ratings'' describes an emergency rating that is a different value from a facility's normal rating. Typically, the emergency rating would be a higher value than the normal rating unless there is specific constraint that prohibits a higher emergency rating.

[8] *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, 61 FR 21,540 (May 10, 1996), FERC Stats. & Regs. ¶ 31,036 (1996) (cross-referenced at 77 FERC ¶ 61,080), *order on reh'g,* Order No. 888–A, 62 FR 12,274 (Mar. 14, 1997), FERC Stats. & Regs. ¶ 31,048 (cross-referenced at 78 FERC ¶ 61,220), *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g,* Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group* v. *FERC,* 225 F.3d 667 (D.C. Cir. 2000), *aff'd sub nom. New York* v. *FERC,* 535 U.S. 1 (2002).

[9] *Open Access Same-Time Information System and Standards of Conduct,* Order No. 889, FERC Stats. & Regs. ¶ 31,035 (1996) (cross-referenced at 75 FERC ¶ 61,078), *order on reh'g,* Order No. 889–A, FERC Stats & Regs. ¶ 31,049 (cross-referenced at 78 FERC ¶ 61,221), *reh'g denied,* Order No. 889–B, 81 FERC ¶ 61,253 (1997).

capability available in the transmission network to accommodate additional requests for transmission services. The Commission in Order No. 890 adopted the current term ATC in the *pro forma* OATT to be consistent with the term generally accepted throughout the industry.[10] For the purposes of this proceeding, ATC will also refer to available flowgate capability.[11]

10. In Order No. 889, the Commission required that ATC and Total Transfer Capability (TTC) be calculated based on a methodology described in the Transmission Provider's tariff, and that those calculations be based on current industry practices, standards and criteria.[12] The Commission also made further changes to its regulations as part of Order No. 889 to ensure accuracy of the data posted on OASIS.[13] For example, the Commission required that entities that calculate ATC or TTC on constrained posted paths make publicly available the underlying data and methodologies.[14]

11. At the time, no formal methodologies existed to calculate ATC, and the Commission encouraged the industry to develop a consistent transmission line rating methodology.[15] While Order No. 888 required transmission providers to include descriptions of ATC methodologies in their tariffs,[16] Order No. 889 required public utilities to post ATC values and certain related information to their OASIS.[17]

B. Order No. 890

12. In Order No. 890, the Commission addressed and remedied opportunities for undue discrimination under the regulations and the *pro forma* OATT adopted in Order Nos. 888 and 889.[18] Among other things, the Commission found that the lack of ATC consistency and transparency throughout the industry allowed for undue discrimination, with transmission providers able to favor themselves and their affiliates over third parties in allocating ATC.[19] The Commission also stated that ATC inconsistencies made it difficult for parties to detect discrimination.[20] In response to these concerns, the Commission directed public utilities, working through North American Electric Reliability Corporation (NERC) Reliability Standards and North American Energy Standards Board (NAESB) business practices development processes, to produce workable solutions to complex and contentious issues surrounding improving the consistency and transparency of ATC calculations.[21] This included the development of standard ATC calculation methodologies, definitions for the components in the ATC equation, and standards for data inputs, assumptions, and information exchanges to be applied across the industry.[22]

C. ATC-Related Reliability Standards, Business Practices, and Commission Regulations

13. The Commission in Order No. 729,[23] pursuant to section 215 of the FPA,[24] approved six Reliability Standards,[25] subsequently referred to as the ''MOD A Reliability Standards'' by NERC, and stated the Commission believes that these Reliability Standards address the potential for undue discrimination by requiring industry-wide transparency and increased consistency regarding all components of the ATC calculation methodology and certain definitions, data, and modeling assumptions.[26]

14. On July 16, 2020, the Commission issued a NOPR[27] proposing to amend its regulations because of the importance of the ATC calculation and as a result of the proposed retirement of NERC's MOD A standards. The Commission proposed to revise its regulations to establish the general criteria transmission owners must use in calculating ATC.[28] The Commission also proposed to adopt the NAESB wholesale electric quadrant

[10] The NERC Glossary defines ATC as: ''A measure of the transfer capability remaining in the physical transmission network for further commercial activity over and above already committed uses. It is defined as Total Transfer Capability (TTC) less Existing Transmission Commitments (including retail customer service), less a Capacity Benefit Margin, less a Transmission Reliability Margin, plus Postbacks, plus counterflows.'' NERC, *Glossary of Terms Used in NERC Reliability Standards* (June 2, 2020), *https://www.nerc.com/pa/Stand/Glossary%20of%20Terms/Glossary_of_Terms.pdf.*

[11] Available flowgate capability is defined in the NERC Glossary as: ''A measure of the flow capability remaining on a Flowgate for further commercial activity over and above already committed uses. It is defined as [total flowgate capability] TFC less Existing Transmission Commitments (ETC), less a Capacity Benefit Margin, less a Transmission Reliability Margin, plus Postbacks, and plus counterflows.'' NERC, *Glossary of Terms Used in NERC Reliability Standards* (June 2, 2020), *https://www.nerc.com/pa/Stand/Glossary%20of%20Terms/Glossary_of_Terms.pdf.*

[12] Order No. 889, FERC Stats. & Regs. ¶ 31,035 at ¶ 31,607.

[13] *Id.* ¶ 31,608.

[14] *See* 18 CFR 37.6 (b)(2)(ii) (stating that, on request, the responsible party must make all data used to calculate ATC, TTC, CBM, and TRM for any constrained posted paths publicly available (including the limiting element(s) and the cause of the limit (*e.g.,* thermal, voltage, stability), as well as load forecast assumptions) in electronic form within one week of the posting.).

[15] Order No. 889, FERC Stats. & Regs. ¶ 31,035 at ¶ 31,607.

[16] The Commission requires ''all public utilities that own, control or operate facilities used for transmitting electric energy in interstate commerce [t]o file open access non-discriminatory transmission tariffs that contain minimum terms and conditions of non-discriminatory service.'' Order No. 888, FERC Stats. & Regs. ¶ 31,036 at 31,635. Public utilities also are ''required to make section 206 compliance filings to meet . . . *pro forma* tariff non-price minimum terms and conditions of non-discriminatory transmission. *Id.* at 31,636. The *pro forma* OATT's ''Methodology To Assess Available Transmission Capability'' is proscribed in Attachment C of the Order. *Id.* at 31,930.

[17] Order No. 889, FERC Stats. & Regs. ¶ 31,035 at 31,587.

[18] *Preventing Undue Discrimination and Preference in Transmission Service,* Order No. 890, 118 FERC ¶ 61,119, *order on reh'g,* Order No. 890–A, 121 FERC ¶ 61,297 (2007), *order on reh'g and clarification,* Order No. 890–B, 123 FERC ¶ 61,299 (2008), *order on reh'g,* Order No. 890–C, 126 FERC ¶ 61,228 (2009), *order on clarification,* Order No. 890–D, 129 FERC ¶ 61,126 (2009).

[19] Order No. 890, 118 FERC ¶ 61,119 at P 83.

[20] *Id.* P 21. In regions with RTOs/ISOs, the RTO/ISO in most cases calculated the ATC for paths within their territory.

[21] *Id.* P 196.

[22] *Id.* P 207.

[23] *Mandatory Reliability Standards for the Calculation of Available Transfer Capability, Capacity Benefit Margins, Transmission Reliability Margins, Total Transfer Capability, and Existing Transmission Commitments and Mandatory Reliability Standards for the Bulk-Power System,* Order No. 729, 129 FERC ¶ 61,155, at P 13 (2009), *order on clarification,* Order No. 729–A, 131 FERC ¶ 61,109, *order on reh'g,* Order No. 729–B, 132 FERC ¶ 61,027 (2010).

[24] 16 U.S.C. 824o.

[25] The Reliability Standards were: MOD–001–1—Available Transmission System Capability; MOD–004–1—Capacity Benefit Margin; MOD–008–1—TRM Calculation Methodology; MOD–028–1—Area Interchange Methodology; MOD–029–1—Rated System Path Methodology; and MOD–030–1—Flowgate Methodology.

[26] Order No. 729, 129 FERC ¶ 61,155 at P 2.

[27] *Standards for Business Practices and Communication Protocols for Public Utilities,* Notice of Proposed Rulemaking, 172 FERC ¶ 61,047, at P 49 (2020).

[28] *Id.* P 50 (proposing new language, shown in italics, for the Commission's regulations governing the calculation of ATC and TTC in 18 CFR 37.6(b)(2)(i)), that calculation methods, availability of information, and requests. Information used to calculate any posting of ATC and TTC must be dated and time-stamped and all calculations shall be performed according to consistently applied methodologies referenced in the Transmission Provider's transmission tariff and shall be based on Commission-approved Reliability Standards, *business practice and electronic communication standards, and related implementation documents,* as well as current industry practices, standards and criteria. *Transmission Providers shall calculate ATC and TTC in coordination with and consistent with capability and usage on neighboring systems, calculate system capability using factors derived from operations and planning data for the time frame for which data are being posted (including anticipated outages), and update ATC and TTC calculations as inputs change. Such calculations shall be conducted in a manner that is transparent, consistent, and not unduly discriminatory or preferential.*)

(WEQ) Business Practice Standards that include commercially relevant requirements from the existing MOD A Reliability Standards as they appeared generally consistent with those criteria.[29] On September 17, 2020, the Commission, in Order No. 873, approved the retirement of 18 Reliability Standard requirements identified by NERC, the Commission-certified Electric Reliability Organization.[30] The Commission also remanded proposed Reliability Standard FAC–008–4 for further consideration by NERC and took no action on the proposed retirement of 56 MOD A Reliability Standard requirements.[31]

D. Reliability Standard FAC–008–3 (Facility Ratings)

15. The requirements of Reliability Standard FAC–008–3 (Facility Ratings) [32] are generally as follows:

- Requirement number 1 (''R1'') requires a generator owner to provide documentation for determining the facility ratings of its generator facility(ies).
- Requirement R2 requires each generator owner to have a documented methodology for determining facility ratings of its equipment connected between the location specified in Requirement R1 and the point of interconnection with the transmission owner.
- Requirement R3 requires each transmission owner to have a documented methodology for determining facility ratings (facility ratings methodology) of its facilities.[33]
- Requirement R6 requires that the generator owner and transmission owner also establish facility ratings for their facilities that are consistent with the associated facility rating methodology or documentation for determining their facility ratings.
- Requirement R7 provides that facility ratings must be provided to other entities as specified in the requirements.
- Requirement R8 requires the identification and documentation of the limiting component for all facilities and the increase in rating if that component were no longer the limiting component (*i.e.,* the rating for the second most limiting component) for facilities associated with an Interconnection reliability operating limit, a limitation of TTC, an impediment to generator deliverability, or an impediment to service to a major load center.
- Requirement R8 also requires entities to provide information to requesting entities regarding their facilities. Requirement R8, Part 8.1 requires an entity to provide the identity of the most limiting equipment of a facility as well as the facility rating to requesting entities. Requirement R8, Part 8.2 requires an entity to provide the identity of the next most limiting equipment of a facility as well as the thermal rating of that equipment.

E. Commission Staff Paper and September 2019 Technical Conference

16. In August 2019, the Commission issued the Commission Staff Paper, ''Managing Transmission Line Ratings'' drawing on Commission staff outreach conducted in spring 2019 with RTOs/ISOs, transmission owners, and trade groups, as well as staff participation in a November 2017 Idaho National Laboratory workshop. The report included background on common transmission line rating approaches, current practices in RTOs/ISOs, a review of pilot projects, and a discussion of potential improvements.[34]

17. On September 10 and 11, 2019, Commission staff convened a technical conference (September 2019 Technical Conference) to discuss what transmission line ratings and related practices might constitute best practices, and what, if any, Commission action in these areas might be appropriate. In particular, the September 2019 Technical Conference covered issues such as: (1) Common transmission line rating methodologies; (2) AAR and DLR implementation benefits and challenges; (3) the ability of RTOs/ISOs to accept and use DLRs; and (4) the transparency of transmission line rating methodologies.[35] Participants at the September 2019 Technical Conference included utilities (some of which implement both AARs and DLRs), technology vendors, RTO/ISO market monitors, and organizations representing customers.

18. In October 2019, the Commission requested comments on questions that arose from the September 2019 Technical Conference.[36] In response, commenters addressed issues related to AARs and DLRs, emergency ratings, and transparency, as discussed below.[37]

III. Technical Background

A. Transmission Line Rating Fundamentals

19. Transmission line ratings represent the maximum transfer capability of each transmission line. A variety of entities use them in their reliability models, including transmission providers, reliability coordinators, transmission system operators, planning authorities, transmission owners, and transmission planners. Transmission line ratings in reliability models are used to determine operating limits and can affect transmission system operator action, such as curtailment, interruption, or redispatch decisions. As market operators, RTOs/ISOs use transmission line ratings in their market models to establish commitment and dispatch. In these market models, transmission line ratings affect congestion, and, thereby, affect the prices of energy, operating reserves, and other ancillary services. Transmission line ratings are based on the most limiting of three types of transmission line ratings/limits: Thermal ratings, voltage limits, and stability limits. Thermal ratings can change with ambient conditions; however, voltage and stability limits are fixed values that limit the power flow on a transmission line from exceeding the point above which there is an unacceptable risk of a voltage or stability problem. Transmission line ratings are dictated by the most limiting element across the entire transmission facility, which includes the overhead conductors and the associated equipment necessary for the transfer or movement of electric energy across a transmission facility (*e.g.,* switches, breakers, busses, metering equipment, relay equipment, etc.).[38]

[29] *Id.* P 51, NAESB WEQ–023 Modeling Business Practice Standards.

[30] *Electric Reliability Organization Proposal to Retire Requirements in Reliability Standards Under the NERC Standards Efficiency Review,* Order No. 873, 85 FR 65,207, 172 FERC ¶ 61,225 (2020).

[31] *Id.* P 4 (noting that the Standard Efficiency Review NOPR indicated that the Commission intended to ''coordinate the effective dates for the retirement of the MOD A Reliability Standards with successor North American Energy Standards Board (NAESB) business practice standards'' and that, on July 16, 2020, ''the Commission issued a NOPR in Docket Nos. RM05–5–029 and RM05–5–030 proposing to amend its regulations to incorporate by reference, with certain enumerated exceptions, NAESB's Version 003.3 Business Practices'').

[32] NERC, Reliability Standard FAC–008–3 (Facility Ratings), *https://www.nerc.com/pa/Stand/Reliability%20Standards/FAC-008-3.pdf.*

[33] Requirements R4 and R5 have been retired effective January 21, 2014.

[34] Commission Staff Paper, *https://www.ferc.gov/sites/default/files/2020-05/tran-line-ratings.pdf.*

[35] Supplemental Notice of Technical Conference, Docket No. AD19–15–000 (Sep. 4, 2019).

[36] Notice Inviting Post-Technical Conference Comments, Docket No. AD19–15–000 (Oct. 2, 2019).

[37] A list of commenters and the abbreviated names used in this NOPR appears in appendix A.

[38] The NERC Glossary defines a facility as ''a set of electrical equipment that operates as a single Bulk Electric System Element (*e.g.,* a line, a generator, a shunt compensator, transformer, etc.)'', defines a facility rating as: ''the maximum or minimum voltage, current, frequency, or real or reactive power flow through a facility that does not violate the applicable equipment rating of any equipment comprising the facility''. NERC, *Glossary*

Continued

20. Thermal ratings are determined by taking into consideration the physical characteristics of the conductor and making assumptions about ambient weather conditions to determine the maximum amount of power that can flow through a conductor while keeping the conductor under its maximum operating temperature. Transmission conductors that exceed their maximum operating temperature can sag and/or become damaged through material weakening (or ''annealing''), resulting in reduced capability and causing potential reliability and/or public safety concerns.

21. Conductor temperatures are impacted by a variety of factors, notably ambient air temperatures. Specifically, increases in ambient air temperatures tend to increase a transmission line's operating temperature. Electric power flowing through a transmission line increases the temperature of the line above ambient temperature due to the line's electrical resistance. Other conditions and phenomena also tend to increase transmission line temperature, particularly solar irradiance intensity. Conversely, some conditions and phenomena tend to lower transmission line temperature, particularly wind. Thermal transmission line limits, therefore, generally decrease with warmer ambient air temperatures and greater solar irradiance intensity, and generally increase with cooler ambient air temperatures and higher wind speeds. Engineering standards help translate line characteristics and ambient weather assumptions into transmission line ratings. The different approaches to transmission line ratings discussed below primarily reflect differences in how frequently ambient weather assumptions are updated (which can range from decades to hours or even minutes) and what types of ambient weather assumptions are updated (air temperature, solar irradiance intensity, wind speed, etc.).

B. Current Transmission Line Rating Practices

22. In practice, thermal rating methodologies have evolved along a spectrum from fully static, with no change in ambient condition assumptions for thermal limits on conductors, to nearly ''real-time'' dynamic ratings. Static ratings are intended to reflect conservative assumptions about the worst-case ambient conditions that equipment might face (*e.g.,* the hottest summer day) and are typically updated only when equipment is changed or ambient condition assumptions are updated. Thus, they often remain unchanged for years or even decades. Seasonal ratings are similar to static ratings in that they change infrequently, but they use different ambient condition assumptions for different seasons.[39]

23. Generally, AARs are transmission line ratings that apply to a time period not greater than one hour, reflect an up-to-date forecast of ambient air temperature (and possibly other forecasted inputs)[40] across the time period to which the rating applies, and is calculated at least each hour, if not more frequently. AAR implementation can be a multi-step process that requires selecting an appropriate line, receiving information about ambient air temperatures (prevailing and forecasted, typically from the National Oceanic and Atmospheric Administration or a private service), rating forecasting, and rating validation. Implementation of AARs often involves transmission owners developing electronic rating ''look-up'' tables for their transmission facilities, which yield transmission line ratings for any air temperature. Transmission line ratings are then determined by using the rating that corresponds to the ambient air temperature that is forecasted over the period of the rating (*e.g.,* hour or 15 or 5 minutes).

24. AAR methodologies usually result in higher transmission line ratings relative to seasonal or static rating methodologies because, while seasonal or static ratings are based on the conservative, worst-case temperature values, AARs are usually based on ambient air temperatures lower than the conservative, worst-case temperature values. For a small percentage of intervals, however, AARs will identify that the near-term ambient temperature conditions are actually more extreme than the long-term assumptions used in seasonal or static ratings, and will therefore result in a line rating that is lower than a seasonal or static rating would have allowed.

25. On the opposite end of the spectrum from static ratings are DLRs, which use assumptions that are updated in near real-time. In addition to ambient air temperature, DLRs can incorporate additional ambient conditions such as wind speed and direction, solar irradiance intensity (considering cloud cover), and/or precipitation. DLRs may also incorporate measurements from sensors installed on or near the line, such as wind speed sensors, line tension sensors, conductor temperature sensors, and/or photo-spatial sensors (*e.g.,* 3–D laser scanning) monitoring line sag. Such weather and other data are not immediately converted to transmission line ratings in real-time. Instead, DLR implementation combines current sensor data with data from the recent past to create reliable short-term forecasts of the relevant weather and other variables for longer periods of time (potentially as granular as five minute increments, but, more likely, larger time periods that could be as long as an hour). Such forecasts are used to develop transmission line ratings that can be depended on by system operators for a specified period (*e.g.,* an hour or 15 or 5 minutes). Under DLR approaches, the use of additional data (beyond the ambient temperature data used in AAR approaches) can allow DLRs to even more accurately reflect transfer capability.

26. DLR methodologies usually result in higher transmission line ratings relative to AAR and other methodologies. However, as discussed above for AAR, for a small percentage of intervals, DLRs will identify that the near-term weather and/or other conditions are actually more extreme than the assumptions under other methodologies, and will therefore result in a line rating that is lower than a static, seasonal, or AAR rating would have allowed. Moreover, the additional weather and conductor data that the sensors can provide, such as wind speed and direction, solar irradiance intensity, precipitation, and line conditions such as tension and sag, improve operational and situational awareness by helping transmission operators to better understand real-time transmission line conditions and potential anomalies, such as possible clearance violations or galloping.

27. While DLRs have unique benefits, they also have unique implementation challenges. The additional data and communications required under DLR approaches increase implementation costs and system complexity. DLR implementation requires the strategic deployment and maintenance of sensors. By increasing the amounts of transmission line rating data and by introducing additional communication nodes inside a transmission owner network, DLRs introduce additional physical and cyber security risks.

of Terms Used in NERC Reliability Standards (June 2, 2020), *https://www.nerc.com/pa/Stand/Glossary%20of%20Terms/Glossary_of_Terms.pdf.*

[39] Although transmission owners typically define seasonal ratings as summer and winter seasonal ratings, transmission owners may create more granular seasonal ratings that could include unique seasonal ratings for the spring and fall seasons.

[40] For example, PJM implements day and night ambient air temperature tables, where the night ambient air temperature table assumes zero solar irradiance. Exelon Comments at 25.

Moreover, DLRs can require additional training or knowledge for some transmission providers or transmission owner personnel.

28. DLRs are not widely deployed in the United States. Transmission owners have tested DLRs on some transmission lines,[41] but they generally have not incorporated DLRs into operations. For transmission owners in RTOs/ISOs, they must also work with the RTO/ISO to determine whether RTO/ISO Energy Management Systems (EMSs) are able to accept a frequently changing transmission line rating signal. If the RTO/ISO EMS cannot accept the information provided by DLRs, such a limitation would significantly reduce the potential benefits of DLRs.

29. Several participants at the September 2019 Technical Conference, have already implemented AARs, including AEP, Dominion, Entergy, and Exelon. ERCOT explained in its testimony that, of its nearly 7,000 transmission lines, approximately two thirds are rated dynamically using a process comparable to what we refer to as AARs.[42] Likewise, PJM explained in its post-conference comments that use of AARs is commonplace among the overwhelming majority of transmission owners in the PJM region.[43] According to Potomac Economics, Entergy and one additional transmission line owner implement AARs in MISO.[44] Outside of ERCOT and PJM, most transmission owners implement seasonal transmission ratings. Seasonal ratings are the norm among non-RTO/ISO transmission owners as well as in CAISO, ISO–NE, NYISO, MISO, and SPP, although at least some transmission owners in RTO/ISO regions use static ratings.[45]

C. Emergency Ratings

30. For short periods of time, most transmission equipment can withstand high currents without sustaining damage. This fact allows transmission owners to develop two sets of ratings for most facilities: Normal ratings and emergency ratings. Normal ratings are ratings that can be safely used continuously (*i.e.,* not time-limited) without overheating the transmission equipment. Emergency ratings are ratings that can be safely used for a limited period of time. This period of time can vary from as short as five minutes to as long as four hours or more.[46]

31. Whether and how a transmission owner establishes emergency ratings is important because emergency ratings are a critical input into determining operating limits in market models, both during normal operations and during post-contingency operations. In general, operating limits (*i.e.,* the maximum allowable MW flow) for any facility or set of facilities are set at a level to ensure that the flows on all facilities will be within applicable facility ratings both during normal operations and during post-contingency operations. Therefore, these operating limits create binding transmission constraints and result in congestion during normal operations and post-contingency, which increases the cost of production for electric energy. Following a contingency, if a transmission provider is able to use emergency ratings, system operators are afforded the flexibility to allow higher loading on transmission facilities for a short time while they reconfigure the transmission system, dispatch generation, or take other measures (*e.g.,* load shedding) to stabilize the system and return it to within normal limits. Because emergency ratings are generally higher than normal ratings, using emergency ratings allows for higher operating limits, and, thus, more efficient system commitment and dispatch solutions. More efficient commitment and dispatch solutions, in turn, reduce the prices paid by consumers for electric energy.

32. However, not all transmission owners use emergency ratings that are different from their normal ratings. For example, Potomac Economics, the market monitor for MISO, NYISO, ISO–NE, and ERCOT, notes that while MISO requires transmission owners to submit both normal and emergency ratings, 63% of transmission line ratings provided to MISO reflect emergency ratings that are equal to the normal ratings.[47] Generally, RTOs/ISOs do not require unique emergency ratings. Instead, transmission owners can decide whether to submit unique emergency ratings, or whether to submit emergency ratings that equal their normal ratings.[48]

D. Rating and Methodology Transparency

33. There are two categories of information relevant to transparency concerns: Transmission line rating methodologies and the resulting transmission line ratings. Generally, transmission line ratings and ratings methodologies are not currently available to transmission providers or the public at large, although certain transmission owners and/or operators make public their transmission line ratings and, less commonly, their ratings methodologies. Certain transmission providers explained that they do not provide such information because it is governed by confidentiality restrictions.[49]

34. The Commission Staff Paper observed that some entities noted the lack of transparency regarding transmission line rating information.[50] At the subsequent September 2019 Technical Conference, some participants expressed a desire for additional line rating transparency regardless of whether the Commission acts on requirements for AARs or DLRs. Potomac Economics stated that additional transparency regarding rating methodologies was ''essential'' for administering an AAR requirement.[51]

[41] For example, some prominent DLR pilot projects have been undertaken in ERCOT, NYISO, and PJM. In ERCOT, ONCOR tested conductor tension-monitor technology, conductor sag, and clearance monitors on eight transmission circuits (138 kilovolt (kV) and 345 kV). In NYISO, the New York Power Authority partnered with the Electric Power Research Institute to install sensor technology designed to measure conductor temperature, weather conditions, and conductor sag on three 230 kV ransmission lines. In PJM, pilot studies were conducted on the 345 kV Cook-Olive transmission line and an additional line to quantify the financial impact of DLRs.

[42] September 2019 Technical Conference, AD19–15, Day One Tr. at 79 (filed Oct. 8, 2019) (September 2019 Technical Conference, Day 1 Tr.).

[43] PJM Comments at 2 (citing Testimony of Michael Kormos (Exelon) at 1. (''Exelon has adopted ambient-adjusted facility ratings for the transmission facilities of five of our six utilities, with Commonwealth Edison scheduled to complete the transition to ambient-adjusted facility ratings next year.''); Testimony of Francisco Velez (Dominion) at 2–3.

[44] Potomac Economics Comments at 6–7.

[45] Commission Staff Paper at 2, 12.

[46] In practice, emergency ratings can vary significantly in duration. As was observed in the September 2019 Technical Conference, there does not appear to be clear standardization of the emergency rating timeframes. September 2019 Technical Conference, Day 1 Tr. at 175.

[47] September 2019 Technical Conference, Day 2 Tr. at 311–312.

[48] For example, SPP and ISO–NE allow their transmission owners to use unique emergency ratings, but neither RTO/ISO specifically requires them, *see* SPP Planning Criteria, Revision 2.2 (3/16/2020), Section 7.2. *See also* ISO–NE, *ISO New England Planning Procedure No. 7: Procedures for Determining and Implementing Transmission Facility Ratings in New England* (Revision 4) (Nov. 7, 2014), *https://www.iso-ne.com/static-assets/documents/rules_proceds/isone_plan/pp07/pp7_final.pdf.*

[49] MISO Transmission Owners claim that some of the information related to the limiting element used to establish a transmission line rating is ''confidential.'' MISO Transmission Owners Comments at 20; Dominion claims that FAC–008's Requirement 8 requires confidential sharing of limiting element information only with ''associated Reliability Coordinator(s), Planning Coordinator(s), Transmission Planner(s), Transmission Owner(s) and Transmission Operator(s) when requested.'' Dominion Comments at 14.

[50] Commission Staff Paper at 28.

[51] September 2019 Technical Conference, Day 2 Tr. at 309.

WATT noted that transmission owners may have an incentive to be overly conservative with their line rating methodologies and that increasing transparency around these methodologies could improve efficiency.[52]

35. At the September 2019 Technical Conference, panelists also discussed auditing of line ratings and rating methodologies. Panelists disagreed over whether methodologies and ratings were sufficiently audited by NERC Regional Entities or other parties to ensure just and reasonable rates.

36. Separate from the outreach and technical conference discussions, NERC Reliability Standard FAC–008–3 requires transmission owners to document their facility ratings methodology. While NERC Regional Entities are responsible for auditing line ratings for compliance with Reliability Standards, FAC–008–3 Requirement R8 allows other entities, including other transmission service providers, planning coordinators, reliability coordinators, or transmission operators, to request facility ratings up to 13 months later for internal examination.[53] Such data requests remain non-public.

37. Lastly, some transmission owners periodically report rating methodologies in FERC Form 715, Part IV.[54]

IV. Need for Reform

A. Transmission Line Ratings

38. For the reasons discussed below, we preliminarily find that transmission line ratings and the rules by which they are established are practices that directly affect the cost of wholesale energy, capacity and ancillary services, as well as the cost of delivering wholesale energy to transmission customers. Because of those relationships, inaccurate transmission line ratings may result in Commission-jurisdictional rates that are unjust and unreasonable.

39. First, most transmission owners implement seasonal or static transmission line rating methodologies. Such seasonal or static line ratings are based on conservative, worst-case assumptions about the long-term conditions, such as the expected high temperatures that are likely to occur over the longer term.[55] While such long-term assumptions may be appropriate in various planning contexts, they often do not reflect the true near-term transfer capability of transmission facilities as relevant to the availability of, and arrangement for, point-to-point transmission service. Thus, they fail to reflect the true cost of delivering wholesale energy to transmission customers.

40. In the RTO/ISO markets, line ratings directly affect the dispatch and unit commitment computations by constraining power flows on individual transmission facilities. The resulting congestion costs are directly reflected in locational marginal prices (LMPs). Outside of RTOs/ISOs, LMPs are not generally used; however, transmission line ratings can still directly affect the cost to deliver wholesale energy to transmission customers by limiting transmission of electric energy under both network transmission service and point-to-point transmission service offered under the *pro forma* OATT.

41. In both RTO/ISO and non-RTO/ISO areas, incorporating near-term forecasts of ambient air temperatures in transmission line ratings would result in more accurately reflecting the actual cost of delivering wholesale energy to transmission customers. Because actual ambient temperatures are usually not as high as the ambient temperatures conservatively assumed in seasonal and static ratings, updating transmission line ratings used in near-term transmission service to reflect ambient temperatures usually results in increased system transfer capability. By increasing transfer capability, congestion costs will, on average, decline because transmission providers will be able to import less expensive power into what were previously constrained areas. For example, Potomac Economics has found that AAR implementation by those not already doing so in MISO alone would have produced approximately $94 million and $78 million in reduced congestion costs in 2017 and in 2018, respectively.[56] Such congestion cost changes and related overall price changes will more accurately reflect the actual congestion on the system and, similarly, more accurately reflect the cost of delivering wholesale energy to transmission customers. Likewise, the ability to increase transmission flows into load pockets may reduce transmission provider reliance on local reserves inside load pockets, which may reduce local reserve requirements and the costs to maintain that required level of reserves.

42. While current line rating practices usually understate transmission capability, they can also overstate transmission capability. While actual ambient temperatures are usually not as high as the assumed seasonal or static temperature input, in some instances actual ambient temperatures exceed those assumed temperatures. In those instances, seasonal or static transmission line rating methodologies result in ratings that reflect more transfer capability than physically exists, and therefore such line ratings allow access to some electric power supplies and/or demand that would not be available if ratings reflected the true transfer capability. Overstating transmission capability, like understating transmission capability, results in wholesale energy rates that fail to reflect the actual cost of delivering wholesale energy to transmission customers, but, by contrast, results in inaccurately low congestion pricing. Moreover, overstating transmission capability may risk damage to equipment, and may prevent occurrences of rates for scarcity pricing or transmission constraint penalty factors that serve as important signals to the market that more generation and/or transmission investment may be needed in the long-term.

43. Second, regarding potential DLR implementation, some RTOs/ISOs may rely on software that cannot accommodate line ratings that frequently change, such as DLRs. Without reflecting such frequent changes to line ratings, such software may serve as a barrier that prevents transmission owners in RTOs/ISOs from implementing DLRs that can better reflect the actual transmission capability of the transmission system. As noted above, in addition to ambient air temperature, other weather conditions such as wind, cloud cover, solar irradiance intensity, and precipitation, and transmission line conditions such as tension and sag, can affect the

[52] September 2019 Technical Conference, Day 1 Tr. at 23.

[53] NERC Reliability Standard FAC–008–3—Facility Ratings, Requirement R8.

[54] FERC Form 715 is a multi-part annual transmission planning and evaluation report which each transmitting utility that operates integrated transmission system facilities rated at or above 100 kilovolts (kV), must annually submit.

[55] For example, transmission providers appropriately utilize conservative long-term assumptions about long-term conditions to incorporate requests for long-term firm point-to-point transmission service, which the *pro forma* OATT defines as ''firm point-to-point transmission service under Part II of the Tariff with a term of one year or more'' (*pro forma* OATT section 1.19) and requests for network integration transmission service, whose applications require 10-year projections of all network resources (*pro forma* OATT section 29.2). Additionally, planning authorities appropriately utilize conservative long-term assumptions in the long-term transmission planning horizon and the near-term transmission planning horizon.

[56] Potomac Economics Comments at 6–7.

amount of transfer capability of a given transmission facility. DLRs incorporate these additional inputs and thereby provide transmission line ratings that are closer to the true thermal transmission line limit than AARs, which can result in rates that even more accurately reflect the costs of delivering wholesale energy to transmission customers. But, even if a transmission owner sought to implement DLRs, the RTO/ISO's EMS may not be able to accept and use the resulting transmission line rating. This inability to automatically accept and use a DLR may prevent the market from benefiting from the more accurate representation of current system conditions that would otherwise produce prices that more accurately reflect the costs of delivering wholesale energy to transmission customers. Therefore, we preliminarily find that current transmission line rating practices in RTOs/ISOs that do not permit the acceptance of DLRs from transmission owners may result in rates that do not reflect the actual costs of delivering wholesale energy to transmission customers.

44. Third, regarding emergency ratings, current transmission line rating practices may fail to use emergency ratings, and in failing to do so, may result in ratings that do not accurately reflect the near-term transfer capability of the system and therefore may result in rates that do not reflect actual costs to delivering wholesale energy to transmission customers. As discussed above, transmission owners often develop two sets of ratings for most facilities: Normal ratings that can be safely used continuously, and emergency ratings that can be used for a specified shorter period of time, typically during post-contingency operations.

45. In RTO/ISO markets, market models, such as security-constrained economic dispatch (SCED) and security-constrained unit commitment (SCUC) models, generally calculate resource dispatch and commitments that ensure that all facilities will be within applicable facility ratings both during normal operations and following any modeled contingency (*e.g.,* following the loss of a transmission line). In ensuring that the system is stable and reliable following a contingency, SCED and SCUC models often allow post-contingency flows on lines to exceed normal ratings for short periods of time, as long as the flows do not exceed the applicable emergency rating for the corresponding timeframe. Because these emergency ratings are a more accurate representation of the flow limits over those shorter timeframes, their use in models of post-contingency flows may produce prices which more accurately reflect actual costs to delivering wholesale energy to transmission customers.

46. While most or all RTO/ISO markets consider both normal and emergency ratings as part of their SCUC and SCED models, not all transmission owners have chosen to incorporate unique emergency ratings into their transmission line rating methodologies. That is, some transmission owners in RTO/ISO regions provide to the RTOs/ISOs emergency ratings that are just a copy of the normal ratings,[57] essentially creating the same situation as if the RTO/ISO did not use emergency ratings at all when modeling contingencies. As discussed above, this may result in the use of less accurate flow limits, and less accurate costs for delivering wholesale energy to transmission customers. According to Potomac Economics, for example, this failure to implement unique emergency ratings resulted in approximately $62 million and $68 million in additional costs in 2017 and in 2018, respectively, in MISO alone.[58] Therefore, we seek comment on whether not using unique emergency ratings, as discussed below, similarly may not be just and reasonable.

B. Transparency

47. We preliminarily find that the current level of transparency into transmission line ratings and transmission line rating methodologies may result in unjust and unreasonable rates. The current level of transparency may prevent transmission provider(s) and market monitors from having the opportunity to validate transmission line ratings. This may result in transmission owners submitting inaccurate near-term transmission line ratings, which may result in rates that do not accurately reflect congestion and reserve costs on the system, as discussed above. For example, without knowing the basis for a given line rating that frequently binds and elevates prices, a transmission provider and/or market monitor cannot determine whether the line rating is miscalculated or accurately calculated.

V. Discussion

A. Transmission Line Ratings

1. Comments

a. Ambient-Adjusted Line Ratings

48. At the September 2019 Technical Conference, participants and staff explored whether the Commission should require the implementation of AARs.[59] Several participants supported a requirement to implement AARs, with several stating their support for AAR implementation as a best practice. Supporters contend that while AAR implementation requires an initial investment to upgrade the EMS, these costs are a manageable way to increase transfer capability.[60] Potomac Economics noted that significant economic benefits would have accrued to market participants if all MISO transmission owners had implemented AARs and unique emergency ratings.[61]

49. Several participants did not support an AAR requirement. Ameren, on behalf of the MISO Transmission Owners, argued that AAR implementation would be costly and complex. PacifiCorp argued that the benefits of implementing AARs and DLRs would not materialize on all lines, and therefore cautioned that the Commission should not require AAR implementation on all lines.[62] Finally, Ameren argued that because forecasting was necessary for day-ahead AAR implementation, there could be liability associated with an incorrect forecast.[63]

50. Following the September 2019 Technical Conference, the Commission requested comments on all conference discussion items, including the appropriateness of a Commission requirement to implement AARs, how a requirement might be structured, whether an AAR requirement should be extended to day-ahead markets, and whether any forecasted ambient conditions other than temperature should be considered in an AAR requirement.

51. Many entities filed comments in support of a requirement to implement AARs, noting that an AAR requirement represents a cost-effective industry best practice that would achieve significant savings to ratepayers. Some transmission owners reiterated points

[57] Here we are describing the situation where the emergency ratings are *arbitrarily* set equal to the normal ratings. On the other hand, there may be some instances where, after a proper technical analysis considering the relevant rating timeframes, the emergency rating is nonetheless equal to the normal rating. As relevant to the discussion here, such ratings would be considered ''unique'' because they were developed from the appropriate, unique technical inputs.

[58] Potomac Economics Comments at 6–7.

[59] Panelists participating in the discussion of a potential requirement to implement AARs included representatives from AEP, Ameren (on behalf of the MISO Transmission Owners), CAISO, Entergy, PacifiCorp, Potomac Economics, and Vistra Energy.

[60] September 2019 Technical Conference, Day 1 Tr. at 142.

[61] *Id.* at 171.

[62] *Id.* at 163.

[63] *Id.* at 148.

made in the September 2019 Technical Conference. AEP explains that it has used AARs in real-time operations for more than a decade and that it monitors temperature zones in its regions and retrieves real-time temperature data for every state estimation process run. AEP states that AARs using real-time and next day forecasted regional temperatures can benefit customers and bring flexibility to transmission operations.[64]

52. Dominion explains that requiring the use of AARs, rather than a default temperature assumption that is ''too conservative,'' will allow transmission line ratings to better reflect forecasted conditions. Dominion cautions, however, against AARs that make overly aggressive assumptions, which would also result in the transmission system being operated ''less conservatively'' and a degradation of grid reliability.[65]

53. Similarly, Exelon states that it would not oppose a properly structured requirement to implement AARs in both real-time and day-ahead markets. Exelon explains that AARs represent a best practice and a cost-effective way to enhance transmission use to the benefit of customers.[66] As background, Exelon explains that PJM requires its transmission owners to provide ambient temperature-dependent ratings for both daytime and nighttime periods (which account for the presence or lack of solar irradiance heating), and for normal, long-term emergency, short-term emergency, and load dump conditions.[67] Exelon explains that implementing AARs results in more accurate transmission line ratings, reducing the likelihood of overloading a line and thus creating reliability benefits. Exelon reiterates its comments from the conference that, while implementing AARs requires initial investments, AARs are a cost-effective way to reduce congestion and enhance reliability.[68]

54. While generally supporting a requirement to implement AARs, AEP, Dominion, and Exelon express caution and request flexibility regarding AAR implementation. Dominion explains that it would not support a requirement for AAR implementation to be fully automated.[69] Dominion and Exelon warn that AAR implementation will not eliminate congestion.[70] Exelon further cautions that an AAR requirement should only apply to transmission facility ratings sensitive to temperature changes,[71] that transmission owners should have flexibility to determine appropriate temperature granularity,[72] and that it may not be appropriate to apply AARs to certain degraded or older assets.[73] AEP cautions that entities that have not implemented AARs before will incur some up-front costs, including internal process development and documentation costs, weather data subscriptions, software changes, and training, but explains that these costs should be manageable.[74] Exelon and AEP both also caution that AAR implementation should be applied only to real-time and day-ahead markets and should not be considered permanent solutions to address thermal constraints identified in long-term transmission planning reliability assessments.[75]

55. Both Potomac Economics and Monitoring Analytics support a requirement for transmission owners to implement AARs that must be updated hourly.[76] Monitoring Analytics states that the ''failure to use AARs means that line ratings in actual use are wrong much of the time,'' which they argue is not acceptable.[77] Potomac Economics estimates that adoption of AARs in MISO by those not already doing so would have produced approximately $78 million and $94 million in annual benefits in 2017 and 2018, respectively. Potomac Economics further estimates the savings derived from Entergy and another unnamed MISO transmission owner's current AAR implementation to have been $51.3 million over 2017 and 2018.[78] Potomac Economics explains that an AAR requirement would enhance reliability by increasing operational and situational awareness, by ensuring transmission line ratings are more accurate, and by ensuring that transmission providers have a better understanding of the capabilities of transmission facilities.[79]

56. DTE, TAPS, Industrial Customers, and OMS each make supportive comments. Citing Entergy's presentation from the September 2019 Technical Conference, DTE explains that using AARs can increase transmission line ratings by up to 25% for lower-voltage facilities and by 5% on higher-voltage facilities, and its ongoing implementation requires only ''one full-time engineer to maintain the associated in-house database, perform modeling updates, and liaison with real-time system operations personnel and IT resources to support automation of the calculations.'' [80] DTE therefore submits that AARs can be implemented without causing any undue burden.[81] DTE states that transmission owners are obligated to implement the most cost-effective solution, and given the experience of other transmission owners that have successfully implemented AARs, DTE contends that transmission owners should be required to implement AARs because they are the most cost-effective solution.[82]

57. TAPS agrees with September 2019 Technical Conference participants, such as AEP, who contended that the Commission should issue a rulemaking requiring AAR implementation, assuming appropriate safeguards.[83] TAPS encourages a requirement for AAR implementation to be part of an effort to ensure more accurate transmission line ratings, as part of good utility practice, and focusing AAR application where congestion reductions might be most meaningful.[84] To identify locations where AAR application would be beneficial, TAPS explains that RTOs/ISOs should have backstop authority to identify transmission facility candidates following a transparent process where the RTO/ISO is directed to independently evaluate the grid for beneficial AAR candidates.[85] Noting the importance for transmission line ratings to be both accurate and applied in a non-discriminatory manner, as well as the challenges of ensuring accuracy and preventing discrimination in the absence of an independent entity facilitating AAR implementation, TAPS explains that the Commission should give serious examination to AAR application in non-RTO/ISO regions.[86]

58. Industrial Customers similarly argue that the Commission, at a minimum, should require transmission owners to implement AARs on the most congested transmission lines and facilities.[87] Industrial Customers explain that AARs provide a more

[64] AEP Comments at 2.

[65] Dominion Comments at 3–4.

[66] Exelon Comments at 1.

[67] *Id.* at 25–26.

[68] *Id.* at 1, 9.

[69] Dominion Comments at 5–6.

[70] Exelon Comments at 10; Dominion Comments at 11.

[71] Exelon Comments at 22–23.

[72] *Id.* at 24.

[73] *Id.* at 23.

[74] AEP Comments at 2–3.

[75] Exelon Comments at 5; AEP Comments at 3.

[76] Potomac Economics Comments at 2–3; Monitoring Analytics Comments at 5.

[77] Monitoring Analytics Comments at 5.

[78] Potomac Economics Comments at 6–7. Potomac Economics explains that estimates of benefits will necessarily be conservative given that the shadow price would increase if the market was controlling to a lower rating.

[79] *Id.* at 8.

[80] DTE Comments at 2.

[81] *Id.*

[82] *Id.* at 3.

[83] TAPS Comments at 4–5.

[84] *Id.* at 9.

[85] *Id.* at 10.

[86] *Id.* at 11.

[87] Industrial Customers Comments at 15.

accurate representation of ATC and contend that using AARs is good utility practice by allowing transmission operators to better optimize existing circuits and reduce electric prices.[88] For these reasons, Industrial Customers contend the Commission should require the implementation of AARs, but, noting the possibility that a cost-benefit comparison may change at a very granular level, only on such facilities where AAR implementation is truly cost-effective.[89]

59. PJM explains that it has derived significant operational value in the adoption of AARs, explaining that its use of AARs has allowed it to take advantage of additional transfer capability that promotes a more reliable system dispatch.[90]

60. Other entities, while not outright supporting a requirement for AAR implementation, offer a more nuanced view. MISO states that if the Commission does require AAR implementation, that requirement should not solely focus on congested facilities. MISO explains that any transmission facility could become the next most limiting element as the system changes, and that therefore AARs should be applied to any facility where temperature is a determining factor.[91]

61. IEEE and NERC offer limited support for AAR implementation. According to IEEE, AARs provide safer transmission line ratings during periods of unexpected extreme ambient conditions exceeding the assumptions that are the basis for static ratings, provide better use of transmission assets, and reduce the need for additional infrastructure investment to service anticipated demand.[92] However, IEEE also highlights disadvantages to AAR implementation. These include necessary upgrades to EMSs, assurances that a utility's EMS is protected from sabotage and cyber tampering, and robust analysis protocols needed to convert changing temperatures into updated transmission line ratings, as well as additional work needed to document AAR protocols in a transmission line rating methodology.[93] NERC cautions that AAR implementation may not increase the reliability of transmission lines if implementation is not properly coordinated to avoid real-time operational confusion,[94] citing an example from during the 2003 blackout of a transmission line rating discrepancy between the transmission owner, transmission operator, and reliability coordinator where each had separate transmission line ratings for the same facility.[95]

62. Opposition to a requirement to implement AARs comes primarily from MISO Transmission Owners, ITC, EEI, NRECA, WATT, and AWEA. Generally, MISO Transmission Owners and ITC state that the industry is not ready to support full implementation of AARs or DLRs.[96] MISO Transmission Owners and ITC state that the Commission should allow industry to continue to explore the use primarily of AARs and secondarily of DLRs through industry groups or pilot programs.[97] MISO Transmission Owners further argue that the Commission should recognize that preserving and protecting transmission system reliability is of paramount importance, and that tying development and implementation of AARs and DLRs to financial incentives or other economic criteria without fully understanding and taking into account the impact on reliability or safety could be contrary to the reliable and safe operation of the transmission grid and create unreasonable risk.[98] One specific cause for concern, according to the MISO Transmission Owners and ITC, is that implementation of AARs can reduce some of the ''margin'' between what the transmission system can actually handle and how it is operated.[99] Moreover, according to MISO Transmission Owners, if real-time ambient temperatures are higher or wind is lower than forecasted day-ahead rating assumptions, AARs could lower ratings near peak load conditions, which could in turn lead to congestion and generation redispatch.[100] Citing safety concerns and the importance of ratings to reliability, ITC also warns that the Commission should not take any action that conflicts with a transmission owner's NERC's obligations.[101]

63. MISO Transmission Owners also contend that the Commission should recognize that the benefits that would be realized from the adoption of AARs or DLRs will vary by system, and may even vary within an RTO/ISO region or within a transmission system.[102] MISO Transmission Owners state that AARs and DLRs may only be cost-effective on a subset of transmission lines, and notes that transmission systems that are constrained by voltage, stability, or certain substation limitations may not benefit from AAR or DLR implementation.[103] MISO Transmission Owners further state that factors such as topology, congestion, and localized climate conditions can affect the benefits of and need for AARs.[104] MISO Transmission Owners add that implementing and maintaining the necessary sensors and making the other investments necessary to implement AARs can be costly, and make the cost of AAR implementation similar to that of DLRs implementation.[105]

64. MISO Transmission Owners argue that there are additional indirect costs to AAR implementation. According to MISO Transmission Owners, these indirect costs are primarily liability-related, including market liability, safety liability, and reliability liability, and these costs would be complex, if not incalculable, to determine.[106] MISO Transmission Owners also argue that, should the Commission require AAR implementation, the Commission should not require AARs be used in the day-ahead markets.[107] According to MISO Transmission Owners, implementation of AARs in the day-ahead markets would increase potential liability and potentially cause congestion. Specifically, MISO Transmission Owners imply that liabilities could result from adjustments to transmission line ratings in real-time should a transmission line rating be determined based on an inaccurate day-ahead forecast and cause real-time congestion and generation re-dispatch.[108] Therefore, because there are no universal benefits to AAR or DLR implementation and because of the resulting direct and indirect costs, MISO Transmission Owners argue that no universal solution is appropriate.[109]

65. EEI echoes many of MISO Transmission Owners' arguments in its opposition to an AAR requirement. EEI explains that because of the initial investment costs, and because the benefits to AAR implementation would vary considerably, a one-size-fits-all requirement to implement AARs would

[88] *Id.* at 14–15.

[89] *Id.* at 14–16.

[90] PJM Comments at 2–3.

[91] MISO Comments at 2–3.

[92] IEEE Comments at 1.

[93] *Id.* at 2–4.

[94] NERC Comments at 3.

[95] Technical Conference, Day 1 Tr. at 91.

[96] MISO Transmission Owners Comments at 1–2; ITC Comments at 2–3.

[97] MISO Transmission Owners Comments at 1–2; ITC Comments at 2–3.

[98] MISO Transmission Owners Comments at 2.

[99] *Id.* at 6; ITC Comments at 3–4.

[100] MISO Transmission Owners Comments at 13.

[101] ITC Comments at 1.

[102] MISO Transmission Owners Comments at 14.

[103] *Id.* at 8–9 (citing Commission Staff Paper at 8–9).

[104] *Id.* at 7.

[105] *Id.*

[106] *Id.*

[107] *Id.* at 12–13.

[108] *Id.* at 12–14.

[109] *Id.* at 7.

not be appropriate.[110] EEI further states that, by requiring transmission owners to consider ambient conditions in transmission line ratings, NERC Reliability Standard FAC–008–3 creates a meaningful incentive for transmission owners to implement AARs. Specifically, EEI argues that transmission owners are required to consider ambient temperatures under FAC–008–3, and are also required rate their lines using technically sound principles, and therefore, any further requirement to implement AARs is unnecessary.[111] EEI emphasizes that AARs and DLRs are only appropriate for real-time and near-real-time operations and are not appropriate to use in system planning.[112]

NRECA states that while it would support a reasoned approach to implementing transmission line rating changes, it does not support a Commission mandate to implement either AARs or DLRs.[113] NRECA does not oppose the use of AARs or DLRs in operations if there are consumer benefits to be gained, but contends that safety and reliability should remain the foremost considerations. Further, NRECA agrees with September 2019 Technical Conference participants who recommended against ''one-size-fit-all'' requirements for transmission ratings and ratings methodologies and, citing the September 2019 Technical Conference, explained that it would not be cost-effective to implement AARs or DLRs on all transmission lines.[114] For these reasons, NRECA emphasizes the need for flexibility to balance the cost and benefits of implementing these rating methods. Moreover, NRECA explains that a one-size fits-all approach poses a distinct risk to Western states and NRECA members in particular, since an AAR or DLR mandate would increase transmission costs disproportionately for rural consumers.[115]

66. WATT asserts that transmission owners should not be required to implement AARs everywhere because, according to WATT, AARs are not sufficiently conservative.[116] WATT argues that at times, AAR implementation may not be conservative enough because AAR implementation can assume too much wind, causing transmission line ratings to be too high, and possibly result in safety violations.[117] Specifically, WATT explains that wind speeds assumed by IEEE and the International Council on Large Electric Systems studies may be too high at certain temperatures and result in transmission line ratings that exceed what a transmission line can safely handle.[118]

67. Finally, rather than recommend Commission action to require AARs, AWEA recommends a process whereby transmission owners should be required to disclose transmission line ratings and, for lines whose limiting element is an overhead conductor, perform a cost-benefit study of the deployment of DLR or other congestion mitigation technologies.[119] AWEA further contends that for lines that are not conductor-limited, transmission owners should be required to perform a cost-benefit study of the upgrade of the terminal equipment or other congestion mitigation technologies.[120] However, in the absence or delay of DLR implementation, AWEA adds that AARs also present benefits and should be considered for implementation.[121]

b. Dynamic Line Ratings

68. WATT states that DLRs are more accurate than AARs, and that DLRs reduce uncertainty relative to AARs by providing accurate information about sag, clearances, and conductor temperatures.[122] WATT recommends transmission owners be required to, for each line that is or is forecast to become heavily congested, disclose nominal ratings and perform a cost-benefit study of the deployment of DLRs, other congestion mitigation technologies, and/or upgrading the terminal equipment, as appropriate.[123] WATT concedes that security can be a concern, but should not be used as a red herring to avoid improvements to the grid's reliability and efficiency.[124]

69. Some commenters recommend pilot programs, a limited or staged implementation of DLRs, and/or requirements to ensure transmission operators can accept and use DLRs, noting these would be helpful in overcoming the challenges related to DLR implementation. Monitoring Analytics recommends that the Commission direct all transmission owners in PJM to start DLR pilot programs.[125] PJM also supports DLR pilot projects, and notes that DLR pilot projects have already taken place on its system.[126] Dominion states that it has partnered with LineVision and EPRI in pilot projects focused on evaluating DLR sensor installations and validating the sensors' data, and contends that more pilot programs could facilitate the adoption of DLRs.[127] Potomac Economics and MISO state that they do not oppose DLR implementation, but contend that AAR implementation should be prioritized.[128] In considering where to begin DLR implementation, WATT contends that the Commission could consider factors such as whether a line is thermally limited, congested, or the average wind speed or other weather parameters would have a strong bearing on the line's rating. WATT also contends that DLRs should be made available at a customer's request.[129]

70. Although some commenters highlight the benefits of DLRs, others stress the challenges associated with DLR implementation. For example, Dominion cautions that DLRs provide only marginal benefits compared to AAR implementation in real-time operations, but also include additional challenges, increased operational burdens, and likely higher uncertainty.[130] MISO, PJM, and MISO Transmission Owners caution that data verification would be necessary when implementing DLRs to protect against intrusion and corruption.[131] MISO Transmission Owners further caution that implementation of DLRs is likely to be complex, resource-intensive, and costly.[132] EEI and Exelon note that implementing DLRs includes additional challenges, such as placing sensors in remote locations, ensuring the cyber security of sensors, and various additional costs.[133] Other commenters urge the Commission to exercise caution regarding further DLR requirements, including ITC, MISO, and PJM,[134] which explain that DLR is a technology still under development and therefore further pilot projects to evaluate the appropriateness of DLR requirements

[110] EEI Comments at 5–7.

[111] *Id.* at 7–8.

[112] *Id.* at 9–10.

[113] NRECA Comments at 2–5.

[114] *Id.* at 4 (citing the opening statements of Dennis D. Kramer on behalf of the MISO Transmission Owners and Rikin Shah on behalf of PacifiCorp, located in Technical Conference, Day 1 Tr. at 147 and 163–65, respectively).

[115] *Id.* at 5–6.

[116] WATT Comments at 2.

[117] *Id.* at 2–5.

[118] *Id.* at 2–4.

[119] AWEA Comments at 2.

[120] *Id.*

[121] *Id.*

[122] WATT Comments at 5.

[123] *Id.* at 2–5.

[124] WATT Reply Comments at 4.

[125] Monitoring Analytics Comments at 5–6.

[126] PJM Comments at 1, 4–6.

[127] Dominion Comments at 8–9.

[128] MISO Comments at 3, 6; Potomac Economics Comments at 13.

[129] WATT Reply Comments at 3.

[130] Dominion Comments at 8–11.

[131] MISO Comments at 8–9; PJM Comments at 8; MISO Transmission Owners Comments at 25.

[132] MISO Transmission Owners Comments at 15–16, 25.

[133] EEI Comments at 8–10; Exelon Comments at 11–13.

[134] ITC Comments at 3–4; MISO Comments at 5–6; PJM Comments at 4–6.

are needed [135] and also that, since AAR implementation is more cost-effective, DLR cost-effectiveness should be reevaluated in light of any AAR requirement.[136]

71. Comments indicate that the ability to incorporate DLRs is uneven. Dominion states that its EMS cannot incorporate DLRs, and that, while PJM's EMS can accept DLRs, that capability is unused. Dominion states that relative to AAR implementation, EMS upgrades are typically needed to support DLRs, which would require fundamental data schema updates. Dominion notes that most ''off-the-shelf'' EMSs can accommodate AARs because they have alternative line ratings sets that can be switched on or off according to ambient temperature.[137]

72. MISO contends that it can accept DLRs, but not the information necessary to calculate the rating itself.[138] MISO Transmission Owners state that some RTOs/ISOs may have the capability now to change transmission line ratings ''on-the-fly'' through their EMSs, while other RTOs/ISOs and their transmission owners would have to update and revise multiple systems to use DLRs in real-time and day-ahead markets.[139] WATT concurs, explaining that RTOs/ISOs and transmission operators currently vary in their ability to incorporate DLRs based on various factors.[140]

73. The idea of requiring studies on the cost-effectiveness of DLRs was generally supported, but commenters disagreed on study details and on whom should conduct the study. WATT and Industrial Customers recommend that RTOs/ISOs study the benefits and effectiveness of DLR on the most congested, thermally limited lines.[141] Dominion states that it is open to studying its most congested lines to determine DLR's cost-effectiveness, but argues that PJM is better suited to assess the costs and congestion relief associated with DLR adoption.[142]

74. MISO Transmission Owners suggest that there may be no single metric for determining which congested lines to target.[143] Exelon states that a DLR cost-effectiveness study could duplicate existing processes, noting that in PJM, transmission owners are able to propose advanced technologies as possible transmission solutions.[144]

c. Emergency Ratings

75. At the September 2019 Technical Conference, Entergy stated that it uses short-term emergency ratings on less than 10% of its facilities.[145] In explaining its reluctance to implement emergency ratings, Entergy stated that the use of emergency ratings carries a high degree of risk based on its potential to degrade the applicable transmission facility, and that the risk and trade-offs must be very carefully balanced.[146] Moreover, given the reliability risks, Entergy further contended that emergency ratings should not be used for economic purposes.[147]

76. While most post-September 2019 Technical Conference comments focused on normal ratings, some commenters also described the current implementation and availability of emergency ratings, typically used for specific durations post-contingency. Commenters discussing emergency ratings include Exelon, PJM, Dominion, Industrial Customers, Potomac Economics, and Monitoring Analytics.

77. Exelon and Monitoring Analytics note that, in addition to normal transmission line ratings, PJM transmission owners are required to provide short-term emergency transmission line ratings, long-term emergency transmission line ratings, and load-dump transmission line ratings.[148] Exelon states that, like AARs, emergency ratings also may not be sensitive to changes in ambient air temperatures if the equipment rating is not sensitive to ambient air temperatures or if the transmission facility is not thermally limited.[149] Monitoring Analytics explains that while PJM typically uses the long-term four-hour emergency rating in SCED/SCUC modeled contingencies, there is no requirement that the ratings differ for these operating conditions.[150]

78. PJM points out that any permitted use of emergency ratings is documented within PJM manuals.[151] Dominion explains that the implementation of emergency ratings, if used, typically assumes first or second contingency conditions, and that the development and usage of emergency ratings should be documented in each transmission owner's transmission line rating methodology.[152] Finally, Industrial Customers clarify that PJM's tariff allows certain flowgate calculations to use emergency ratings.[153]

79. Potomac Economics explains that because most binding real-time constraints are based on contingencies, operators model the additional flows that would occur on a monitored facility post-contingency, and MISO must be prepared to return flows below normal ratings within the prescribed time period. Thus, Potomac Economics states that unique emergency ratings may enable operating at higher levels for longer post-contingency.[154] Potomac Economics and Industrial Customers [155] explain that the MISO Transmission Owners Agreement calls for transmission owners to provide emergency ratings, which can reliably accommodate flow for two to four hours, for all contingency constraints.[156] However, Potomac Economics notes that 63% of all post-contingency ratings used by MISO are actually the normal ratings.[157] Had unique emergency ratings been used in MISO, Potomac Economics contends, the market cost savings would have been approximately $62 and $68 million in 2017 and 2018, respectively.[158]

2. Proposal

80. To remedy potentially unjust and unreasonable rates, we make several proposals related to AARs, DLRs and emergency ratings. We propose to require all transmission providers to implement AARs on the transmission lines over which they provide transmission service. We propose a staggered approach to the proposed AAR requirement that would prioritize implementation on congested lines (within one year from the date of the compliance filing for implementation of the proposed reforms to become effective), and propose to require a less aggressive implementation of AARs on all other lines (within two years from the date of the compliance filing for implementation of the proposed reforms to become effective).

81. In addition, we propose to require all RTOs/ISOs to implement the systems and procedures necessary to allow transmission owners to electronically update transmission line ratings at least

[135] PJM Comments at 5–6; ITC Comments at 3–4.

[136] MISO Comments at 6.

[137] Dominion Comments at 8.

[138] MISO Comments at 5.

[139] MISO Transmission Owners Comments at 16.

[140] WATT Comments at 7.

[141] *Id.;* Industrial Customers Comments at 16.

[142] Dominion Comments at 10–11.

[143] MISO Transmission Owners Comments at 16–17.

[144] Exelon Comments at 29–30.

[145] Technical Conference, Day 1 Tr. at 159.

[146] *Id.*

[147] *Id.* at 293–94.

[148] Exelon Comments at 25; Monitoring Analytics Comments at 3.

[149] Exelon Comments at 10.

[150] Monitoring Analytics Comments at 3.

[151] PJM Comments at 7.

[152] Dominion Comments at 15.

[153] Industrial Customers Comments at 17.

[154] Potomac Economics Comments at 4.

[155] Industrial Customers Comments at 12 (citing MISO, MISO Rate Schedules, Transmission Owner Agreement, Appendix B, Section V (30.0.0)).

[156] Potomac Economics Comments at 4.

[157] *Id.* at 5.

[158] *Id.* at 6.

hourly. We also seek comment on whether to apply this requirement to transmission providers located outside of RTO/ISO markets.

82. Finally, with regard to emergency ratings, we seek comment on whether to require transmission providers to use unique emergency ratings.

a. Ambient-Adjusted Line Ratings and Seasonal Line Ratings

i. Proposed Requirements

83. Having preliminarily found that the use of transmission line ratings that are based on long-term assumptions is not just and reasonable, we propose, pursuant to section 206 of the FPA to revise the *pro forma* OATT to require all transmission providers to implement AARs and seasonal line ratings on the transmission lines over which they provide transmission service, under certain circumstances. This requirement would ensure that transmission line ratings accurately reflect the availability of transmission in real-time.

84. In proposing to require the implementation of AARs and seasonal transmission line ratings, we propose to define transmission line ratings as the maximum transfer capability of a transmission line, computed in accordance with a written line rating methodology and consistent with Good Utility Practice, considering the technical limitations (such as thermal flow limits) on conductors and relevant transmission equipment, as well as technical limitations of the Transmission System (such as system voltage and stability limits). Relevant transmission equipment may include, but is not limited to, circuit breakers, line traps, and transformers.

85. We propose to implement these requirements through a new Attachment M to the *pro forma* OATT titled Transmission Line Ratings. Within the proposed Attachment M, different line rating requirements would apply in the context of different types of transmission service, as discussed below.

(a) Point-to-Point Transmission Service

86. The first proposed AAR requirement applies to the availability of and requests for ''near-term point-to-point transmission service,'' (under section 15, section 17, and section 18 of the *pro forma* OATT) which we propose to define as point-to-point transmission service ending within 10 days of the date of the request. We propose to require transmission providers to use AARs as the relevant transmission line ratings when (1) evaluating requests for near-term point-to-point transmission service, (2) responding to requests for information on the availability of potential near-term point-to-point transmission service (including requests for ATC or other information related to potential service), and (3) posting ATC or other information related to near-term point-to-point transmission service to the their OASIS site. Through the definition of ''near-term point-to-point transmission service,'' we propose to limit the AAR requirement to requests for transmission service ending within 10 days of the date of the request. We propose this 10-day limit both because it appears to be a reasonable cut-off beyond which forecasts may not be accurate enough for AARs to provide significant value, and because we believe such a limit would reasonably accommodate requests for weekly point-to-point transmission service. However, we seek comment on the appropriateness of this 10-day limit.

87. For other (longer-term) point-to-point transmission service requests, we propose to require transmission providers to use seasonal line ratings as the relevant transmission line ratings when (1) evaluating requests for such service, (2) responding to requests for information on the availability of such service (including requests for ATC or other information related to such potential service), and (3) posting ATC or other information related to such service to their OASIS site. In proposing to require seasonal ratings, however, we propose to limit the duration of a season to three months. We do not propose to require the use of AARs for evaluations of longer-term service because we expect that ambient air temperature forecasts for such future periods have more uncertainty than near-term forecasts, and thus tend to converge to the longer-term ambient air temperature forecasts used in seasonal line ratings.

88. We also propose to require that transmission providers use AARs as the relevant transmission line ratings when determining whether to curtail or interrupt point-to-point transmission service (under section 14.7 of the *pro forma* OATT) if such curtailment or interruption is both necessary because of a reduction in transmission capability anticipated to occur (start and end) within the next 10 days. For determining the necessity of curtailment or interruption of point-to-point transmission service in other (beyond 10 days) situations, we propose to require transmission providers to use seasonal line ratings as the relevant transmission line ratings.

(b) Network Transmission Service

89. For network transmission service, we propose to require transmission providers to evaluate requests to designate network resources (under section 30 of the *pro forma* OATT) or network load (under section 31 of the *pro forma* OATT) based on seasonal line ratings, because such designations are generally long-term requests and seasonal line ratings better reflect conditions over a longer-term than AARs. In proposing to require seasonal ratings for evaluation of network service requests, however, we propose to limit the duration of a season to three months. Additionally, we propose to require that transmission providers use AARs as the relevant transmission line ratings when determining whether to curtail network service or secondary network service (under section 33 of the *pro forma* OATT) or redispatch network service or secondary network service (under sections 30.5 and/or 33 of the *pro forma* OATT), if such curtailment or redispatch is both necessary because of issues related to flow limits on transmission lines and anticipated to occur (start and end) within 10 days of such determination. For determining the necessity of curtailment or redispatch of network service or secondary network service in other (beyond 10 days) situations, we propose to require transmission providers to use seasonal line ratings as the relevant transmission line ratings.

(c) RTOs/ISOs

90. With respect to RTOs/ISOs, we recognize that such entities have Commission-approved variations from the *pro forma* OATT to manage congestion and initiate curtailments and/or redispatch of transmission service within their footprints (although generally not at their borders) through mechanisms such as SCED and SCUC. To accommodate these variations, we propose that RTOs/ISOs comply with the proposed requirements by revising their tariffs to require implementation of AARs within their SCED and SCUC models (and in any relevant related models) in both the day-ahead and real-time markets and any intra-day reliability unit commitment or reliability assessment commitment. For the real-time market, we propose that RTOs/ISOs update the AARs at least hourly. For any point-to-point transmission service offered by RTOs/ISOs (*e.g.,* at their borders), we propose that the AAR requirements discussed above for point-to-point service would apply.

(d) Implementation Timeline

91. We propose to apply the proposed requirements for AARs and seasonal line ratings to all transmission lines, rather than targeting only congested transmission lines, as suggested by some commenters. However, we propose to prioritize the implementation of AARs and seasonal line ratings on historically congested transmission lines. Specifically, we propose to require that AARs and seasonal line ratings be implemented on historically congested lines within one year from the date of the compliance filing for implementation of any final rule, and on all other lines within two years from the date of the compliance filing for implementation of any final rule. For purposes of this proceeding, we propose that the term ''historically congested line'' mean a transmission line that was congested at any time in the five years prior to the effective date of any final rule.[159]

92. We propose to require implementation of AARs on *all* transmission lines and not only on congested lines, because any transmission facility, whether or not historically congested, could become the most limiting element as the system changes, a point argued by MISO.[160] The 2019 FERC NERC Staff Report on the January 2018 South Central cold weather event illustrates this point.[161] As shown in that event, during times of emergency or system stress, flows may change considerably from normal operations and the increased transmission capability provided through AARs may prove valuable even on lines not typically congested.

93. Nevertheless, we recognize that a staggered implementation schedule would allow RTOs/ISOs and transmission owners to focus implementation on transmission lines where AAR implementation is likely to provide the most benefits and gain operational experience with the new AAR requirements prior to full implementation.

(e) Implementation Considerations

94. As a practical matter, the proposed requirements related to AARs and seasonal line ratings would entail specific implementation and on-going obligations on the part of the transmission provider. First, the proposed AAR requirement would necessitate that transmission providers implement an automated system that can take as an input a 10-day forecast of ambient air temperatures at locations across its service area, and calculate up-to-date AAR values for each of the 240 hours in the next 10 days and for each of their transmission lines. Under the proposed requirement, for an AAR value to be ''up-to-date,'' a transmission provider must update AAR values at least every hour. We propose that transmission providers use such AAR values when evaluating requests for transmission service (or developing ATC or other information related to potential transmission service) that will occur within the next 10 days by determining (among other things) whether the transmission provider can accommodate the requested service request without violating the AAR in any hour.

95. Under the proposed AAR requirement, transmission providers would also need to arrange to have the appropriate forecasts available to support the AAR determinations discussed above. Based on information from the 2017 Idaho National Laboratory conference on DLRs, we understand that existing users of advanced line ratings such as AARs or DLRs use a variety of approaches to produce those ratings and the forecasts that underly them. Such approaches range from using vendors to handle most of the tasks related to developing forecasts and related line ratings, to performing much or most of those tasks in-house based on developed expertise and a subscription to a weather data service, with various approaches in between. We do not propose to stipulate the approach that transmission providers take to develop AAR values under our proposed requirements, as long as they execute these responsibilities consistent with good utility practice.

96. The proposed seasonal line rating requirement, as defined in proposed Attachment M, would require similar implementation obligations as for the proposed AAR requirement discussed above, although for seasonal line ratings the transmission provider would be (1) calculating line ratings for future years (instead of calculating ratings for all hours within the next 10 days for AARs), and (2) running the seasonal rating system and calculating seasonal ratings every month (instead of calculating AARs at least every hour).

97. System safety and reliability are paramount to the proposed requirements for transmission line ratings. The proposed tariff language requires the transmission provider to develop transmission line ratings (including the forecasts that underpin AARs and seasonal line ratings) consistent with good utility practice, and the definition of ''Good Utility Practice'' in section 1.15 of the *pro forma* OATT requires consistency with safety and reliability, among other things. While we expect the nature of our proposed requirements to provide transmission providers with the latitude (and obligation) to develop accurate, safe, and reliable line ratings in the first instance, we also propose, in an abundance of caution, to make explicit in the tariff language proposed herein that if a transmission provider determines, consistent with good utility practice, that it must temporarily use a rating different than otherwise required by the tariff in order to ensure the safety or reliability of the transmission system, it may do so. While we expect that such alternate line rating authority would be needed infrequently, if ever, we provide the clarification related to such temporary ratings to resolve any instance where a transmission provider reasonably believes that the tariff requirements for transmission line ratings conflict with system safety or reliability.

ii. Justification and Response to Comments

98. While there are differences across transmission systems, simply accounting for ambient air temperatures in transmission line ratings can reliably increase power transfer capability and significantly lower production costs at a manageable implementation cost.[162] For example, as noted above, Potomac Economics estimates that the benefits to AAR implementation in MISO alone would have produced approximately $94 million and $78 million in reduced congestion costs in 2017 and in 2018, respectively.[163] While several entities note implementation costs as a barrier, these costs are mostly initial investments in upgraded OASIS and/or EMS and ratings databases.[164] Once

[159] Congestion is a characteristic of the transmission system produced by a binding transmission constraint such that the rates for wholesale electric energy, exclusive of losses, at different locations of the transmission system are not equal.

[160] MISO Comments at 2–3.

[161] 2019 FERC and NERC Staff Report, The South Central United States Cold Weather Bulk Electric System Event of January 17, 2018, at 96 (July 2019) (FERC and NERC Staff Report), *https://www.ferc.gov/sites/default/files/2020-05/07-18-19-ferc-nerc-report_0.pdf.*

[162] AEP Comments at 3.

[163] Potomac Economics Comments at 6–7.

[164] While most commenters only mention the need for software changes (AEP Comments at 3) or mention the need for EMS upgrades and ratings databases to ensure AARs are implemented in near-term transmission service (Exelon Comments at 5–6), we also note that OASIS and/or related systems might also need to be upgraded in order to ensure ATC postings for near-term point-to-point transmission service transmission service requests

Continued

these systems are upgraded, adding AARs to additional lines appears to have a minimal incremental cost.[165]

99. Between the two possible approaches to increasing transmission line rating accuracy, AARs and DLRs, our proposal to require transmission providers to implement AARs in near-term transmission service is based on our preliminary finding that an AAR requirement strikes a more appropriate balance between benefits and challenges. While DLRs can represent more accurate transmission line ratings than AARs, DLRs also present additional costs and challenges that AARs do not present. Relative to AARs, these additional costs and challenges include placing sensors in remote locations, ensuring the cyber security of sensors, and various additional costs.[166] However, we seek comment on whether to require transmission providers to implement DLRs across their systems or on certain transmission lines that have the most to benefit from a dynamic rating.

100. In response to comments from OMS and Potomac Economics that suggest the Commission focus on the most heavily congested lines,[167] we note that our proposal, as discussed above, is to prioritize the implementation of AARs on historically congested transmission lines first.

101. In response to concerns articulated by MISO Transmission Owners that day-ahead forecasts could be inaccurate, causing differences between day-ahead and real-time transmission line ratings and therefore uplift,[168] we observe that day-ahead markets already rely upon forecasts for weather to inform next-day load and intermittent generation availability. Instead, we agree with PJM that temperatures can be forecast within a reasonable degree of certainty,[169] and we note that within our proposal transmission providers can (consistent with good utility practice) determine the needed degree of certainty when constructing their forecasts of ambient air temperature. We also preliminarily agree with MISO that, because one of the goals of the day-ahead market is to align prices with those eventually determined in the real-time market, maintaining policy consistency between the day-ahead and real-time markets, where practical, is desirable.[170]

102. We agree with some commenters that not all transmission line ratings are affected by ambient air temperature, either because the technical transfer capability of the limiting conductors and/or limiting transmission equipment is not dependent on ambient air temperature, or because the transmission line's transfer capability is limited by a transmission system limit (such as a system voltage or stability limit) which is not dependent on ambient air temperature.[171] Our proposed *pro forma* OATT language accommodates such transmission lines without requiring unwarranted calculations or updates. Specifically, our proposed *pro forma* OATT language provides that where the transmission provider determines that the rating of a transmission line is not affected by ambient air temperature, the transmission provider may use a transmission line rating for that line that is not an AAR or seasonal line rating.

103. Finally, in response to Exelon's comments that AARs should not be implemented in transmission planning, we agree and reiterate that we are only proposing to require AAR implementation for certain aspects of near-term transmission service.[172]

104. Some entities argue that requiring AAR implementation would lead to operational and reliability concerns. MISO Transmission Owners caution that any AAR requirement could make operational or safety incidents more likely by reducing some of the margin between what a set of transmission facilities can safely handle at that point in time and the current operating levels.[173] ITC and NRECA raise similar reliability questions.[174] WATT contends that at times, AAR implementation may not be conservative enough because AAR implementation can assume too much wind. We do not find these concerns persuasive. We note that the ''safety margin'' cited by commenters is not dependable—it exists only during periods where the ambient air temperature happens to be lower than the temperature assumed when the static or seasonal line rating was calculated. We further note that the margin is lowest precisely during the hottest periods, which represent periods of high system stress when a dependable reliability margin would be most valuable. Furthermore, transmission providers that find they need a reliability margin have existing Commission-approved mechanisms, such as the transmission reliability margin (TRM) component of ATC, for establishing such a margin on a consistent and transparent basis. With respect to assumptions about ambient conditions, under our proposal, transmission owners have latitude, consistent with good utility practice, to develop assumptions about ambient conditions that result in transmission line ratings that reflect what transmission flows the system can safely and reliably accommodate.

105. Moreover, as Exelon points out, AARs would correct the existing occasional overestimations of transmission line ratings during periods where the actual ambient air temperature is greater than the temperature assumed when the rating was calculated. As a result, we believe that implementation of AARs will reduce transmission line ratings when extreme high temperature events occur, reducing the likelihood of inadvertently overloading a transmission line.[175] Moreover, consistent with PJM's and Potomac Economics' comments, we believe that because AARs will typically increase transmission line ratings when actual temperatures are lower than long-term assumptions, the resulting increased transmission capability will provide operators additional flexibility, which promotes reliability.[176] Specifically, by increasing the available transmission capability, system operators would be provided more options to manage congestion, and potentially ameliorate system conditions during an emergency. This is consistent with the 2019 FERC NERC Staff Report on the January 2018 South Central cold weather event, which, for example, identified and recommended adoption of transmission line ratings that better consider ambient temperature conditions. In this instance, implementing AARs would have been one way to potentially introduce additional transmission capability, which would have provided operators additional flexibility to transfer additional power to an area experiencing a potential reliability event, and thereby preventing the need for possible generator redispatch (reducing available contingency reserves), transmission reconfiguration,

also reflect AARs. For this reason, we describe initial costs to include OASIS and/or EMS upgrade costs.

[165] AEP Comments at 2–3.

[166] EEI Comments at 8–10; Exelon Comments at 11–13.

[167] OMS Comments at 2; Potomac Economics Comments at 9–10.

[168] MISO Transmission Owners Comments at 7.

[169] PJM Comments at 3.

[170] MISO Comments at 3.

[171] Dominion Comments at 3; Exelon Comments at 10, 22–23; September 2019 Technical Conference, Day 1 Tr. at 141 (AEP opening statement to Panel Three).

[172] Exelon Comments at 4–5.

[173] MISO Transmission Owners Comments at 6.

[174] ITC Comments at 3–4; NRECA Comments at 3.

[175] *See* Exelon Comments at 9.

[176] *See* PJM Comments at 2; Potomac Economics Comments at 8.

and/or transmission loading relief,[177] and helping mitigate future cold weather reliability events.[178] Implementing AARs may also improve the ability to schedule and perform planned equipment outages for maintenance purposes and project upgrades.[179]

106. Additionally, RTOs/ISOs already periodically request *ad hoc* transmission line rating changes based on differences between actual and assumed ambient temperatures.[180] These requests are typically needed to either manage congestion or support reliable grid operations, but further demonstrate the benefits of AAR implementation. Our proposed AAR requirements would help ensure all market participants are consistently able to access the benefits of such transmission line rating changes.

b. RTO/ISO Capability To Allow Electronic Updates to Line Ratings

107. Having preliminary found above that the use of transmission line ratings that are based on long-term assumptions may not be just and reasonable, we propose, pursuant to section 206 of the FPA, to revise the Commission's regulations to require RTOs/ISOs to establish and implement the systems and procedures necessary to allow transmission owners to electronically update transmission line ratings (for each period for which transmission line ratings are calculated) at least hourly. We propose to require that such data be submitted by transmission owners directly into an RTO's/ISO's EMS through Supervisory Control and Data Acquisition (SCADA) or related systems.[181] Absent these capabilities, the voluntary implementation of DLRs by transmission owners in some RTOs/ISOs would be of limited value, as their more dynamic ratings would not be incorporated into RTO/ISO markets.

108. We expect that many of the systems and procedures RTOs/ISOs would need to develop under this proposal are likely to already be required as part of compliance with the requirement proposed in the previous section for transmission providers to adopt AAR. Nonetheless, we seek comment on the additional costs, if any, needed to comply with this proposed requirement that RTOs/ISOs also be able to accommodate frequently updated transmission line ratings from transmission owners. We also seek comment on whether there is any need to extend this same requirement to transmission providers that operate outside of an RTO/ISO.

109. Finally, we seek comment on whether to require RTOs/ISOs to conduct a one-time study of the cost effectiveness of DLR implementation, and if so, what details/format any such study should include.

c. Emergency Ratings

110. We seek comment on whether to require transmission providers to use unique emergency ratings. As discussed above, we expect that such ratings would not be arbitrarily set equal to the normal ratings, but rather developed from the appropriate, unique technical inputs.[182] We understand that many RTOs/ISOs already have requirements in place for transmission owners to provide emergency ratings. However, we also understand that many of the emergency ratings provided to RTOs/ISOs by transmission owners may be the same as the normal (pre-contingency) ratings. While Potomac Economics explains that 63% of all post-contingency ratings used by MISO are the same as their normal ratings,[183] we do not have comparable information from other RTO/ISO regions or information regarding whether non-RTO/ISO regions tend to use unique emergency ratings. For this reason, we seek comment on the degree to which other transmission providers use or are provided with unique emergency ratings and the emergency rating durations that are commonly used.

111. We recognize that there may be tradeoffs in requiring transmission owners to implement unique emergency ratings and therefore seek comment on the costs and benefits of such a requirement. On one hand, as Potomac Economics explains, emergency ratings result in additional capability being made available in shorter timeframes.[184] Because the transmission system is operated to withstand contingencies, the use of unique emergency ratings, where appropriate, allows for greater flows during normal conditions as well.[185] Such additional transmission capability can provide significant cost savings and afford transmission providers additional flexibility in how to respond to unforeseen events.

112. On the other hand, we recognize that there are concerns that the use of emergency ratings could impact reliability. As Entergy explained in the September 2019 Technical Conference, the use of emergency ratings may degrade affected transmission facilities and ultimately reduce the equipment's useful life.[186] Therefore, we request comment on whether and how a requirement to implement unique emergency rating would impact the useful life of transmission equipment as well as on the feasibility of calculating emergency ratings on transmission equipment other than conductors and transformers.

B. Transparency

113. While some transmission owners and/or operators make both their transmission line ratings and/or ratings methodologies public, many do not. While NERC Regional Entities are responsible for auditing line ratings for compliance with Reliability Standards, FAC–008–3 R8 allows other entities, including other Transmission Service Providers, Planning Coordinators, Reliability Coordinators, or Transmission Operators, to request facility ratings up to 13 months later for internal examination.[187] Such data requests remain non-public. However, NERC has proposed retiring FAC–008–3 R8, which would end the option of non-public facility rating requests.[188]

1. Comments

114. During the September 2019 Technical Conference, some participants expressed a desire for additional transmission line rating transparency. Potomac Economics stated that additional transparency regarding rating methodologies was ''essential'' for administering an AAR requirement.[189] WATT noted that transmission owners may have an incentive to be overly conservative with

[177] FERC and NERC Staff Report at 56–57.

[178] *Id.* at 96.

[179] Commission Staff Paper at 12 (describing outreach discussions that noted that the increased transfer capability, which typically results from *ad hoc* transmission line rating uprates (but would also result from AAR implementation) provides RTOs/ISOs additional options to manage challenges due to maintenance outages).

[180] *Id.* at 10 and 21.

[181] The NERC Glossary defines ''Supervisory Control and Data Acquisition'' as: ''A system of remote control and telemetry used to monitor and control the transmission system.'' NERC, *Glossary of Terms Used in NERC Reliability Standards* (June 2, 2020), *https://www.nerc.com/pa/Stand/Glossary%20of%20Terms/Glossary_of_Terms.pdf.*

[182] *See supra* note 7, at P6 and note 58 at P 46.

[183] Potomac Economics Comments at 5.

[184] *Id.* at 4.

[185] *See supra* P 31.

[186] September 2019 Technical Conference, Day 2 Tr. at 293–294.

[187] NERC Standard MOD–001–1a—Available Transmission System Capability, R9.

[188] NERC, Petition of the North American Electric Reliability Corporation for Approval of Revised and Retired Reliability Standards Under the NERC Standards Efficiency Review, Docket No. RM19–16–000 (filed June 7, 2019). In the SER NOPR, the Commission sought further information on NERC's proposed retirement of FAC–008 R7 and R8 inquiring how such requirements are redundant.

[189] Michael Chiasson, Potomac Economics, *FERC Technical Conference on Managing Line Ratings: AD19–15 Panel 5—Transparency of Transmission Line Rating Methodologies* (Sept. 11, 2019).

their transmission line rating methodologies, and that increasing transparency around these methodologies could improve efficiency.[190] Conversely, many transmission owners at the September 2019 Technical Conference stated that they did not believe additional transparency requirements should be required.[191]

115. Arguing in favor of further transparency, Potomac Economics presented data showing a large variation in transmission line ratings for similar lines. In addition, Potomac Economics pointed to instances when the same ratings were used for a given transmission line in both summer and winter, and instances in which the same ratings were used for both emergency and normal operations. Potomac Economics explained that, in MISO, 30% of lines use the same ratings for summer as they do for winter. Potomac Economics further noted that, at least during the winter, 63% of lines use emergency ratings that are equal to their normal ratings.[192]

116. However, some panelists argued that current transparency levels were adequate. For example, AEP stated that it has shared details of its facility rating methodology and assumptions in past technical industry publications and noted that review of facility rating parameters and assumptions is common in competitive transmission development.[193] MISO Transmission Owners stated that FERC Form No. 715 data in many cases describe the rating methodology.[194] Similarly, the Exelon representative stated that their NERC Regional Entity, ReliabilityFirst, validates some of Exelon's ratings against the ratings methodology Exelon provides. Exelon stated that PJM publishes ratings and guidelines for transmission owners on facility ratings, and that Exelon tries to make their methodology closely conform to PJM's guidelines.[195] NYISO noted that it publishes seasonal rating sets as part of its operating studies, making them available to all interested parties. NYISO also stated that it makes the transmission line ratings to which it secures the system available on a limited basis to all interested parties.[196]

117. Regarding RTO/ISO audits of transmission line ratings, MISO indicated that their audit process was more of a ''sanity check'' rather than a comprehensive validation of line ratings.[197] Similarly, SPP described its use of ''reasonability limits'' that gets the transmission owner to ''sign-off'' on upper and lower bounds to cap the amount by which transmission line ratings can change and thereby ''get rid of possible erroneous data or anything else that shouldn't be used.'' [198]

118. Following the September 2019 Technical Conference, the Commission requested comments on a variety of issues involving transparency. Specifically, the Commission asked whether transmission owners' transmission line rating methodologies and transmission line ratings should be made more transparent, and, if so, how and to what extent. The Commission requested comment on who should have access to this information. The Commission also requested comment on whether transmission owners or other entities, such as NERC Regional Entities or RTOs/ISOs, should be required to develop a database to document each transmission facility's most limiting element, what burdens would be associated with reporting and maintaining such a database, and who should have access to such a database and what levels of confidentiality protections would need to exist for such a limiting elements database. Finally, the Commission asked whether requests from transmission system operators to transmission owners to allow an *ad hoc* increase in transmission line ratings above seasonal or static ratings should be publicly posted.

119. Commenters were divided over the extent to which the Commission should require further transparency with regard to transmission line ratings and transmission line rating changes. Commenters in support of greater transmission line rating methodology transparency include Potomac Economics and Monitoring Analytics, which argue that transmission line rating methodologies should be fully transparent and public.[199] Potomac Economics contends that, should AARs be required, additional transparency regarding rating methodologies and independent oversight is ''essential.'' Potomac Economics states that very little information is shared with MISO on transmission owner rating methodologies or calculations, and that the ability to validate transmission line rating methodologies and calculations by RTOs/ISOs and other transmission providers would enhance reliability by increasing operational and situational awareness and identifying incorrect ratings.[200]

120. OMS agrees that rating methodologies should be as transparent as possible and suggests incorporating the transparency model applied to load forecasting methodologies.[201] Industrial Customers also support methodology transparency, suggesting that the Commission enable market monitors, customers, and other stakeholders (such as state commissions) to have broad access to transmission line rating methodologies, assumptions, and values.[202] PJM supports a requirement for additional transmission line rating transparency, explaining that it currently posts ratings on the PJM website every 15 minutes, including ad hoc changes.[203] DTE states that transmission owners currently have a monopoly on all transmission line rating information, and suggests that enhanced transmission line rating transparency could help identify more cost-effective congestion management solutions.[204] TAPS agrees that greater transmission line rating transparency is essential,[205] encouraging the Commission to enforce greater transmission line rating accuracy through FPA section 206 authority regarding non-discriminatory open access instead of through FPA section 215 authority over reliability.[206] Finally, WATT also suggests that additional transmission line rating transparency is appropriate.[207] WATT contends that transmission owners should face no additional litigations risk if they post and follow their transmission line rating methodologies and are subject to audit by an independent entity. Instead, WATT suggests that more accurate transmission line ratings should reduce litigation risks.[208]

121. Other commenters, while not fully opposed, were less supportive of increased rating methodology transparency, citing reasons such as lack of need and concerns that their ratings will be challenged and subject to increased litigation. Dominion, EEI, Exelon, MISO Transmission Owners, and AEP all generally contend that the

[190] September 2019 Technical Conference, Day 1 Tr. at 23 and 25.

[191] *Id.* at 281–82.

[192] September 2019 Technical Conference, Day 2 Tr. at 311–12.

[193] AEP Comments at 5.

[194] September 2019 Technical Conference, Day 2 Tr. at at 322.

[195] *Id.* at 297.

[196] *Id.* at 243.

[197] *Id.* at 264.

[198] *Id.* at 247.

[199] Potomac Economics Comments at 15; Monitoring Analytics Comments at 4.

[200] Potomac Economics Comments at 14–16.

[201] OMS Comments at 3–4.

[202] Industrial Customers Comments at 13.

[203] PJM Comments at 6–7.

[204] DTE Comments at 4.

[205] TAPS Comments at 8.

[206] *Id.* at 11–12.

[207] WATT Comments at 8–9.

[208] WATT Reply Comments at 3.

current transparency provisions are satisfactory and expressed concerns about challenges or litigation upon publication of transmission line rating methodologies.[209] For example, while Exelon does not oppose posting transmission line ratings, it states that the PJM transparency method is sufficient, suggesting that no further transmission line rating transparency requirements is necessary.[210] MISO Transmission Owners do not believe that increased transparency will improve reliability, adding that information on transmission line rating methodologies is already provided through FERC Form No. 715.[211] MISO Transmission Owners contend that transmission line ratings should not be reviewed or challenged by market participants because such parties do not bear reliability obligations and that justifying transmission owner ratings to market participants would be costly.[212] Similarly, while AEP states that it would support any rule that required the publication of transmission line rating methodologies, AEP also suggests it is unnecessary and requests protection from litigation.[213] Finally, NERC states that it does not see a reliability benefit to increasing the transparency of rating methodologies, noting that it ended its own requirements for sharing rating methodologies in 2013,[214] and that it already audits for compliance with the NERC Reliability Standards.[215]

122. Regarding the transparency of ad hoc line transmission line ratings changes specifically, commenters against further transparency include ITC and MISO. ITC contends they should not be posted because change requests may not be granted,[216] and MISO argues that publicly posting ad hoc ratings would be unduly burdensome with no commensurate benefit.[217]

123. Finally, regarding audits, comments were split on whether additional audits are needed. Those that describe the current auditing and review procedures as adequate include NRECA, NERC, ITC, EEI, Exelon, the MISO Transmission Owners, Dominion, and AEP.[218] These commenters largely believe the current transmission line rating review and audit procedures are sufficient,[219] or that new NERC standards are the appropriate path for auditing changes.[220] Conversely, Industrial Customers, Monitoring Analytics, TAPS, DTE, Potomac Economics, and WATT contend that additional oversight would be beneficial.[221] These commenters argue that lax line ratings oversight is pervasive,[222] that transmission providers should review all line ratings,[223] that NERC Reliability Standards are not suitable for auditing,[224] and that the Commission should occasionally audit.[225]

2. Proposal

124. To remedy any potentially unjust and unreasonable rates caused by inaccurate transmission line ratings, we propose, pursuant to section 206 of the FPA, to revise the Commission's regulations to require transmission owners to share transmission line ratings for each period for which transmission line ratings are calculated (with updated ratings shared each time ratings are calculated) and transmission line rating methodologies with their transmission provider(s) and, in regions served by an RTO/ISO, also with the market monitor(s) of that RTO/ISO.

125. We preliminarily find that this proposal will afford transmission providers and market monitors more operational and situational awareness. Because transmission line ratings and transmission line rating methodologies will be shared only with transmission providers and, in regions served by an RTO/ISO, also with the market monitor(s) of that RTO/ISO rather than with the broader public, we believe that this proposal should address confidentiality concerns as well as litigation risks and compliance burdens.

126. We preliminarily find that this proposal to require transmission owners to share transmission line ratings and transmission line rating methodologies with their transmission provider(s) and, in regions served by an RTO/ISO, also with the market monitor(s) of that RTO/ISO, will enhance operational and situational awareness by ensuring that transmission providers know the effect that changes in ambient temperature would have on transmission line ratings within their system. This information is critical to transmission providers because it allows them to reasonably anticipate increases and decreases in transmission capability and coordinate system operations accordingly. Moreover, we believe that sharing transmission line rating methodologies with transmission providers and, in regions served by an RTO/ISO, also with the market monitor(s) of that RTO/ISO will provide transmission providers and market monitors the information necessary to verify the resulting transmission line ratings and to identify potential errors.

127. We disagree with suggestions that further transparency measures are not needed. To the contrary, the proposed requirement would provide transmission providers and market monitors, where applicable, essential information needed both to validate transmission line ratings and to ensure operational and situational awareness. While current NERC Reliability Standards provide some transparency regarding transmission line ratings and methodologies, current transparency levels may be insufficient to ensure accurate transmission line ratings and, thereby just and reasonable rates. Moreover, while some commenters note that they already provide transmission line rating methodologies pursuant to FERC Form No. 715, Form No. 715 collects information that relates only to transmission line rating methodologies used in long-term transmission planning analyses. By contrast, the proposal would apply to transmission line ratings and methodologies used in near-term transmission service. In addition, while § 37.6 of the Commission's regulations requires all data used to calculate ATC, TTC, TRM, and CBM for congested paths be made publicly available upon request, such data may not necessarily include the transmission line rating methodology and may not be well suited for RTOs/ISOs, which typically make ATC available only at external seams.

128. While we propose to limit the sharing of a transmission owner's transmission line ratings and transmission line rating methodologies

[209] AEP Comments at 5; Dominion Comments at 13; EEI Comments at 11–12; Exelon Comments at 33; MISO Transmission Owners Comments at 18–19.

[210] Exelon Comments at 14–15.

[211] MISO Transmission Owners Reply Comments at 9 (citing FERC Form No. 715, at part IV(D)).

[212] MISO Transmission Owners Comments at 19–20.

[213] AEP Comments at 4–5.

[214] NERC Comments at 4 (citing *Electric Reliability Organization Proposal to Retire Requirements in Reliability Standards,* Order No. 788, 145 FERC ¶ 61,147 (2013) (retiring NERC Reliability Standard FAC–008, R4 and R5)).

[215] *Id.* at 5–6.

[216] ITC Comments at 6.

[217] MISO Comments at 8.

[218] NRECA Comments at 7; NERC Comments at 5–6; ITC Comments at 6; EEI Comments at 10–11; Exelon Comments at 17–19; MISO Transmission Owners Comments at 22–25; Dominion Comments at 16; AEP Comments at 4–5.

[219] ITC Comments at 6; EEI Comments at 10–11; Exelon Comments at 17–19; MISO Transmission Owners Comments at 22–25; Dominion Comments at 16; AEP Comments at 4–5.

[220] NRECA Comments at 7.

[221] Industrial Customer Comments at 10–14; Monitoring Analytics Comments at 4–5; TAPS Comments at 12–13; DTE at 6–8; Potomac Economics Comments at 18; WATT Comments at 9.

[222] Industrial Customer Comments at 13–14.

[223] Monitoring Analytics Comments at 4–5; Potomac Economics Comments at 18.

[224] TAPS Comments at 12–13.

[225] WATT Comments at 9.

to only the transmission owner's transmission providers and, in regions served by an RTO/ISO, also to the market monitor(s) of that RTO/ISO, we acknowledge that sharing such information with other interested parties may yield benefits. Sharing transmission line ratings and transmission line rating methodologies with other interested parties allows for greater transparency, and in the case of transmission providers, may aid efforts to manage congestion along mutual seams and may be beneficial for the study of affected systems during the interconnection process. For this reason, we seek comment on whether to require transmission owners to share upon request their transmission line ratings and rating methodologies with transmission providers other than the transmission owner's own transmission providers. We also seek comment on whether to require transmission owners to make their transmission line ratings and rating methodologies available to other interested stakeholders, including posting information on their OASIS pages or other password protected online forum.

129. In response to arguments that additional auditing of transmission line ratings to ensure accuracy is needed, while we propose no new auditing requirements, we reiterate that the Commission will continue to conduct reviews of line ratings as a component of broader tariff compliance audits.

VI. Compliance

130. We propose that each public utility transmission provider be required to submit a compliance filing within 60 days of the effective date of any final rule. We note that this compliance deadline would be for public utility transmission providers to submit proposed AAR tariff changes, RTOs/ISOs to submit proposed tariff changes designed to maintain systems and procedures needed to allow for the use of AARs and DLRs, and for transmission owners to submit tariff changes implementing the proposed transparency reforms or for each entity to otherwise comply with any final rule. We understand that implementing the reforms required by any final rule in this proceeding may be a complex endeavor. However, we preliminarily find that implementation of these reforms is important to ensure rates are just and reasonable. Therefore, for the AAR reforms, we propose a staggered approach that would prioritize implementation on historically congested lines (within one year from the date of the compliance filing for implementation to any final rule), and propose to require a less aggressive implementation of AARs on all other lines (within two years from the date to the compliance filing for implementation of any final rule). For the DLR reforms, we propose that tariff changes filed in response to a final rule in this proceeding must become effective within one year from the date of the compliance filing for implementation to any final rule. Likewise, for the transparency reforms, we propose that tariff changes filed in response to any final rule in this proceeding must become effective within one year from the date of the compliance filing to any final rule in this proceeding.

131. Some public utility transmission providers may have provisions in their existing *pro forma* OATTs or other document(s) subject to the Commission's jurisdiction that the Commission has deemed to be consistent with or superior to the *pro forma* OATT or are permissible under the independent entity variation standard or regional Reliability Standard. Where these provisions would be modified by this final rule, public utility transmission providers must either comply with this proposed requirements or demonstrate that these previously-approved variations continue to be consistent with or superior to the *pro forma* OATT as modified by the proposed requirements or continue to be permissible under the independent entity variation standard or regional Reliability Standard.[226]

132. We seek comment on whether 60 days is sufficient time for public utility transmission providers to develop new tariff language in response to the final rule.

133. To the extent that any public utility transmission provider believes that it already complies with the reforms proposed in this proceeding, the public utility transmission provider would be required to demonstrate how it complies in the compliance filing required 60 days after the effective date of any final rule in this proceeding. To the extent that any public utility transmission provider believes that its existing market rules are consistent with or superior to the reforms adopted in any final rule, the Commission will entertain those at that time.

134. As discussed above, we propose the following compliance timelines for the proposals in this NOPR:

Proposed due date (from the date of the compliance filing to any eventual final rule)	Proposed compliance obligation
1 year	Requirement for Transmission Providers to implement AARs on historically congested transmission lines.
2 years	Requirement for Transmission Providers to implement AARs on all other transmission lines.
1 year	Requirement for RTOs/ISOs to establish and implement the systems and procedures necessary to allow transmission owners to electronically update transmission line ratings at least hourly.
1 year	Requirement for transmission owners to share transmission line ratings and transmission line rating methodologies with their respective transmission provider(s) and, in RTOs/ISOs, their respective market monitor(s).

VII. Information Collection Statement

135. The information collection requirements contained in this NOPR are subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act of 1995.[227] OMB's regulations require approval of certain information collection requirements imposed by agency rules.[228] Upon approval of a collection of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

136. This NOPR would, pursuant to section 206 of the FPA, reform the *pro forma* Open Access Transmission Tariff (OATT) and the Commission's regulations to improve the accuracy and transparency of transmission line

[226] See 18 CFR 35.28(c)(1)(vi).

[227] 44 U.S.C. 3507(d).

[228] 5 CFR 1320.11.

ratings used by transmission providers. These provisions would affect the following collections of information: FERC–516H, Pro Forma Open Access Transmission Tariff (Control No. 1902–0297); and FERC–725A, Mandatory Reliability Standards for the Bulk-Power System (Control No. 1902–0244).

137. Interested persons may obtain information on the reporting requirements by contacting Ellen Brown, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426 via email (*DataClearance@ferc.gov*) or telephone ((202) 502–8663).

138. The Commission solicits comments on the Commission's need for this information, whether the information will have practical utility, the accuracy of the burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

139. Please send comments concerning the collections of information and the associated burden estimates to the Office of Information and Regulatory Affairs, Office of Management and Budget, through *www.reginfo.gov/public/do/PRAMain.* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Numbers 1902–0096 and 1902–0244 in the subject line of your comments. Comments should be sent within 60 days of publication of this notice in the **Federal Register**.

140. Please submit a copy of your comments on the information collections to the Commission via the eFiling link on the Commission's website at *http://www.ferc.gov.* Comments on the information collection that are sent to FERC should refer to RM20–16–000.

141. *Title:* Pro Forma Open Access Transmission Tariff (FERC–516H) and Mandatory Reliability Standards for the Bulk-Power System (FERC–725A).

142. *Action:* Proposed revision of collections of information in accordance with Docket No. RM20–16–000 and request for comments.

143. *OMB Control Nos.:* 1902–0297 (FERC–516H) and 1902–0244 (FERC–725A).

144. *Respondents:* Transmission owners, transmission service providers, generation owners, and RTOs/ISOs.

145. *Frequency of Information Collection:* One time and annually.

146. *Necessity of Information:* The proposed reform to the *pro forma* Open Access Transmission Tariff (OATT) and the Commission's regulations, if adopted, would improve the accuracy and transparency of transmission line ratings used by transmission providers. Specifically, the proposal would require: (1) Transmission providers to implement ambient-adjusted ratings on the transmission lines over which they provide transmission service; (2) Regional Transmission Organizations (RTOs) and Independent System Operators (ISOs) to establish and implement the systems and procedures necessary to allow transmission owners to electronically update transmission line ratings at least hourly; and (3) transmission owners to share transmission line ratings and transmission line rating methodologies with their respective transmission provider(s) and, in RTOs/ISOs, with their respective market monitor(s).

147. *Internal Review:* The Commission has reviewed the changes and has determined that such changes are necessary. These requirements conform to the Commission's need for efficient information collection, communication, and management within the energy industry. The Commission has specific, objective support for the burden estimates associated with the information collection requirements.

148. Our estimates are based on the NERC Compliance Registry as of September 3, 2020, which indicates that 78 transmission service providers,[229] 797 generator owners,[230] and 289 transmission owners are registered within the United States and are subject to this proposed rulemaking.[231] There are also 6 RTOs/ISOs in the United States subject to this proposed rulemaking.

149. *Public Reporting Burden:* The burden and cost estimates below are based on the need for applicable entities to revise documentation, already required by the *pro forma* OATT and the Commission's regulations as well as the NERC Reliability Standard FAC–008–3, Facility Ratings.[232]

150. The Commission estimates that the NOPR would affect the burden [233] and cost of FERC–516H and FERC–725A as follows:

PROPOSED CHANGES IN NOPR IN DOCKET NO. RM20–16–000

Area of modification	Number of respondents	Annual estimated number of responses per respondent	Annual estimated number of responses (column B × column C)	Average burden hours & cost [234] per response	Total estimated burden hours & total estimated cost (column D × column E)
A.	B.	C.	D.	E.	F.
FERC–516H, Pro Forma Open Access Transmission Tariff (Control No. 1902–0297)					
For point-to-point transmission service requests within ten days, use AARs in determining ATC and TTC. (One-Time Burden in Year 1).	129 (TOs [235] not in RTOs/ISOs [236]).	1	129	1,440 hrs; $120,485	185,760 hrs; $15,542,539.

[229] The transmission service provider (TSP) function is a NERC registration function which is similar to the transmission provider that is referenced in the pro forma OATT. The TSP function is being used as a proxy to estimate the number of transmission providers that are impacted by this proposed rulemaking.

[230] Of the 797 generator owners listed in the September 3, 2020 NERC Compliance Registry, we estimate that 10% of all NERC registered generator owners own facilities between the step-up transformer and the point of interconnection. For this reason, we estimate that only 80 generator owners are affected.

[231] The number of entities listed from the NERC Compliance Registry reflects the omission of the Texas RE registered entities.

[232] The burden associated with Reliability Standard FAC–008–3, approved by the Commission under section 215 of the FPA, is included in the OMB-approved inventory for FERC–725A. Reliability Standard FAC–008–3 has not been revised in this proceeding however the requirements proposed in this proposed rulemaking under section 206 of the FPA affects the burden for three requirements in Reliability Standard FAC–008–3.

[233] ''Burden'' is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

PROPOSED CHANGES IN NOPR IN DOCKET NO. RM20–16–000—Continued

Area of modification	Number of respondents	Annual estimated number of responses per respondent	Annual estimated number of responses (column B × column C)	Average burden hours & cost [234] per response	Total estimated burden hours & total estimated cost (column D × column E)
A.	B.	C.	D.	E.	F.
Where network transmission service is provided, use hourly AARs to determine curtailment or redispatch of network service. (One-Time Burden in Year 1).	160 (to account for those TOs in RTOs/ISOs that are not included in the line above).	1	160	1,440 hrs; $120,485	230,400 hrs; $19,277,568.
Implement software and systems to communicate the required line ratings with relevant parties. (One-Time Burden in Year 1).	78 (TSPs [237])	1	78	320 hrs; $26,774	24,960 hrs; $2,088,403.
RTOs/ISOs implement software with the ability to accommodate AARs in both the day-ahead and real-time markets on an hourly basis. (One-Time Burden in Year 1).	6 (RTOs/ISOs) ..	1	6	320 hrs; $26,774	1920 hrs; $160,646.
Compliance Filings (One-Time Burden in Year 1).	295 (TOs and (RTOs/ISOs).	1	295	160 hrs; $13,387	47,200 hrs; $3,949,224.
Compliance Filings (One-Time Burden in Year 2).	289 (TOs)	1	289	160 hrs; $13,387	46,240 hrs; $3,868,901.
RTOs/ISOs establish the systems and procedures necessary to allow transmission owners to update line ratings on an hourly basis directly into an EMS. (One-Time Burden in Year 1).	6 (RTOs/ISOs) ..	1	6	960 hrs; $80,323	5,760 hrs; $481,939.
Transmission owners update forecasts and ratings, and share transmission line ratings and facility ratings methodologies w/transmission providers and, if applicable, RTOs/ISOs & market monitors (Year 1 and Ongoing).	289 (TOs)	1	289	160 hrs; $13,387	46,240 hrs; $3,868,901.
Net Subtotal for FERC–516H (Year 1).	.....	.....	373	4,800 hrs; $401,616	542,240 hrs; $45,369,221.
Net Subtotal for FERC–516H (Year 2).	.....	.....	289	320 hrs; $26,774	92,480 hrs; $7,737,802.
Net Subtotal for FERC–516H (Ongoing).	.....	.....	289	160 hrs; $13,387	46,240 hrs; $3,868,901.
FERC–725A, Mandatory Reliability Standards for the Bulk-Power System—Reliability Standard FAC–008–3					
Review and update facility ratings methodology, Requirements R2 and R3. (One-Time Burden in Year 1).	369 (TO & GO) [238].	1	369	40 hrs; $3,347	14,760 hrs; $1,234,969.
Determine facility ratings consistent with methodology, Requirement R6. (Burden in Year 1 and Ongoing).	369 (TO & GO) [238].	1	369	8 hrs; $669	2,952 hrs; $246,994.
Net Subtotal for FERC–725A (Year 1).	.....	.....	369	48 hrs; $4,016	17,712 hrs; $1,481,963.
Net Subtotal for FERC–725A (Ongoing).	.....	.....	369	8 hrs; $669	2,952 hrs; $246,994.

151. For the purposes of estimating burden in this NOPR, we conservatively

[234] The hourly cost (for salary plus benefits) uses the figures from the Bureau of Labor Statistics (BLS) for three positions involved in the reporting and recordkeeping requirements. These figures include salary (based on BLS data for May 2019, *http://bls.gov/oes/current/naics2_22.htm*) and benefits (based on BLS data for December 2019; issued March 19, 2020, *http://www.bls.gov/news.release/ecec.nr0.htm*) and are Manager (Code 11–0000 $97.15/hour), Electrical Engineer (Code 17–2071 $70.19/hour), and File Clerk (Code 43–4071 $34.79/hour). The hourly cost for the reporting requirements ($83.67) is an average of the cost of a manager and engineer. The hourly cost for recordkeeping requirements uses the cost of a file clerk.

[235] Transmission Owners. While the proposed AAR reforms apply to transmission providers, we compute an implementation burden based on the number of transmission owners because transmission owners typically calculate

estimate these values based on the maximum number of entities and burden. As discussed elsewhere in this NOPR, some entities may, for example, already use AARs in their existing operations, in which case the actual burden associated with specific proposals associated with the use of AARs would be lower than the estimate. On the other hand, we also acknowledge that changing approaches to facility ratings may require extra testing and training for some entities to ensure reliable operations and gain familiarity with the approach. We estimate that the majority of the additional burden associated with this NOPR occurs in the first year, and that, once established, the ongoing burden will closely approach the existing burden of operating the transmission system. We seek comment on the estimates in the table above and the assumptions described here.

VIII. Environmental Analysis

152. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[239] We conclude that neither an Environmental Assessment nor an Environmental Impact Statement is required for this NOPR under § 380.4(a)(15) of the Commission's regulations, which provides a categorical exemption for approval of actions under sections 205 and 206 of the FPA relating to the filing of schedules containing all rates and charges for the transmission or sale of electric energy subject to the Commission's jurisdiction, plus the classification, practices, contracts, and regulations that affect rates, charges, classification, and services.[240]

IX. Regulatory Flexibility Act

153. The Regulatory Flexibility Act of 1980 [241] generally requires a description and analysis of proposed and final rules that will have significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) sets the threshold for what constitutes a small business. Under SBA's size standards,[242] RTOs/ISOs, planning regions, and transmission owners all fall under the category of Electric Bulk Power Transmission and Control (NAICS code 221121), with a size threshold of 500 employees (including the entity and its associates).[243]

154. The six RTOs/ISOs (SPP, MISO, PJM, ISO–NE, NYISO, and CAISO) each employ more than 500 employees and are not considered small.

155. We estimate that 337 transmission owners and six planning authorities are also affected by the NOPR. Using the list of transmission owners from the NERC Registry (dated September 3, 2020), we estimate that approximately 68% of those entities are small entities.

156. We estimate that 80 generation owners own facilities between the step-up transformer and the point of interconnection. We estimate again that 68% of these are small entities.

157. We estimate that 78 transmission service providers are affected by the NOPR. We estimate again that 68% of these are small entities.

158. We estimate additional one-time costs associated with the NOPR (as shown in the table above) of:

—$93,710 for each RTO/ISO (FERC–516H)
—$134,541 for each transmission owner (FERC–516H)
—$3,347 for each transmission owner (FERC–725A)
—$13,387 for each affected generation owner (FERC–516H)
—$3,347 for each generation owner (FERC–725A)
—$26,774 for each transmission service provider (FERC–516H)

159. Therefore, the estimated additional one-time cost per entity ranges from $16,734 to $137,219.

160. We estimate that the majority of the additional burden associated with this NOPR occurs in the first year (as shown in the table above), and that, once established, the ongoing burden will closely approach the existing burden of operating the transmission system.

161. According to SBA guidance, the determination of significance of impact ''should be seen as relative to the size of the business, the size of the competitor's business, and the impact the regulation has on larger competitors.'' [244] We do not consider the estimated cost to be a significant economic impact. As a result, we certify that the proposals in this NOPR will not have a significant economic impact on a substantial number of small entities.

X. Comment Procedures

162. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due January 22, 2021. Comments must refer to Docket No. RM20–16–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

163. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's website at *http://www.ferc.gov.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

164. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC, 20426.

165. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

XI. Document Availability

166. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). At this time, the Commission has suspended access to the Commission's Public Reference

transmission line ratings and are therefore likely to be the entities that update computations to determine the effect of changing ambient air temperatures on transmission line ratings.

[236] Regional Transmission Organizations/Independent System Operators.

[237] Transmission Service Providers.

[238] This number reflects 289 transmission owners and 10% of the 797 generator owners estimated to own facilities between the step-up transformer and the point of interconnection.

[239] Regulations Implementing National Environmental Policy Act of 1969, Order No. 486, 52 FR 47,897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987).

[240] 18 CFR 380.4(a)(15).

[241] 5 U.S.C. 601–612.

[242] 13 CFR 121.201.

[243] The RFA definition of ''small entity'' refers to the definition provided in the Small Business Act, which defines a ''small business concern'' as a business that is independently owned and operated and that is not dominant in its field of operation. The Small Business Administrations' regulations at 13 CFR 121.201 define the threshold for a small Electric Bulk Power Transmission and Control entity (NAICS code 221121) to be 500 employees. See 5 U.S.C. 601(3), citing to Section 3 of the Small Business Act, 15 U.S.C. 632.

[244] U.S. Small Business Administration, *A Guide for Government Agencies How to Comply with the Regulatory Flexibility Act,* at 18 (May 2012), *https://www.sba.gov/sites/default/files/advocacy/rfaguide_0512_0.pdf.*

Room due to the President's March 13, 2020 proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19).

167. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

168. User assistance is available for eLibrary and the Commission's website during normal business hours from the Commission's Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202)502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

List of Subjects in 18 CFR Part 35

Electric power rates, Electric utilities, Reporting and recordkeeping requirements.

By direction of the Commission.

Issued: November 19, 2020.

Kimberly D. Bose,

Secretary.

In consideration of the foregoing, the Commission is proposing to amend Part 35, Chapter I, Title 18, Code of Federal Regulations, as follows.

PART 35—FILING OF RATE SCHEDULES AND TARIFFS

■ 1. The authority citation for part 35 continues to read as follows:

Authority: 16 U.S.C. 791a-825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

■ 2. Amend § 35.28 as follows:

■ a. In paragraph (b), revise paragraphs (10) and (11) and add paragraphs (12) and (13);

■ b. In paragraph (c), add paragraph (5); and

■ c. In paragraph (g), revise the paragraph (g) subject heading, paragraph (12) subject heading, and paragraph (12)(i).

The additions and revisions read as follows:

§ 35.28 Non-discriminatory open access transmission tariff.

* * * * *

(b) * * *

(10) *Ambient-adjusted line rating* means a transmission line rating that applies to a time period of not greater than one hour and reflects an up-to-date forecast of ambient air temperature across the time period to which the rating applies.

(11) *Dynamic line rating* means a transmission line rating that applies to a time period of not greater than one hour and reflects up-to-date forecasts of inputs such as (but not limited to) ambient air temperature, wind, solar irradiance intensity, transmission line tension, or transmission line sag.

(12) *Energy Management System* (EMS) means a computer control system used by electric utility dispatchers to monitor the real-time performance of the various elements of an electric system and to dispatch, schedule, and/or control generation and transmission facilities.

(13) *Supervisory Control and Data Acquisition* (SCADA) means a computer system that allows an electric system operator to remotely monitor and control elements of an electric system.

(c) * * *

(5) Every public utility that owns, controls, or operates facilities must have on file a joint pool-wide or system-wide open access transmission tariff, which provides for the following to be shared with its transmission provider(s) (and its Market Monitoring Unit(s), if applicable):

(i) Transmission line ratings for each period for which transmission line ratings are calculated (with updated ratings shared each time ratings are calculated); and

(ii) Written transmission line rating methodologies used to calculate the transmission line ratings provided under paragraph (c)(5)(i).

* * * * *

(g) *Tariffs and operations of Commission-approved independent system operators and regional transmission organizations—*

* * * * *

(12) *Transmission line ratings. (i)* Each Commission-approved independent system operator or regional transmission organization must establish and maintain systems and procedures necessary to allow transmission owners to electronically update transmission line ratings (for each period for which transmission line ratings are calculated) at least hourly, with such data submitted by transmission owners directly into the independent system operator's or regional transmission organization's Energy Management System through Supervisory Control And Data Acquisition or related systems.

Note: The following appendix will not be published in the Code of Federal Regulations.

Appendix A: List of Short Names/Acronyms of Commenters

Short name/acronym	Commenter
AEP	American Electric Power Company, Inc.
AWEA	American Wind Energy Association.
CAISO	California Independent System Operator Corporation.
Dominion	Dominion Energy Services, Inc.
DESC	Dominion Energy South Carolina.
DEV	Dominion Energy Virginia.
DTE	DTE Electric Company.
EEI	Edison Electric Institute.
ELCON	Electricity Consumers Resource Council.
Entergy	Entergy Services, LLC.
ERCOT	Electric Reliability Council of Texas.
Exelon	Exelon Corporation.
IEEE	The Institute of Electrical and Electronics Engineers.
Industrial Customers	Includes ELCON, the PJM Industrial Customers Coalition, and the Coalition of MISO Transmission Customers.
ITC	International Transmission Company d/b/a ITCTransmission, Michigan Electric Transmission Company, LLC, ITC Midwest LLC, and ITC Great Plains, LLC.
MISO	Midcontinent Independent System Operator, Inc.

Short name/ acronym	Commenter
MISO Transmission Owners.	The MISO Transmission Owners consists of: Ameren Services Company, as agent for Union Electric Company d/b/a Ameren Missouri, Ameren Illinois Company d/b/a Ameren Illinois and Ameren Transmission Company of Illinois; American Transmission Company LLC; Big Rivers Electric Corporation; Central Minnesota Municipal Power Agency; City Water, Light & Power (Springfield, IL); Cleco Power LLC; Cooperative Energy; Dairyland Power Cooperative; Duke Energy Business Services, LLC for Duke Energy Indiana, LLC; East Texas Electric Cooperative; Great River Energy; Hoosier Energy Rural Electric Cooperative, Inc.; Indiana Municipal Power Agency; Indianapolis Power & Light Company; International Transmission Company d/b/a ITCTransmission; ITC Midwest LLC; Lafayette Utilities System; Michigan Electric Transmission Company, LLC; MidAmerican Energy Company; Minnesota Power (and its subsidiary Superior Water, L&P); Missouri River Energy Services; MontanaDakota Utilities Co.; Northern Indiana Public Service Company LLC; Northern States Power Company, a Minnesota corporation, and Northern States Power Company, a Wisconsin corporation, subsidiaries of Xcel Energy Inc.; Northwestern Wisconsin Electric Company; Otter Tail Power Company; Prairie Power Inc.; Southern Illinois Power Cooperative; Southern Indiana Gas & Electric Company (d/b/a Vectren Energy Delivery of Indiana); Southern Minnesota Municipal Power Agency; Wabash Valley Power Association, Inc.; and Wolverine Power Supply Cooperative, Inc.
NERC	North American Electric Reliability Corporation.
NRECA	National Rural Electric Cooperative Association.
NYISO	New York Independent System Operator, Inc.
ISO–NE	ISO New England Inc.
ITC	ITC Transmission.
OMS	Organization of MISO States.
PJM	PJM Interconnection, L.L.C.
SPP	Southwest Power Pool, Inc.
TAPS	Transmission Access Policy Study Group.
WATT	Working for Advanced Transmission Technologies.

Note: The following appendix will not be published in the Code of Federal Regulations.

Appendix B: *Pro Forma* Open Access Transmission Tariff

ATTACHMENT M

Transmission Line Ratings

General

The Transmission Provider will implement Ambient-Adjusted Ratings and Seasonal Line Ratings on the transmission lines over which it provides Transmission Service, as provided below.

Definitions

The following definitions apply for purposes of this Attachment:

(1) ''Transmission Line Rating'' means the maximum transfer capability of a transmission line, computed in accordance with a written line rating methodology and consistent with Good Utility Practice, considering the technical limitations (such as thermal flow limits) on conductors and relevant transmission equipment, as well as technical limitations of the Transmission System (such as system voltage and stability limits). Relevant transmission equipment may include, but is not limited to, circuit breakers, line traps, and transformers.

(2) ''Ambient-Adjusted Rating'' (AAR) means a Transmission Line Rating that:

(a) Applies to a time period of not greater than one hour.

(b) Reflects an up-to-date forecast of ambient air temperature across the time period to which the rating applies.

(c) Is calculated at least each hour, if not more frequently.

(3) ''Seasonal Line Rating'' means a Transmission Line Rating that:

(a) Applies to a specified season, where seasons are defined by the Transmission Provider to not include more than three months in each season.

(b) Reflects an up-to-date forecast of ambient air temperature across the relevant season over which the rating applies.

(c) Is calculated monthly, if not more frequently, for each season in the future for which Transmission Service can be requested.

(4) ''Near-Term Point-To-Point Transmission Service'' means Point-To-Point Transmission Service which ends not more than ten days after the Transmission Service request date. When the description of obligations below refers to either a request for information about the availability of potential Transmission Service (including, but not limited to, a request for ATC), or to the posting of ATC or other information related to potential service, the date that the information is requested or posted will serve as the Transmission Service request date.

(5) ''Historically Congested Transmission Line'' means a transmission line that was congested (*i.e.,* whose Transmission Line Rating was a binding constraint) at any time on or between [insert date five years prior to the effective date of this final rule] and [insert the effective date of this final rule].

System Reliability

If the Transmission Provider reasonably determines, consistent with Good Utility Practice, that the temporary use of a Transmission Line Rating different than would otherwise be required under the Obligations of the Transmission Provider set forth in this Attachment is necessary to ensure the safety and reliability of the Transmission System, then the Transmission Provider will use such an alternate rating.

Obligations of Transmission Provider

After the relevant dates specified below in the Implementation section of this Attachment, the Transmission Provider will have the following obligations.

The Transmission Provider must use AARs as the relevant Transmission Line Ratings when performing any of the following functions: (1) Evaluating requests for Near-Term Point-To-Point Transmission Service, (2) responding to requests for information on the availability of potential Near-Term Point-To-Point Transmission Service (including requests for ATC or other information related to potential service), or (3) posting ATC or other information related to Near-Term Point-To-Point Transmission Service to the Transmission Provider's OASIS site.

The Transmission Provider must use AARs as the relevant Transmission Line Ratings when determining the necessity of curtailment or interruption of Point-To-Point Transmission Service (under section 14.7) if such curtailment or interruption is both necessary because of issues related to flow limits on transmission lines and anticipated to occur (start and end) within the next 10 days. For determining the necessity of curtailment or interruption of Point-To-Point Transmission Service in other situations, the Transmission Provider must use Seasonal Line Ratings as the relevant Transmission Line Ratings.

The Transmission Provider must use AARs as the relevant Transmission Line Ratings when determining the necessity of curtailment (under section 33) or redispatch (under sections 30.5 and/or 33) of Network Integration Transmission Service or secondary service if such curtailment or redispatch is both necessary because of issues related to flow limits on transmission lines and anticipated to occur (start and end) within the following 10 days. For determining the necessity of curtailment or redispatch of Network Integration Transmission Service or secondary service in other situations, the Transmission Provider must use Seasonal Line Ratings as the relevant Transmission Line Ratings.

The Transmission Provider must use Seasonal Line Ratings as the relevant

Transmission Line Ratings when evaluating requests for any Transmission Service not otherwise covered above in this section (including, but not limited to, requests for non-Near-Term Point-To-Point Transmission Service or requests to designate or change the designation of Network Resources or Network Load), and when developing any ATC or other information posted or provided to potential customers related to such services.

In developing forecasts of ambient air-temperature for AARs and Seasonal Line Ratings, the Transmission Provider must develop such forecasts consistent with Good Utility Practice and on a non-discriminatory basis.

Exception: Where the Transmission Provider determines, consistent with Good Utility Practice, that the Transmission Line Rating of a transmission line is not affected by ambient air temperature, the Transmission Provider may use a Transmission Line Rating for that line that is not an AAR or Seasonal Line Rating. Examples of such a transmission line include (1) a transmission line where the technical transfer capability of the limiting conductors and/or limiting transmission equipment is not dependent on ambient air temperature, and (2) a transmission line whose transfer capability is limited by a Transmission System limit (such as a system voltage or stability limit) which is not dependent on ambient air temperature.

Implementation

The Transmission Provider will implement the use of AARs and Seasonal Line Ratings as required in this Attachment in accordance with the following schedule.

Prior to these implementation dates, the requirements above will not apply.

(1) Historically Congested Transmission Lines: Transmission Provider will complete implementation of AARs and Seasonal Line Ratings for Historically Congested Transmission Lines not later than [insert date one year after the date of the compliance filing to the final rule].

(2) Other Transmission Lines: Transmission Provider will complete implementation of AARs and Seasonal Line Ratings for any other transmission lines not later than [insert date two years after the date of the compliance filing to the final rule].

[FR Doc. 2020–26107 Filed 1–19–21; 8:45 am]

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Part III

Department of Health and Human Services

45 CFR Parts 160 and 164

Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 160 and 164

[Docket No.: HHS–OCR–0945–AA00]

RIN 0945–AA00

Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement

AGENCY: Office for Civil Rights, Office of the Secretary, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Department of Health and Human Services (HHS or ''the Department'') is issuing this Notice of Proposed Rulemaking (NPRM) to modify the Standards for the Privacy of Individually Identifiable Health Information (Privacy Rule) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). These modifications address standards that may impede the transition to value-based health care by limiting or discouraging care coordination and case management communications among individuals and covered entities (including hospitals, physicians, and other health care providers, payors, and insurers) or posing other unnecessary burdens. The proposals in this NPRM address these burdens while continuing to protect the privacy and security of individuals' protected health information.

DATES: Comments due on or before March 22, 2021.

ADDRESSES:

You may submit comments to this proposed rule, identified by RIN 0945–AA00 by any of the following methods:

- *Federal eRulemaking Portal.* You may submit electronic comments at *http://www.regulations.gov* by searching for the Docket ID number HHS–OCR–0945–AA00. Follow the instructions *http://www.regulations.gov* online for submitting comments through this method.
- *Regular, Express, or Overnight Mail:* You may mail comments to U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement NPRM, RIN 0945–AA00, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201.

All comments received by the methods and due date specified above will be posted without change to content to *http://www.regulations.gov,* including any personal information provided about the commenter, and such posting may occur before or after the closing of the comment period.

The Department will consider all comments received by the date and time specified in the **DATES** section above, but, because of the large number of public comments normally received on **Federal Register** documents, the Department is not able to provide individual acknowledgments of receipt.

Please allow sufficient time for mailed comments to be timely received in the event of delivery or security delays. Electronic comments with attachments should be in Microsoft Word or Portable Document Format (PDF).

Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

Docket: For complete access to background documents or posted comments, go to *http://www.regulations.gov* and search for Docket ID number HHS–OCR–0945–AA00.

FOR FURTHER INFORMATION CONTACT: Marissa Gordon-Nguyen at (800) 368–1019 or (800) 537–7697 (TDD).

SUPPLEMENTARY INFORMATION:

The discussion below includes an executive summary, a description of the statutory and regulatory background of the proposed rule, a section-by-section discussion of the need for the proposed rule, a description of the proposed modifications, and a regulatory impact statement and other required regulatory analyses. The Department solicits public comment on all aspects of the proposed rule. The Department requests that persons commenting on the provisions of the proposed rule precede their discussion of any particular provision or topic with a citation to the section of the proposed rule being discussed.

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I. Executive Summary

A. Overview

In this notice of proposed rulemaking (NPRM), the Department proposes modifications to the Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule), issued pursuant to section 264 of the Administrative Simplification provisions of title II, subtitle F, of HIPAA.[1] The Privacy Rule is one of several rules, collectively known as the HIPAA Rules,[2] that protect the privacy and security of individuals' medical records and other protected health information (PHI), *i.e.,* individually identifiable health information maintained or transmitted by or on behalf of HIPAA covered entities (*i.e.,* health care providers who conduct covered health care transactions electronically, health plans, and health care clearinghouses).

The proposals in this NPRM support the Department's Regulatory Sprint to Coordinated Care (Regulatory Sprint), described in detail below. Specifically, the proposals in this NPRM would amend provisions of the Privacy Rule that could present barriers to coordinated care and case management—or impose other regulatory burdens without sufficiently compensating for, or offsetting, such burdens through privacy protections. These regulatory barriers may impede the transformation of the health care system from a system that pays for procedures and services to a system of value-based health care that pays for quality care.

The Department, which delegated the authority to administer HIPAA privacy standards to the Office for Civil Rights (OCR), developed many of the proposals contained in this NPRM after careful consideration of public input received in response to the Department's December 2018 *Request for Information on Modifying HIPAA Rules to Improve Coordinated Care* (2018 RFI).[3]

B. Summary of Major Provisions

The Department proposes to modify the Privacy Rule to increase permissible disclosures of PHI and to improve care coordination and case management by:

- Adding definitions for the terms electronic health record (EHR) and personal health application.
- Modifying provisions on the individuals' right[4] of access to PHI by:
  - Strengthening individuals' rights to inspect their PHI in person, which includes allowing individuals to take notes or use other personal resources to view and capture images of their PHI;
  - shortening covered entities' required response time to no later than 15 calendar days (from the current 30 days) with the opportunity for an extension of no more than 15 calendar days (from the current 30-day extension);
  - clarifying the form and format required for responding to individuals' requests for their PHI;
  - requiring covered entities to inform individuals that they retain their right to obtain or direct copies of PHI to a third party when a summary of PHI is offered in lieu of a copy;
  - reducing the identity verification burden on individuals exercising their access rights;
  - creating a pathway for individuals to direct the sharing of PHI in an EHR among covered health care providers and health plans, by requiring covered health care providers and health plans to submit an individual's access request to another health care provider and to receive back the requested electronic copies of the individual's PHI in an EHR;
  - requiring covered health care providers and health plans to respond to certain records requests received from other covered health care providers and health plans when directed by individuals pursuant to the right of access;
  - limiting the individual right of access to direct the transmission of PHI to a third party to electronic copies of PHI in an EHR;[5]
  - specifying when electronic PHI (ePHI) must be provided to the individual at no charge;
  - amending the permissible fee structure for responding to requests to direct records to a third party; and
  - requiring covered entities to post estimated fee schedules on their websites for access and for disclosures with an individual's valid authorization[6] and, upon request, provide individualized estimates of fees for an individual's request for copies of PHI, and itemized bills for completed requests.
- Amending the definition of health care operations to clarify the scope of permitted uses and disclosures for individual-level care coordination and case management that constitute health care operations.
- Creating an exception to the ''minimum necessary'' standard for individual-level care coordination and case management uses and disclosures. The minimum necessary standard generally requires covered entities to limit uses and disclosures of PHI to the minimum necessary needed to accomplish the purpose of each use or disclosure. This proposal would relieve covered entities of the minimum necessary requirement for uses by, disclosures to, or requests by, a health plan or covered health care provider for care coordination and case management activities with respect to an individual, regardless of whether such activities

[1] Subtitle F of title II of HIPAA (Pub. L. 104–191,110 Stat. 1936 (August 21, 1996)) added a new part C to title XI of the Social Security Act, Public Law 74–271, 49 Stat. 620 (August 14, 1935), (*see* sections 1171–1179 of the Social Security Act, 42 U.S.C. 1320d–1320d–8)), as well as promulgating section 264 of HIPAA (codified at 42 U.S.C. 1320d–2 note), which authorizes the Secretary to promulgate regulations with respect to the privacy of individually identifiable health information. The Privacy Rule has subsequently been amended pursuant to the Genetic Information Nondiscrimination Act (GINA), title I, section 105, Public Law 110–233, 122 Stat. 881 (May 21, 2008) and the Health information Technology for Economic and Clinical Health (HITECH) Act, Public Law 111–5, 123 Stat. 226 (February 17, 2009).

[2] *See also* the HIPAA Security Rule, 45 CFR parts 160 and 164, subparts A and C, the HIPAA Breach Notification Rule, 45 CFR part 164, subpart D, and the HIPAA Enforcement Rule, 45 CFR part 160, subparts C, D, and E.

[3] 83 FR 64302 (December 14, 2018).

[4] Under the HIPAA Privacy Rule, and in this NPRM, an individual's rights generally include the ability of the individual's personal representative to exercise those rights on the individual's behalf. *See* 45 CFR 164.502(g).

[5] This proposed rule uses the terms ''electronic copies'' and ''in an electronic format'' interchangeably.

[6] This proposed rule uses the term ''authorization'' to refer to an authorization under 45 CFR 164.508.

constitute treatment or health care operations.

• Clarifying the scope of covered entities' abilities to disclose PHI to social services agencies, community-based organizations, home and community based service (HCBS) providers,[7] and other similar third parties that provide health-related services, to facilitate coordination of care and case management for individuals.

• Replacing the privacy standard that permits covered entities to make certain uses and disclosures of PHI based on their ''professional judgment'' with a standard permitting such uses or disclosures based on a covered entity's good faith belief that the use or disclosure is in the best interests of the individual. The proposed standard is more permissive in that it would presume a covered entity's good faith, but this presumption could be overcome with evidence of bad faith.

• Expanding the ability of covered entities to disclose PHI to avert a threat to health or safety when a harm is ''serious and reasonably foreseeable,'' instead of the current stricter standard which requires a ''serious and imminent'' threat to health or safety.

• Eliminating the requirement to obtain an individual's written acknowledgment of receipt of a direct treatment provider's Notice of Privacy Practices (NPP).

• Modifying the content requirements of the NPP to clarify for individuals their rights with respect to their PHI and how to exercise those rights.

• Expressly permitting disclosures to Telecommunications Relay Services (TRS) communications assistants for persons who are deaf, hard of hearing, or deaf-blind, or who have a speech disability, and modifying the definition of business associate to exclude TRS providers.

• Expanding the Armed Forces permission to use or disclose PHI to all uniformed services, which then would include the U.S. Public Health Service (USPHS) Commissioned Corps and the National Oceanic and Atmospheric Administration (NOAA) Commissioned Corps.

The Department carefully considered the extent to which each proposed modification would impact privacy protections compared to the likely benefit of making PHI more available for coordination of care or case management. These and other considerations are fully described for each proposal below.

C. Effective and Compliance Dates

The effective date of a final rule would be 60 days after publication. Covered entities and their business associates would have until the ''compliance date'' to establish and implement policies and practices to achieve compliance with any new or modified standards. Except as otherwise provided, 45 CFR 160.105 provides that covered entities and business associates must comply with the applicable new or modified standards or implementation specifications no later than 180 days from the effective date of any such change. The Department previously noted that the 180-day general compliance period for new or modified standards would not apply where a different compliance period is provided in the regulation for one or more provisions.[8]

The Department believes that compliance with the proposed modifications should require no longer than the standard 180-day period provided in 45 CFR 160.105, and thus propose a compliance date of 180 days after the effective date of a final rule.[9] Accordingly, OCR would begin enforcement of the new and revised standards 240 days after publication of a final rule.

The Department requests comment on whether the 180-day compliance period is sufficient for covered entities and business associates to revise existing policies and practices and complete training and implementation. For proposed modifications that would be difficult to accomplish within the 180-day timeframe, the Department requests information about the types of entities and proposed modifications that would necessitate a longer compliance period, how much longer such compliance period would need to be to address such issues, as well as the complexity and scope of changes and the impact on entities and individuals of a longer compliance period.

D. Care Coordination and Case Management Described

On January 30, 2017, President Donald Trump issued Executive Order (E.O.) 13771, ''Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs,'' [10] followed by E.O. 13777, ''Enforcing the Regulatory Reform Agenda.'' These executive orders make clear ''the policy of the United States to alleviate unnecessary regulatory burdens placed on the American people . . .'' [11] In several public speeches, Secretary of Health and Human Services Alex M. Azar II identified the value-based transformation of the Nation's healthcare system as one of his top priorities for the Department, and described how it relates to a reduction of regulatory burden. In a 2018 speech to the Federation of American Hospitals, Secretary Azar committed to addressing ''government burdens that may be getting in the way of integrated, collaborative, and holistic care for the patient, and of structures that may create new value more generally.'' [12] Secretary Azar also explained the need for regulatory reform in his remarks to the Better Medicare Alliance: ''The barriers to effective coordination among providers are much steeper than just excessive paperwork. . . . Addressing these regulations that impede care coordination are part of a much broader regulatory reform effort at HHS.'' [13]

In support of this priority, HHS Deputy Secretary Eric D. Hargan explained, before the Joint Commission on May 29, 2019, that care coordination is a necessary component of achieving value-based care:

It's about coordination, above all—we're focused on understanding how regulations are impeding coordination among providers

[7] For purposes of this proposed rule, the Department refers to home and community-based services (HCBS) providers as they are described and referenced in the context of the Medicaid program. *See* generally 42 CFR part 441 subparts G, K, and M. *See also* National Quality Forum stating that HCBS ''refers to an array of services and supports delivered in the home or other integrated community setting that promote the independence, health and well-being, self-determination, and community inclusion of a person of any age who has significant, longer-term physical, cognitive, sensory, and/or behavior health needs.'' ''Quality in Home and Community Based Service to Support Community Living: Addressing Gaps in Performance Measurement Final Report'' (September 2016), available at *https://www.qualityforum.org/Publications/2016/09/Quality_in_Home_and_Community-Based_Services_to_Support_Community_Living__Addressing_Gaps_in_Performance_Measurement.aspx.*

[8] *See* 78 FR 5566, 5569 (Jan 25, 2013).

[9] *See* 45 CFR 160.104(c)(1), which requires the Secretary to provide at least a 180-day period for covered entities to comply with modifications to standards and implementation specifications in the HIPAA Rules.

[10] Available at *https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/.*

[11] Available at *https://www.govinfo.gov/content/pkg/FR-2017-03-01/pdf/2017-04107.pdf.*

[12] Remarks on Value-Based Transformation to the Federation of American Hospitals, Alex M. Azar II, Federation of American Hospitals, March 5, 2018, available at *https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-value-based-transformation-to-the-federation-of-american-hospitals.html.*

[13] Remarks on the Trump Administration Healthcare Vision, Secretary Alex M. Azar II, Better Medicare Alliance, July 23, 2019, available at *https://www.hhs.gov/about/leadership/secretary/speeches/2019-speeches/remarks-on-the-trump-administration-healthcare-vision.html.*

that can provide better, lower cost patient care, and then reforming these regulations consistent with the laws and their intents. And, finally, it's about care. Regulating health care means regulating some of the most intimate decisions and relationships in our lives—deciding where and when to seek health care, how to make decisions with our doctors and family members, and more.[14]

More recently, the Secretary praised the advancement of coordinated care with the publication of final rules on interoperability, access to health information, and certification of electronic health record technology. The Secretary stated, ''These rules are the start of a new chapter in how patients experience American healthcare, opening up countless new opportunities for them to improve their own health, find the providers that meet their needs, and drive quality through greater coordination.'' [15] And, when announcing the publication of a final rule modifying regulations on the confidentiality of substance use disorder treatment records, the Secretary stated, ''This reform will help make it easier for Americans to discuss substance use disorders with their doctors, seek treatment, and find the road to recovery.'' [16]

The Department intends for this proposed rule to support the full scope of care coordination and case management activities to further the Department's goal of achieving value-based health care. Although neither care coordination nor case management has a precise, commonly agreed upon definition, both refer broadly to a set of activities aimed at promoting cooperation among members of an individual's health care delivery team, including family members, caregivers, and community based organizations. To encompass these broad categories of activities, the Department offers a non-exhaustive list of examples for understanding care coordination and case management in the context of this NPRM, rather than proposing limited definitions. The Department welcomes comment on the examples and descriptions herein and on any additional definitions, examples, or scenarios that would be helpful for regulated entities and the public to understand what constitutes care coordination and case management.

For example, the Department's Office of Inspector General (OIG), in conjunction with the Department, issued a proposed rule as part of the Department's Regulatory Sprint to Coordinated Care. Under proposed safe harbors for the anti-kickback statute, OIG proposes to define ''coordination and management of care'' as the ''deliberate organization of patient care activities and sharing of information between two or more value-based enterprise (VBE) participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target population.'' [17]

Additionally, as noted by the Centers for Medicare & Medicaid Services (CMS) in a recent RFI, ''care coordination is a key aspect of systems that deliver value.'' [18] As CMS describes in guidance on the Medicaid benefit for children and adolescents, ''care coordination'' includes a range of activities that link individuals to services and improve communication flow. The guidance states that the various definitions of this term share three key concepts: Comprehensive coordination (involving coordination of all services, including those delivered by systems other than the health system), patient-centered coordination (designed to meet the needs of the patient), and access and follow-up (described as ensuring the delivery of appropriate services and information flow among providers and back to the primary care provider).[19] In 2019 CMS issued a fact sheet associated with the Medicaid health home benefit, which includes six mandatory core elements for access to and coordination of care: Comprehensive care management, care coordination, health promotion, comprehensive transitional care and follow-up, individual and family support, and referral to community and social services. The term ''case management'' is defined in the Medicaid context for state plans as ''services furnished to assist individuals, eligible under the (Medicaid) State plan who reside in a community setting or are transitioning to a community setting, in gaining access to needed medical, social, educational, and other services.'' [20] In the context of HCBS waivers, case management ''usually entails (but is not limited to) conducting the following functions: Evaluation and/or re-evaluation of level of care, assessment and/or reassessment of the need for waiver services, development and/or review of the service plan, coordination of multiple services and/or among multiple providers, linking waiver participants to other federal, state and local programs, monitoring the implementation of the service plan and participant health and welfare, addressing problems in service provision, and responding to participant crises.'' [21]

The Department's Agency for Healthcare Research and Quality (AHRQ) describes care coordination as ''the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of health care services.'' [22] AHRQ describes a broad approach to care coordination as involving commonly used practices to improve health care delivery, including teamwork, care management, medication management, health information technology, and patient-centered medical homes. AHRQ also describes a ''specific care coordination'' approach that closely aligns with individual patient needs. Examples include creating a proactive care plan, patient monitoring and follow-up, supporting patient self-management goals, and linking to community resources.[23]

Another frequently cited definition comes from the National Quality Forum (NQF), the consensus-based entity recognized by the Department, which defines ''care coordination'' as ''a multidimensional concept that includes effective communication among healthcare providers, patients, families, and caregivers; safe care transitions; a longitudinal view of care that considers the past, while monitoring present

[14] *See* the full text of Deputy Secretary Hargan's remarks at *https://www.hhs.gov/about/leadership/eric-d-hargan/speeches/remarks-to-the-joint-commission-board.html (May 29, 2019).*

[15] *See* the full text of Secretary Azar's remarks at *https://www.cms.gov/newsroom/press-releases/hhs-finalizes-historic-rules-provide-patients-more-control-their-health-data.*

[16] *See* the full text of Secretary Azar's remarks available at *https://www.hhs.gov/about/news/2020/07/13/health-privacy-rule-42-cfr-part-2-revised-modernizing-care-coordination-americans-seeking-treatment.html.*

[17] 84 FR 55694, 55762 (October 17, 2019).

[18] 83 FR 29524 (June 25, 2018).

[19] ''Making Connections: Strengthening Care Coordination in the Medicaid Benefit for Children & Adolescents,'' Centers for Medicare and Medicaid Services, page 3 (September 2014), available at *https://www.medicaid.gov/medicaid/benefits/downloads/epsdt-care-coordination-strategy-guide.pdf.*

[20] 42 CFR 440.169.

[21] ''Instructions, Technical Guide and Review Criteria, Application for § 1915(c) Home and Community Based Waiver'' (January 2019) available at *https://www.nasddds.org/uploads/documents/Version3.6InstructionsJan2019.pdf.*

[22] ''Care Coordination, Quality Improvement, Agency for Healthcare Research and Quality'' (2014), available at *https://www.ahrq.gov/research/findings/evidence-based-reports/caregaptp.html* (citing McDonald KM, Sundaram V, Bravata DM, et al., ''Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies: Volume 7—Care Coordination, Technical Reviews,'' No. 9.7, conducted for AHRQ (2007)).

[23] *Ibid.*

delivery of care and anticipating future needs; and the facilitation of linkages between communities and the healthcare system to address medical, social, educational, and other support needs that align with patient goals.'' [24]

Definitions of ''case management'' are equally varied. The Case Management Society of America (CMSA) defines case management as ''a collaborative process of assessment, planning, facilitation, care coordination, evaluation and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote patient safety, quality of care, and cost effective outcomes.'' [25] The American Case Management Association (ACMA) describes case management in hospital and health care systems as ''a collaborative practice model including patients, nurses, social workers, physicians, other practitioners, caregivers and the community.'' The ACMA's approach to case management encompasses communication and seeks to facilitate care along a continuum through effective resource coordination. The goals of case management include the achievement of ''optimal health, access to care and appropriate utilization of resources, balanced with the patient's right to self-determination.'' [26]

II. Statutory Authority [27] and Regulatory History

A. Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the HIPAA Rules

The Administrative Simplification provisions of HIPAA provide for the establishment of national standards to protect the privacy and security of individuals' health information and established civil money and criminal penalties for violations of the requirements, among other provisions.[28] Under HIPAA, the Administrative Simplification provisions originally applied to three types of entities, known as ''covered entities'': Health care providers who transmit health information electronically in connection with any transaction for which the Department has adopted an electronic transaction standard, health plans, and health care clearinghouses.[29] As discussed more fully below, through a subsequent statute and its implementing regulations, some of the provisions of the Privacy Rule now also directly apply to the business associates [30] of covered entities.[31]

The Department issued its first regulation to implement HIPAA, the Privacy Rule, on December 28, 2000.[32] The Department has modified the Privacy Rule several times since then to address new statutory requirements and to strengthen, refine, or add flexibility to privacy requirements in specific circumstances.[33]

The Privacy Rule protects individuals' medical records and other individually identifiable health information created, received, maintained, or transmitted by or on behalf of covered entities, which are collectively defined as PHI. The Privacy Rule protects individuals' PHI by regulating the circumstances under which covered entities and their business associates may use or disclose PHI and by requiring covered entities to have safeguards in place to protect the privacy of PHI. As part of these protections, covered entities are required to have contracts or other arrangements in place with business associates that use PHI to perform functions for or on behalf of, or provide services to, the covered entity and that require access to PHI to ensure that these business associates also protect the privacy of PHI. The Privacy Rule also establishes the rights of individuals with respect to their PHI, including the right to receive adequate notice of a covered entity's privacy practices, the right to request restrictions of uses and disclosures, the right to access (*i.e.,* to inspect and obtain a copy of) their PHI, the right to request an amendment of their PHI, and the right to receive an accounting of disclosures.[34]

The Department established the right of individuals to access their PHI in the 2000 Privacy Rule,[35] 45 CFR 164.524, ''Access of individuals to protected health information.'' Section 164.524 included requirements for timely action by covered entities, form and format of copies, the denial of access, and documentation. Certain provisions, such as the requirement for covered entities to provide individuals access to PHI in the form or format requested by the individual if readily producible, and the permission for covered entities to impose a reasonable, cost-based fee for copies, were expanded through the subsequent enactment of the HITECH Act and the 2013 Omnibus Final Rule modifying the Privacy Rule (the 2013 Omnibus Rule).[36]

OCR has delegated authority from the Secretary to make decisions regarding the implementation, interpretation, and enforcement of the Privacy Rule. Under this authority, OCR also administers and enforces the Security Rule, which requires covered entities and their business associates to implement certain administrative, physical, and technical safeguards to protect ePHI; and the Breach Notification Rule, which requires covered entities to provide notification to affected individuals, the Secretary of HHS, and, in some cases, the media, following a breach of unsecured PHI, and requires a covered entity's business associate that experiences a breach of unsecured PHI to notify the covered entity of the breach.

With respect to the HIPAA Enforcement Rule, which contains provisions addressing compliance, investigations, the imposition of civil money penalties for violations of the HIPAA Rules, and procedures for hearings, OCR also acts based on its delegated authority.

[24] ''Care Coordination Endorsement Maintenance Project 2016–2017,'' available at *http://www.qualityforum.org/Projects/c-d/Care_Coordination_2016-2017/Care_Coordination_2016-2017.aspx,* discussing a multi-phased effort to provide guidance and measurement of care coordination activities, including endorsing a 2006 definition of care coordination as ''a function that helps ensure that the patient's needs and preferences for health services and information sharing across people, functions, and sites are met over time.'' *See the full definition at https://www.tnaap.org/documents/nqf-definition-and-framework-for-measuring-care-co.pdf.*

[25] ''What Is A Case Manager?'' Case Management Society of America *(2017),* available at *http://www.cmsa.org/who-we-are/what-is-a-case-manager/.*

[26] ''Definition of Case Management,'' American Case Management Association, available at *https://www.acmaweb.org/section.aspx?sID=4.*

[27] While not relevant to this rulemaking, the Department also has authority to modify the Privacy Rule under GINA.

[28] *See* 42 U.S.C. 1320d–1–1320d–9. With respect to privacy standards, Congress directed HHS to ''address at least the following: (1) The rights that an individual who is a subject of individually identifiable health information should have. (2) The procedures that should be established for the exercise of such rights. (3) The uses and disclosures of such information that should be authorized or required.'' 42 U.S.C. 1320d–2 note.

[29] *See* 42 U.S.C. 1320d–1 (applying administrative simplification provisions to covered entities).

[30] A business associate is a person, other than a workforce member, that performs certain functions or activities for or on behalf of a covered entity, or that provides certain services to a covered entity involving the disclosure of PHI to the person. *See* 45 CFR 160.103.

[31] *See* 42 U.S.C. 17934 and HHS Office for Civil Rights Fact Sheet on Direct Liability of Business Associates under HIPAA, (May 2019), available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html.*

[32] 65 FR 82462 (December 28, 2000).

[33] *See* 67 FR 53182 (August 14, 2002), 78 FR 5566 (January 25, 2013), 79 FR 7289 (February 6, 2014) and 81 FR 382 (January 6, 2016).

[34] *See* 45 CFR 164.520, 164.522, 164.524, 164.526 and 164.528.

[35] 65 FR 82462 (December 28, 2000).

[36] 78 FR 5566 (January 25, 2013).

B. The Health Information Technology for Economic and Clinical Health (HITECH) Act and the 2013 Omnibus Rule

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009,[37] enacted February 17, 2009, is designed to promote the widespread adoption and standardization of health information technology (health IT). Subtitle D of title XIII, entitled ''Privacy,'' contains amendments to sections 1176 and 1177 of the Social Security Act designed to strengthen the privacy and security protections established under HIPAA. These provisions extended the applicability of certain Privacy Rule requirements and all of the Security Rule requirements to the business associates of covered entities; required HIPAA covered entities and business associates to provide for notification of breaches of unsecured PHI (implemented by the Breach Notification Rule); established new limitations on the use and disclosure of PHI for marketing and fundraising purposes; prohibited the sale of PHI; required consideration of whether a limited data set can serve as the minimum necessary amount of information for uses and disclosures of PHI; and expanded individuals' rights to access electronic copies of their PHI in an EHR, to receive an accounting of disclosures of their PHI with respect to ePHI, and to request restrictions on certain disclosures of PHI to health plans. In addition, subtitle D strengthened and expanded HIPAA's enforcement provisions.

Section 13405(e) of the HITECH Act strengthened the Privacy Rule's right of access with respect to covered entities that use or maintain an EHR. Under Subtitle D of Title XIII of the HITECH Act, ''The term ''electronic health record'' means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.'' [38] The HITECH Act does not define the term ''clinician.'' Section 13405(e) provides that when a covered entity uses or maintains an EHR with respect to PHI of an individual, the individual shall have a right to obtain from the covered entity a copy of such PHI in an electronic format, and that the individual may direct the covered entity to transmit such copy directly to the individual's designee, provided that any such choice is clear, conspicuous, and specific. Section 13405(e) also provides that any fee imposed by the covered entity for providing such an electronic copy shall not be greater than the entity's labor costs in responding to the request for the copy.

On July 14, 2010, the Department issued an NPRM to modify the HIPAA Rules consistent with the HITECH Act (2010 NPRM).[39] Among other changes, the 2010 NPRM proposed to modify the Privacy Rule to address individual access rights to certain electronic PHI, including proposed requirements with respect to the form, format, and manner of access requested; the ability of the individual to direct a copy to a designee; and fee limitations for providing the requested access. In the 2010 NPRM, the Department acknowledged that section 13405(e) of the HITECH Act ''applies by its terms'' only to PHI in EHRs.[40] However, the Department proposed to rely on its broad statutory authority under HIPAA section 264(c) to issue regulations expanding the HITECH Act requirements to avoid ''a complex set of disparate requirements for access'' such as different requirements for access to paper versus electronic records.[41] The Department further explained its proposed implementation of the HITECH Act provisions:

> As such, the Department proposes to use its authority under section 264(c) of HIPAA to prescribe the rights individuals should have with respect to their individually identifiable health information to strengthen the right of access as provided under section 13405(e) of the HITECH Act more uniformly to all protected health information in one or more designated record sets electronically, regardless of whether the designated record set is an electronic health record.[42]

The 2013 Omnibus Rule finalized 45 CFR 164.524(c)(2)(ii), providing that if the individual's requested PHI is maintained in one or more designated record sets [43] ''electronically'', and if the individual requests an electronic copy, the covered entity must provide the individual with access to his or her PHI in the electronic form and format requested by the individual if it is readily producible in such form and format.[44] Alternatively, if the form and format of the PHI are not readily producible, the covered entity must provide the PHI in a readable electronic form and format as agreed to by the covered entity and individual.[45] The Department also noted that the Privacy Rule, as first finalized in 2000, already applied the right of access to PHI held in designated record sets, and required a covered entity to provide the PHI in the ''form and format'' requested by the individual, including electronically, if ''readily producible.'' [46]

The 2013 Omnibus Rule also finalized 45 CFR 164.524(c)(3)(ii) providing that covered entities must transmit a copy of an individual's PHI directly to a third party designated by the individual if the individual's request for access directs the covered entity to do so.[47] The Department noted that, in contrast to other access requests by individuals pursuant to 45 CFR 164.524, requests to transmit a copy of PHI to a third party must be in writing, signed by the individual, and clearly identify the designated third party and where to send the copy of the PHI. In finalizing this provision, the Department cited section 13405(e) of the HITECH Act and section 264(c) of HIPAA, and stated that the finalized provision was consistent with its prior interpretation and would apply without regard to whether the PHI was in electronic or paper form.[48]

With respect to fees for access, the 2000 Privacy Rule permitted a covered entity to impose only a reasonable, cost-based fee for a copy of PHI under the right of access, which was limited to: (1) The costs of supplies and labor for copying; (2) postage to mail the copy; and (3) preparation of a summary or explanation of PHI if agreed to by the individual.[49] As noted above, section 13405(e)(2) of the HITECH Act provided that, where a covered entity uses or maintains an EHR, any fee for providing electronic copies (or summary or explanation) of PHI shall not be greater than the entity's labor costs in responding to the request. Therefore, to implement the fee provisions of the HITECH Act, the 2013 Omnibus Rule

[37] Public Law 111–5, 123 Stat. 115 (February 17, 2009) (codified at 42 U.S.C. 201 note).

[38] *See* 42 U.S.C. 17921(5), definition of ''Electronic health record.''

[39] *See* 75 FR 40868 (July 14, 2010).

[40] 75 FR 40868, 40901 (July 14, 2010).

[41] *Ibid.*

[42] *Ibid.*

[43] A ''Designated record set'' is defined as (1) A group of records maintained by or for a covered entity that is: (i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals. (2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity. 45 CFR 164.501.

[44] 78 FR 5566, 5633 (January 25, 2013).

[45] *Ibid.*

[46] *Ibid.*

[47] *Id.* at 5634.

[48] *Ibid.*

[49] *See Id.* at 5635.

amended 45 CFR 164.524(c)(4) to provide that fees could include, in addition to postage and preparation of a summary or explanation when applicable, only the following: (i) Labor for copying the PHI requested by the individual, whether in paper or electronic form; and (ii) supplies for creating the paper or electronic media if the individual requested the PHI be provided on portable format.[50]

In the 2013 Omnibus Rule, the Department described the labor for copying PHI, whether in paper or electronic form, as one factor that may be included in a reasonable, cost-based fee.[51] It also noted that rather than propose more detailed considerations for this factor in regulatory text, it retained all prior interpretations of labor with respect to paper copies—that is, that the labor cost of copying does not include costs associated with searching and retrieval of requested PHI.[52] For example, labor for copying PHI may include the labor necessary to reproduce and transfer the PHI in the form and format and manner requested or agreed to by the individual, such as by converting electronic information in one format to the format requested by or agreed to by the individual, or transferring electronic PHI from a covered entity's data system(s) to portable electronic media or email. The Department also explained that the reorganization and addition of the phrase ''electronic media'' reflected its understanding that section 13405(e)(2) of the HITECH Act allowed for the inclusion of only labor costs in the fee for electronic copies, and by implication, excluded costs for supplies that are used to create the electronic copy (*e.g.,* computers, scanners). Finally, the Department explained that its interpretation of the HITECH Act would permit a covered entity to charge a reasonable and cost-based fee for any electronic media it provided, as requested or agreed to by an individual.[53]

In 2016, to educate the public about the individual right of access and clarify covered entities' obligations to fulfill this right, OCR issued extensive guidance (2016 Access Guidance) on how OCR interprets and implements 45 CFR 164.524. The 2016 Access Guidance comprises a comprehensive fact sheet and a set of frequently asked questions (FAQs) that provide additional detail.[54]

Among other clarifications, the guidance included the Department's interpretation and intention that, as an expansion of the individual right of access, the right to direct a copy of PHI to a third party incorporated the general access right's pre-existing conditions and requirements, including its fee limitations. Accordingly, the guidance expressly stated that the access fee limitation applied, regardless of whether the individual requested that the copy of PHI be sent to the individual, or directed the copy of PHI to a third party designated by the individual.

On January 23, 2020, by memorandum opinion and order in *Ciox Health, LLC* v. *Azar, et al.* (*Ciox* v. *Azar*),[55] the U.S. District Court for the District of Columbia vacated: (1) The Department's expansion of the HITECH Act's ''third-party directive'' (*i.e.,* the right of an individual to direct a copy of PHI to a third party) beyond requests for an electronic copy of PHI in an EHR; and (2) the extension of the individual ''patient rate'' for fees for copies of PHI directed to third parties. More specifically, the court held that 45 CFR 164.524(c)(3)(ii), as added to the Privacy Rule by the 2013 Omnibus Rule, exceeded the statutory authority in section 13405(e)(2) of the HITECH Act, which granted a limited right to individuals to direct a copy of ePHI in an EHR to a third party in an electronic format. Further, the court ruled that the Department impermissibly broadened the application of the access fee limitation (known as the ''patient rate'') to apply to copies of PHI directed to third parties, insofar as the Department failed to subject this requirement, first expressly stated in the 2016 Access Guidance, to notice and comment rulemaking.

Consistent with the court's opinion, which the Department did not appeal, the Department takes the opportunity of this NPRM to seek public comment on proposals to: (1) Narrow the scope of the access right to direct records to a third party to only electronic copies of PHI in an EHR; and (2) apply new fee limitations to the access right to direct a copy of PHI to a third party, as described more fully below.

C. 21st Century Cures Act

The 21st Century Cures Act (Cures Act)[56] was enacted on December 13, 2016, to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes. The Cures Act added certain provisions to the Public Health Service Act (PHSA)[57] relating to health IT.[58] While the Department is not proposing a rule under the Cures Act in this NPRM, the proposals in this NPRM take into consideration certain provisions of the Cures Act that facilitate the exchange of health information, and thus provide helpful context for this rulemaking. Section 4004 of the Cures Act added section 3022 of the PHSA (42 U.S.C. 300jj–52), the ''information blocking'' provision. Section 3022(a)(1) defines information blocking as a ''practice that, except as required by law or specified by the Secretary pursuant to rulemaking, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.'' The definition of information blocking also includes two different knowledge requirements. If a practice is conducted by a health IT developer, exchange, or network, the definition requires that such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access to, exchange of, or use of, electronic health information. If a practice is conducted by a health care provider, the definition requires that such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access to, exchange of, or use of, electronic health information. Section 3022(a)(1)(A) excludes from the definition of information blocking practices that are required by law, and reasonable and necessary activities identified by the Secretary in rulemaking.

The Office of the National Coordinator for Health Information Technology (ONC) published a final rule[59] that implements the statutory definitions of the information blocking provision and finalizes the proposed

[50] *Id.* at 5635–36.

[51] *Id.* at 5636.

[52] *Ibid.*

[53] *Ibid.*

[54] *See https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html for the full text of the* 2016 Access Guidance.

[55] No. 18–cv–0040–APM (D.D.C. January 23, 2020).

[56] Public Law 114–255, 130 Stat. 1033 (December 13, 2016) (codified at 42 U.S.C. 201 note). Cures Act Title IV—Delivery amended the PHSA, 42 U.S.C. 201 *et seq.*

[57] 42 U.S.C. 201 *et seq.*

[58] *See generally* Cures Act sections 4003 Interoperability (amending section 3000 of the PHSA (42 U.S.C. 300jj)); and 4004 Information Blocking (amending Subtitle C of title XXX of the PHSA by adding 42 U.S.C. 300jj–52).

[59] *See* 85 FR 25642 (May 1, 2020) available at *https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf.*

eight reasonable and necessary activities (referred to as exceptions) that do not constitute information blocking for purposes of the definition set forth in section 3022(a)(1). These regulatory exceptions are finalized in the ONC rule, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (ONC Cures Act Final Rule), and include the Privacy Exception, which expressly applies to a practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy when the practice meets all of the requirements of at least one of the sub-exceptions in 45 CFR 171.202.[60]

Based on authority granted to it by the Cures Act, the OIG has proposed a rule that addresses enforcement.[61] Section 3022(b)(1) of the PHSA authorizes OIG to investigate any claim that a health IT developer of certified health IT or other entity offering certified health IT, a health care provider, or a health information exchange or network, engaged in information blocking. Section 3022(b)(2)(A) provides for civil monetary penalties for a health IT developer of certified health IT or other entity offering certified health IT, as well as for a health information exchange or network, that is determined to have committed information blocking. Section 3022(b)(2)(B) of the PHSA provides that any health care provider that is determined to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking. The OIG's proposed rule would codify these authorities.[62]

The Cures Act also requires health IT developers participating in the ONC Health IT Certification Program [63] (Certification Program) to publish application programming interfaces (APIs) and allow health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law.[64] ONC's Cures Act rule carries out this charge.

For example, by requiring developers of certified health IT, including EHR technology, to make secured, standards-based APIs (certified APIs) available, ONC's rule creates mechanisms by which individuals can readily exercise their Privacy Rule right of access, thus empowering individuals to electronically access, share, and use their electronic health information. This approach gives individuals the ability to electronically access and share their health information with mobile applications of the individuals' choice. Likewise, CMS's new interoperability rule contains requirements similar to the ONC Cures Act Final Rule.[65] Finally, section 4006 of the Cures Act directs ONC and OCR to jointly promote patient access to health information in a manner that would ensure the information is available in a form convenient for the patient, in a reasonable manner, without burdening the health care provider involved.

Taken together, implementation of the above Cures Act requirements through the ONC and CMS rules will support covered entities (and their business associates) that use health information technology in a manner that enables them to respond more timely to individual requests for access to ePHI. Further, the ONC Cures Act Final Rule requirements for certified health IT to use secure, standards-based APIs will allow individuals to more readily access their ePHI and support disclosures of PHI by covered health care providers and health plans for individual-level care coordination and case management purposes. This regulatory context informs the proposals that follow.

III. Need for the Proposed Rule and Proposed Modifications

In light of ongoing concerns that regulatory barriers across the Department impede effective delivery of coordinated, value-based health care, in June 2018, the Department launched the Regulatory Sprint to Coordinated Care to promote care coordination and facilitate a nationwide transformation to value-based health care. The Department initiated the Sprint by publishing a series of RFIs to solicit public input on regulatory barriers to coordinated care that it should modify, remove, or clarify through guidance and subsequent proposed regulations. After considering public comment, on August 26, 2019, the Department published a NPRM to modify 42 CFR part 2, the regulatory scheme protecting the confidentiality of substance use disorder (SUD) treatment information held by HHS-funded treatment programs.[66] On October 17, 2019, the HHS Office of Inspector General (OIG) published a NPRM, ''Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements.'' [67] On the same day, CMS published a NPRM, ''Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations.'' [68]

This NPRM, proposing modifications to the Privacy Rule, continues the Department's Regulatory Sprint, taking into consideration public comment received on the 2018 RFI published by OCR. The 2018 RFI solicited public input on 53 questions asking whether and how the Department could modify the HIPAA Rules to support care coordination and case management, and promote value-based care, while preserving the privacy and security of PHI. The Department organized the 2018 RFI questions around several key themes for which it sought input and examples of how best to address care coordination through three specific content areas:

- *Promoting information disclosure for care coordination and case management.* The 2018 RFI sought input on individuals' right to access their own PHI in accordance with the provisions contained in 45 CFR 164.524, and the amount of time covered entities should be permitted to respond to individuals' requests for access. The RFI also solicited input on whether health care clearinghouses should be subject to the individual access requirements, and whether disclosures of PHI for care coordination and case management to non-provider covered entities should be excepted from the minimum necessary requirements. Further, the RFI asked for public input on whether the Privacy Rule should require covered entities and business associates to disclose PHI when requested by another covered entity for treatment, payment, health care operations, or some combination or subset of these categories of disclosures. Finally, the RFI asked whether there should be an express regulatory permission for HIPAA covered entities to disclose PHI to social services agencies and/or community based organizations.

[60] *See* 45 CFR 171.202.

[61] *See* proposed rule, 85 FR 22979 (June 23, 2020). Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules. *https://www.federalregister.gov/d/2020-08451/p-17.*

[62] *Ibid.*

[63] In general, the HITECH Act provides the National Coordinator with the authority to establish a program or programs for the voluntary certification of health IT, and requires the Secretary to adopt certification criteria. *See* 42 U.S.C. 300jj–11.

[64] *See* Cures Act section 4002 (amending section 3001(c)(5) of the PHSA).

[65] *See* 85 FR 25510 (May 1, 2020).

[66] 84 FR 44568 (August 26, 2019).

[67] 84 FR 55694 (October 17, 2019).

[68] 84 FR 55766 (October 17, 2019).

• *Promoting parental and caregiver involvement and addressing the opioid crisis and serious mental illness (SMI).* The 2018 RFI sought input to help determine whether and how to modify the Privacy Rule to address the opioid crisis and SMI, and promote family involvement in the care of loved ones experiencing these health situations. The RFI also sought comment on how the Department could amend the Privacy Rule to increase the disclosure of information by providers to family members experiencing difficulties obtaining health information about parents, spouses, minor and adult children, and other loved ones when needed to coordinate their care or otherwise be involved in their treatment (or the payment for such treatment).

• *Notice of Privacy Practices (NPP).* The 2018 RFI sought input on whether the Department should eliminate or modify the Notice of Privacy Practices signature and recordkeeping requirements associated with distribution of the Notice of Privacy Practices. The Privacy Rule, at 45 CFR 164.520(c)(2)(ii), currently requires a covered health care provider that has a direct treatment relationship with an individual to make a good faith effort to obtain a written acknowledgment of receipt of the provider's NPP; if unable to obtain the written acknowledgment, the covered health care provider must document its good faith effort to do so and the reason for not obtaining an individual's acknowledgment, and maintain the documentation for six years.[69] The 2018 RFI sought public comment on whether changing the requirements related to the acknowledgment of receipt could reduce administrative burden on covered health care providers and address confusion about the purpose and effect of the requirements. The 2018 RFI also asked whether and how other aspects of the Notice of Privacy Practices provisions (*e.g.,* content requirements) could be changed to ensure that individuals are informed about their rights and covered entities' privacy practices.

In addition to the three major topics described above, the RFI sought information about implementing a requirement of the HITECH Act to include disclosures by a covered entity for treatment, payment, and health care operations through an EHR in an accounting of disclosures.[70] Based on the comments received in response to the 2018 RFI, and the history of previous rulemaking on this topic, the Department intends to address this requirement in future rulemaking.

The Department received over 1,300 comments in response to the 2018 RFI, from many types of individuals and entities, including covered entities, patients, family caregivers, professional associations, privacy advocates, mental health professionals and advocates, business associates, researchers, and government organizations. The Department provides a more complete description of the 2018 RFI topics and responsive comments below.[71]

A. Individual Right of Access [72] (45 CFR 164.524)

General Policy Considerations

The ability of individuals to access and direct disclosures of their own health information is key to the coordination of their care. Patients are at the center of each health care encounter. As such, 45 CFR 164.524 of the Privacy Rule generally requires HIPAA covered entities (health plans and most health care providers) [73] to provide individuals, upon request, with access to their PHI in one or more designated record sets maintained by or for the covered entity. As finalized in 2013, this right includes the right to inspect or obtain a copy, or both, of the PHI, and to access the PHI in the form and format requested if readily producible. Individuals have a right to access this PHI for as long as the information is maintained by a covered entity, or by a business associate on behalf of a covered entity, regardless of the date the information was created; whether the information is maintained on paper or in an electronic system onsite, remotely, or archived; or where the PHI originated (*e.g.,* from the covered entity, another health care provider, the patient, etc.). The individual right to inspect PHI held in a designated record set, either in addition to obtaining copies or in lieu thereof, requires covered entities to arrange with the individual for a convenient time and place to inspect the PHI. The right of access also includes the right to direct the covered entity to transmit an electronic copy of PHI in an EHR to a designated person or entity of the individual's choice.[74]

While OCR has issued extensive guidance and performed outreach to the public and regulated entities regarding the individual right of access, OCR continues to hear—through complaints, comments on the 2018 RFI, reports,[75] and anecdotal accounts—that individuals frequently face barriers to obtaining timely access to their PHI, in the form and format requested, and at a reasonable, cost-based fee. Associated delays or lack of patient access to their PHI may inhibit care coordination and contribute to worse health outcomes for individuals,[76] and contribute to burden on individuals and systems.

The 2018 RFI also requested information about current barriers or delays that health care providers face when attempting to obtain PHI from covered entities for treatment purposes. Specifically, the RFI asked whether the Privacy Rule could be modified to improve care coordination and case management by requiring covered entities and business associates to disclose PHI when requested by another covered entity for treatment purposes, for payment and health care operations purposes generally, or, alternatively, only for specific payment or health care operations purposes. The RFI further requested input on the effects of various potential requirements, including the creation of unintended burdens for covered entities or individuals, how much it would cost covered entities to comply, and whether any limitations should be placed on such disclosure requirements.

[69] *See* 45 CFR 164.520(e) and 45 CFR 164.530(j)(2).

[70] *See* 42 U.S.C. 17935(c).

[71] Throughout this preamble, the phrases ''majority of commenters'' or ''general consensus'' are used to mean a majority of commenters that have commented on the particular issue or consensus among commenters who have commented on the issue being discussed. These statements should not be interpreted to mean all commenters who have commented on the 2018 RFI, but only those who commented on the particular issue being discussed.

[72] Throughout this NPRM, references to the individual right of access and individual access requests include access requests by the personal representative of an individual.

[73] The third type of covered entity, a health care clearinghouse, is not subject to the same individual access requirements as covered health care providers and health plans. *See* 45 CFR 164.500(b)(1) for a list of Privacy Rule provisions that apply to a health care clearinghouse in its role as a business associate of another covered entity.

[74] In accordance with the court order in *Ciox* v. *Azar,* the Department is not enforcing a right to direct to a third party non-electronic copies of PHI or copies of PHI that are not in an EHR. These types of disclosures to third parties continue to be permitted with a valid authorization.

[75] Lye CT, Forman HP, Gao R, et al. ''Assessment of US Hospital Compliance With Regulations for Patients' Requests for Medical Records.'' JAMA Network Open. Published online October 05, 2018(6):e183014. doi:10.1001/jamanetworkopen.2018.3014.

[76] *See e.g.,* The Joint Commission, ''Transitions of Care: The need for collaboration across entire care continuum,'' *https://www.jointcommission.org/assets/1/6/TOC_Hot_Topics.pdf* (listing transfer of health information as foundational to safe transitions of care); Hesselink, G., Schoonhoven, L., Barach, P., Spijker, A., Gademan, P., Kalkman, C., Liefers, J., Vernooij-Dassen, M., & Wollersheim, H. (2012). ''Improving patient handovers from hospital to primary care: A systematic review.'' Annals of Internal Medicine, 157(6), 417428.

After careful review of the responses to the 2018 RFI and the Department's analysis of the current Privacy Rule, the Department proposes to amend the Privacy Rule to strengthen the individual right of access and to remove barriers that may limit or discourage coordinated care or case management among covered entities and individuals, or otherwise impose regulatory burdens. Additionally, consistent with the court's decision in *Ciox* v. *Azar,*[77] the Department proposes to modify aspects of the individual's right under the Privacy Rule to direct a covered entity to transmit a copy of PHI to a third party.

Summary of Proposals To Modify the Individual Right of Access

The Department proposes to amend the individual right of access by incorporating definitions into the Privacy Rule that are necessary to implement key privacy provisions of the HITECH Act. The Department's proposed definitions for electronic health record and personal health application in 45 CFR 164.501 build on language from the HITECH Act definitions of electronic health record [78] and personal health record.[79] The Department also proposes to strengthen the individual right of access by strengthening the right to inspect and obtain copies of PHI and by shortening the time limits for covered entities to respond to access requests. The Department addresses requirements regarding the form and format in which covered entities must respond to individuals' requests for access, by clarifying that ''readily producible'' copies of PHI include copies of ePHI requested through secure, standards-based APIs using applications chosen by individuals, and that they also include copies in any form and format required by applicable state and other laws. The Department proposes that the individual right to direct a copy of PHI to a third party be limited to a right to direct an electronic copy of PHI in an EHR to a third party. To clearly distinguish between the scope and requirements of the individual right to inspect and obtain copies of PHI and the right to direct the transmission of electronic copies of PHI in an EHR to a third party, the Department proposes to list these distinct rights of access in separate paragraphs in the regulatory text:

- The individual right to inspect and obtain copies of PHI within the current rule requires covered entities to provide the requested information (with some exceptions) within a specific time limit and for a limited fee. This NPRM proposes to retain this individual right to inspect and obtain copies of PHI at 45 CFR 164.524(c).
- The right of an individual to direct the transmission of electronic copies of PHI in an EHR to a third party is established by the HITECH Act and interpreted by the *Ciox* v. *Azar* decision to apply only to PHI in an EHR. The proposed rule would codify the *Ciox* v. *Azar* limits into regulatory text at 45 CFR 164.524(d).
- The Department also proposes to create a pathway for individuals to direct the sharing of an electronic copy of PHI in an EHR among covered health care providers and health plans. The NPRM proposes to require a covered health care provider or health plan (the ''Requestor-Recipient''), at the individual's direction, to submit the individual's access request regarding his or her own ePHI to another covered health care provider (the ''Discloser''), requesting that the Discloser transmit the ePHI maintained by or on behalf of the Discloser in its EHR to the Requestor-Recipient. This new right would be inserted within the right to direct an electronic copy of PHI in an EHR to a third party, at proposed 45 CFR 164.524(d)(7).

Finally, with respect to fees charged by covered entities to individuals exercising the right of access, the Department proposes to adjust and clarify the fees that covered entities may charge for copies of PHI, and require covered entities to provide advance notice of approximate fees for copies of PHI requested under the access right or with an individual's valid authorization. The Department also proposes technical clarifications to the Privacy Rule provision requiring business associates to disclose PHI as needed for the covered entity to fulfill its obligations under the right of access.

1. Adding Definitions for Electronic Health Record or EHR and Personal Health Application'' (45 CFR 164.501)

The Privacy Rule currently does not define the term ''electronic health record.'' However, the HITECH Act codifies a definition of EHR that applies to that Act's privacy and security provisions for covered entities and business associates.[80] As part of this NPRM's proposal to modify the scope of the access right regarding PHI in an EHR, the Department proposes to add a definition of EHR in 45 CFR 164.501 that expands on the HITECH Act definition to clarify some of its terms:

> *Electronic health record* means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff. Such clinicians shall include, but are not limited to, health care providers that have a direct treatment relationship with individuals, as defined at § 164.501, such as physicians, nurses, pharmacists, and other allied health professionals. For purposes of this paragraph, ''health-related information on an individual'' covers the same scope of information as the term ''individually identifiable health information'' as defined at § 160.103.

The Privacy Rule does not define the term ''clinician'' and the Department has not identified a uniform statutory or regulatory definition. For example, the term ''clinician'' is not included among the several definitions of ''Health care provider'' in the Social Security Act, which includes a long list of health care professionals as well as ''any other person furnishing health care services or supplies.'' [81] Section 13101 of the HITECH Act, adding Title XXX—Health Information Technology and Quality to the PHSA, includes a definition for ''health care provider'' that appears to distinguish the term ''clinicians'' from other types of practitioners, but does not specify a basis for the distinction: ''. . . and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.'' [82] CMS offers a definition of ''clinician'' within its guidance materials discussing quality measures: ''The term *clinician* refers to a

[77] No. 18–cv–0040–APM (D.D.C. January 23, 2020).

[78] 42 U.S.C. 17921(5): ''The term ''electronic health record'' means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.''

[79] *Id.* at 17921(11): ''The term ''personal health record'' means an electronic record of PHR identifiable health information (as defined in section 13407(f)(2) [of the HITECH Act]) on an individual that can be drawn from multiple sources and that is managed, shared, and controlled by or primarily for the individual.'' Sec. 13407(f)(2) of the HITECH Act defines ''PHR identifiable health information'' as individually identifiable health information, as defined in section 1171(6) of the Social Security Act (42 U.S.C. 1320d(6)), and includes, with respect to an individual, information (A) that is provided by or on behalf of the individual; and (B) that identifies the individual or with respect to which there is a reasonable basis to believe that the information can be used to identify the individual. 42 U.S.C. 17937(f)(2).

[80] *See* 42 U.S.C. 17921(5) for the HITECH Act definition: ''The term ''electronic health record'' means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.''

[81] *See e.g.,* Social Security Act section 1171(3) (42 U.S.C. 1320d (3)) (defining ''Health care provider'' to include a provider of services (cross-referencing the definition with that in 42 U.S.C. 1861(u)), and any other person furnishing health care services or supplies.

[82] 42 U.S.C. 300jj (3), definition of ''Health care provider''.

healthcare professional qualified in the clinical practice of medicine. Clinicians are those who provide principal care for a patient where there is no planned endpoint of the relationship; expertise needed for the ongoing management of a chronic disease or condition; care during a defined period and circumstance, such as hospitalization; or care as ordered by another clinician. Clinicians may be physicians, nurses, pharmacists, or other allied health professionals.'' [83]

Consistent with the breadth of these various definitions, the Department proposes to interpret ''authorized health care clinicians and staff'' to at least include covered health care providers who are able to access, modify, transmit, or otherwise use or disclose PHI in an EHR, and who have direct treatment relationships with individuals; and their workforce members (as workforce is defined at 45 CFR 160.103) [84] who support the provision of such treatment by virtue of their qualifications or job role. Accordingly, an EHR would include electronic records consulted by any covered health care provider, or a workforce member of such a covered health care provider, so long as the provider has a direct treatment relationship with individuals. The Department does not propose to include covered health care providers who have indirect treatment relationships with individuals. By definition, providers with indirect treatment relationships deliver health care based on the orders of another health care provider, and they typically provide services, products, or reports to another health care provider (*e.g.,* a provider with a direct treatment relationship with the individual).[85] Accordingly, the direct treatment provider that receives such services, products, or reports would be the entity documenting information in the EHR.

For example, an EHR would include electronic lab test reports created by workforce members of a large health system who are licensed clinical laboratory personnel, and who perform clinical lab tests for patients treated by the health system. Likewise, electronic billing records created, gathered, managed, and consulted by workforce members of a covered health care provider that has a direct treatment relationship with an individual (*e.g.,* a hospital) would be included in the term EHR because health care billing information is health-related information. The Department recognized as early as 2013 that many direct treatment providers use electronic practice systems that integrate functions such as scheduling and billing with providers' EHRs.[86] Additionally, the American Academy of Family Physicians, in presenting definitions for both ''electronic health record'' and ''electronic medical record,'' has noted that ''electronic health record'' refers to ''computer software that physicians use to track all aspects of patient care. Typically this broader term also encompasses the practice management functions of billing, scheduling, etc.'' [87]

In contrast, the term EHR would not include health-related electronic records of covered health care providers that only supply durable medical equipment to other providers, who then provide the equipment to individuals, and thus do not have direct treatment relationships with individuals.

With respect to the types of information in an EHR, the Department proposes to equate ''health-related information on an individual'' in regulatory text with the scope of the familiar, defined term, individually identifiable health information or IIHI.[88] While the HITECH Act does not define ''health-related information,'' section 13101 of the HITECH Act defines ''health information'' by reference to section 1171(4) of the Social Security Act,[89] which is consistent with the definition of the term contained in the Privacy Rule. Therefore, the Department believes it is reasonable to interpret the term ''health-related information'' to be at least as broad as ''Health information,'' as defined in the Privacy Rule at 45 CFR 164.501.[90] The Department notes that ''Health information'' includes not only clinical, but billing and other data. Therefore, the broader term ''health-related information'' could be expected to include such data and not be limited to clinical data.

Further, the Department interprets ''on an individual,'' for HIPAA purposes to refer to information that is ''individually identifiable.'' Health information that is not individually identifiable (*e.g.,* that is de-identified) is not protected by HIPAA. Thus, a definition of ''health-related information on an individual'' that encompasses information outside the scope of IIHI would not create an administrable standard under the HIPAA Rules. The Department seeks comment on the scope of this proposed definition for EHR, including billing records for health care.[91]

The Department also believes it is necessary to define a new term in the Privacy Rule, ''Personal health application'' (or ''personal health app''), by drawing on the definition of a personal health record in the HITECH Act.[92] This term would be added to 45 CFR 164.501. More and more, individuals use personal health applications to access and manage their personal health information, and in this proposed rule, the Department proposes to revise the right of access to clarify that it includes the right of an individual to access electronic copies of the individual's PHI, and that one of the mechanisms by which a request for access can be fulfilled is by transmitting an electronic copy of an individual's PHI to a personal health application used by the individual. To support the

[83] Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/QMY-Clinicians.*

[84] This NPRM uses the terms ''workforce member'' and ''staff'' interchangeably.

[85] *See* 45 CFR 164.501 (definition of ''Direct treatment relationship'').

[86] *See* Assistant Secretary for Planning and Evaluation (ASPE) report, ''The Feasibility of Using Electronic Health Data for Research on Small Populations, Information Available in an Electronic Health Record'' (September 1, 2013), available at *https://aspe.hhs.gov/report/feasibility-using-electronic-health-data-research-small-populations.*

[87] *See* American Academy of Family Physicians (AAFP), ''Introduction to Electronic Health Records (EHRs)'' available at *https://www.aafp.org/practice-management/health-it/product/intro.html.*

[88] 45 CFR 160.103 provides in part that IIHI is ''a subset of health information, including demographic information . . . created or received by a health care provider, health plan, employer or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual.'' *See* 45 CFR 160.103 for the full definition.

[89] *See* 42 U.S.C. 300jj (4) (adding section 3000(4) to the PHSA, definition of Health care provider).

[90] *Health information* means any information, including genetic information, whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. 45 CFR 164.501.

[91] Note that the HITECH Act definition of ''Electronic health record,'' 42 U.S.C. 17921(5), applies only to HIPAA covered entities and business associates. ONC's regulations at 45 CFR Subchapter D—Health Information Technology, do not define an EHR, but do include definitions for a *2015 Edition Base EHR* and a *Qualified EHR.* CMS has also proposed a definition of EHR in its proposed rule; *Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations. See* 84 FR 55766 (October 19, 2019), *https://www.federalregister.gov/d/2019-22028/p-535.*

[92] *See* 42 U.S.C. 17921(11). ''The term ''personal health record'' means an electronic record of PHR identifiable health information (as defined in section 17937(f)(2) of this title) on an individual that can be drawn from multiple sources and that is managed, shared, and controlled by or primarily for the individual.''

Department's proposal to address the use of personal health applications in the right of access, the Department proposes to define personal health application in the HIPAA Rules as ''an electronic application used by an individual to access health information about that individual in electronic form, which can be drawn from multiple sources, provided that such information is managed, shared, and controlled by or primarily for the individual, and not by or primarily for a covered entity or another party such as the application developer.'' [93] Put another way, a personal health application is a service offered directly to consumers. The covered entity does not manage, share, or control the information, nor does the application developer manage the information on behalf of or at the direction of a health care provider or health plan (*e.g.,* through a patient ''portal'' that the entity uses to manage individuals' access to the PHI it maintains), or another party that collects or manages PHI for its own purposes (*e.g.,* a research organization). Instead, individuals (or their personal representatives) use a personal health application for the individuals' own purposes, such as to monitor their own health status and access their own PHI using the application. For example, individuals might request weight, vital signs, and other health information from their health care providers to either store it in the personal health application or to direct transmission to other persons. The Department notes that a personal health application is not acting on behalf of, or at the direction of a covered entity, and therefore would not be subject to the privacy and security obligations of the HIPAA Rules. However, the Department supports providing individuals with information that will assist them in making the best choices for themselves when selecting a personal health application or other applications that are not being provided on behalf of or at the direction of a covered entity.[94]

The Department requests comment on the proposed definition of personal health application, including the types of activities encompassed in the terms ''managed,'' ''shared,'' and ''controlled,'' and on the Department's assumptions about the use of such applications by individuals. The proposed definition of personal health application is meant to be consistent with the HITECH Act definition of personal health record (PHR),[95] but specifically addresses certain health applications, which may or may not be PHRs.[96]

Taken together, the proposed definitions for EHR and personal health application would help clarify the proposed modifications to the right of access, including the scope of the modified right of individuals to direct a covered health care provider to transmit an electronic copy of PHI in an EHR to a designated third party.

2. Strengthening the Access Right To Inspect and Obtain Copies of PHI

The individual right of access under the Privacy Rule includes a right to ''inspect and obtain a copy of'' PHI in a designated record set at 45 CFR 164.524(a)(1).[97] The Department proposes to strengthen the access right to inspect and obtain copies of PHI by incorporating a portion of the 2016 Access Guidance, discussed below, into a new provision of the Privacy Rule. To do so, the Department proposes to retain the substance of the current right at 45 CFR 164.524(a)(1), but redesignate current 45 CFR 164.524(a)(1)(i) and (ii) as 45 CFR 164.524(a)(1)(i)(A) and (B). The Department also proposes to add a new right at 45 CFR 164.524(a)(1)(ii) that generally would enable an individual to take notes, videos, and photographs, and use other personal resources to view and capture PHI in a designated record set as part of the right to inspect PHI in person. The Department does not propose to impose a requirement on covered entities that would result in the taking of an intellectual property right, and does not believe that an individual recording their own PHI in a designated record set through video, still camera photos, or audio recordings would be inconsistent with federal and state recording laws or intellectual property rights protections. However, the Department requests comment on this point and examples of possible unintended consequences of the proposal. Additionally, the Department invites comments on whether covered entities should be permitted to provide copies of PHI in lieu of in-person inspection of PHI when necessary to protect the health or safety of the individual or others, such as during a pandemic; and if so, whether the Department should establish additional rights for individuals in such circumstances, such as the right to receive such copies for free. The Privacy Rule currently does not provide covered entities with the opportunity to deny or delay (beyond 30 days plus one 30-day extension) the right to inspect PHI in person to prevent the spread of an infectious disease, or address the ability to provide a reasonable alternative based on the need to protect the health or safety of the individual or others due to a pandemic or other public health emergency.

Under this proposal, covered entities generally would be required to allow individuals to take notes, videos, and photographs using personal resources after arranging a mutually convenient time and place for the individual to inspect their PHI in a designated record set, such as in a medical records office. This would be accomplished by redesignating the first paragraph of 45 CFR 164.524(a)(1) as subsection (i) and creating a new subsection (ii). Covered entities would be required to provide such access without imposing a fee under proposed 45 CFR 164.524(c)(4(ii). Additionally, the Department proposes to extend the right to inspect to situations where mutually convenient times and places include points of care where PHI in a designated record set is readily available for inspection by the patient, for example, by viewing x-rays, ultrasounds, or lab results in conjunction with a health care appointment with a treating provider. The Department anticipates that the time and place where an individual obtains health care treatment generally would be considered a convenient time and place for the individual to inspect the PHI that is immediately available in the treatment area. This provision would be added to 45 CFR 164.524(c)(3) as part of the implementation specifications regarding the time and manner of access, as follows: ''When protected health information is readily available at the point of care in conjunction with a health care appointment, a covered health care provider is not permitted to delay the right to inspect.''

In these circumstances, a covered health care provider would not be permitted to delay the right to inspect. The Department believes that it is common for individuals to take notes during a visit where health care

[93] This proposed definition of personal health application would not apply to or otherwise affect the requirements of the ONC Cures Act Final Rule or the CMS Interoperability and Patient Access Rule.

[94] *See* 85 FR 25642, 25814 (May 1, 2020) for an extensive discussion of how a covered entity may provide individuals with such information, in the ONC Cures Act Final Rule preamble regarding *Interference Versus Education When an Individual Chooses Technology to Facilitate Access.*

[95] ''[A]n electronic record of PHR identifiable health information (as defined in section 13407(f)(2)) on an individual that can be drawn from multiple sources and that is managed, shared, and controlled by or primarily for the individual.'' 42 U.S.C. 17921(11).

[96] The same software could be a personal health application under the proposed Privacy Rule definition and also be a personal health record under the HITECH Act for other purposes, to the extent it meets both definitions.

[97] *See* 45 CFR 164.524(a).

treatment is provided and that individuals could benefit from taking photographs or recordings of PHI, contained in a designated record set, during such visits. This provision would not extend the right beyond the records maintained by or for a covered entity as described in the definition of designated record set in the Privacy Rule.[98]

The Department seeks comment on whether to require covered health care providers to allow individuals to record PHI in this manner as part of the Privacy Rule access right; whether conditions or limitations should apply to ensure that a covered health care provider does not experience unreasonable workflow disruptions (*e.g.,* limitations on time spent recording PHI in conjunction with a health care appointment); any potential unintended consequences of a new requirement to allow inspection of PHI that is readily available at the point of care in conjunction with a health care appointment; and how to determine when PHI is ''readily available.''

Under proposed section 164.524(a)(1)(ii), the Department would not require a covered entity to allow the individual to connect a personal device, such as a thumb drive, to the covered entity's information systems. The Department does not expect a covered entity to tolerate unacceptable security risks (which would violate the HIPAA Security Rule) in order to accomplish a non-secure mode of data transfer to the requestor.[99]

The Department believes that the proposed changes would eliminate persistent barriers that individuals face when seeking to inspect or obtain copies of their PHI, as described above in Section III.A. At the same time, a provision at the end of the new subsection (ii) of 45 CFR 164.524(a)(1) would provide, ''[A] covered entity is not required to allow an individual to connect a personal device to the covered entity's information systems and may impose requirements to ensure that an individual records only protected health information to which the individual has a right of access.'' Consistent with this provision, a covered entity could establish reasonable policies and safeguards to ensure, for example, that an individual's use of personal resources minimizes disruptions to the covered entity's operations, and is used in a way that enables the individual to copy or otherwise memorialize only the PHI in the individual's designated record set to which the individual is entitled pursuant to the right of access. However, a covered entity would not be permitted to establish such policies and safeguards that impose unjustified or unreasonable barriers to individual access. See proposed 45 CFR 164.524(b)(1)(ii).

3. Modifying the Implementation Requirements for Requests for Access and Timely Action in Response to Requests for Access

a. Current Provisions and Issues To Address

Section 164.524(b)(1) of title 45 CFR requires a covered entity to permit an individual to inspect or to obtain a copy of PHI about the individual that is maintained in a designated record set, and to require individuals to make such a request in writing, provided the covered entity informs the individual of the writing requirement. Although the Department did not solicit commit in the 2018 RFI about this section of the Privacy Rule, the Department believes it is appropriate to solicit comment on a proposal to expressly prohibit a covered entity from imposing unreasonable measures that would impede an individual's right of access. The Department believes such a proposal would support the goal of improving coordination of care for individuals, as further discussed below.

Section 164.524(b)(2) of title 45 CFR requires a covered entity to act on an individual's request to exercise their right of access no later than 30 days after receipt of the request, with an option to extend the time to take action by an additional 30 days after providing written explanation and the date by which the entity will complete its action on the request. To assess whether the time limit could be shortened to better serve individuals seeking to exercise their right to access their records, in the 2018 RFI, the Department solicited public comments on this timeframe, the feasibility of covered entities meeting a shorter time limit, recommended time limits, and whether access to PHI maintained by covered entities in electronic format should be subject to different timeliness requirements than non-electronic records (*e.g.,* paper).

Many commenters on the 2018 RFI preferred a uniform standard for providing access to PHI regardless of the record format (*e.g.,* electronic or non-electronic). Simplicity, consistency, and uniformity of requirements were cited as priorities above other considerations, such as differing technical capabilities with respect to different formats. Commenters cited numerous factors other than whether the information is in electronic or non-electronic form that affect a covered entity's ability to timely fulfill access requests, such as the nature of the requested information, whether the records are stored off-site, the need for professional or legal review based on state law or 42 CFR part 2 requirements to segregate information that cannot be released at all or without authorization, and the size and complexity of the covered entity. Covered health care provider comments further described a number of factors that can affect access times for the production of electronic records, including PHI residing in multiple IT systems in varying formats and requests covering long periods of time, or covering a high volume of records related to complex and intensive medical treatment that must be collated and put into the requested electronic format or medium.

Citing these factors, health care providers who commented on this topic generally did not believe that requiring access to electronic records more quickly than non-electronic records would improve the overall speed of providing access to all of an individual's requested PHI, and some commenters expressed concern that doing so may negatively affect timely access to non-electronic records. To support this point, many described how fulfilling a single access request may encompass the production of both electronic and non-electronic records (sometimes referred to as a ''hybrid'' request or record). Commenters also reported that applying different time requirements for different parts of an individual's record would add complexity, potentially creating additional administrative burdens and barriers to compliance.

Of the commenters who offered specific timeframes concerning current practices, about half reported providing records within 15 days and half stated that they take up to 30 days. Health care entities subject to shorter response times required under state law (including requirements in California and Texas)[100] commented that they are able to meet those shorter time limits. Also, among commenters providing a specific recommendation for shorter access time limits, the most suggested timeframe was 14 to 15 days, consistent with the deadlines in those states. Some commenters recommended prioritizing certain types of requests based on their

[98] 45 CFR 164.501.

[99] *See* discussion of security considerations in the 2016 Access Guidance, available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html. See also* 45 CFR 164.308(a)(1).

[100] *See* Cal. Health & Safety Code 12110, Tex. Health & Safety Code 241.154 (hospitals), Tex. Occupations Code 159.006 (physicians), and Tex. Health & Safety Code 181.102 (other providers with an EHR).

purpose: Two-thirds of organizational commenters who responded to this question stated that requests for continuity of care purposes or urgent medical needs should be prioritized.

Individual commenters described delays in obtaining access, including inconsistent or incomplete uploading of electronic records to health information exchanges, entities that routinely respond to access requests on day 29 with a demand for additional clarifying information in writing in order to process the requests, and entities that only respond when threatened with legal action. They also described the harmful effects on health when the process to access records is too complicated or when the provision of records is delayed or denied.

Examples from consumers included needing to repeat tests and procedures because medical history information was not available, which is both expensive and leads to delays in needed treatment; delayed referrals and inaccurate diagnoses based on incomplete information; and lack of timely information needed for self-care. Sometimes health decisions have to be made quickly, and individuals need access to information in a timely manner to fully participate in their care or obtain an urgent second opinion from another medical professional.

Among commenters that opposed shorter timelines, many stated that covered entities would be burdened if they had to provide access within a shorter period. Several commenters stated that they would have to increase expenditures on staff, diverting resources from treating patients, and at least one mentioned the need to increase investment in information technology. Some commenters expressed particular concern that shorter access time limits would place an undue burden on smaller entities.

b. Proposals

To address the barriers to timely access described above, the Department proposes to modify the Privacy Rule as follows.

i. Requests for Access

Section 164.524(b) of title 45 CFR currently requires covered entities to permit individuals exercising their right of access to inspect or to obtain a copy of their PHI that is contained in a designated record set, and permits covered entities to require access requests in writing, provided that the covered entity informs the individual of that requirement. The Department proposes to modify the Privacy Rule to expressly prohibit a covered entity from imposing unreasonable measures on an individual exercising the right of access that create a barrier to or unreasonably delay the individual from obtaining access.[101] Specifically, in proposed new section 164.524(b)(1)(ii),[102] the Department proposes to clarify that, while an entity may require individuals to make requests for access in writing (as currently provided in the second sentence of section 164.524(b)(1)), it would not be permitted to do so in a way that impedes access.

To help define ''unreasonable measures'' for covered entities, the Department proposes to include and compare, in regulatory text, non-exhaustive specific examples of reasonable and unreasonable measures that some covered entities have imposed (as described in public comments or individuals' complaints submitted to the Department), or may be likely to impose. For example, proposed section 164.524(b)(1)(ii) compares a standard form containing the minimum information that is needed to process a request for access against a form requiring extensive information from the individual that is not necessary to fulfill the request; requiring the use of the form containing unnecessary information is an unreasonable measure. Other examples of unreasonable measures in the proposed regulatory text include requiring the individual to obtain notarization of the individual's signature, or accepting individuals' written requests only in paper form, only in person at the covered entity's facility, or only through the covered entity's online portal. Similarly, the Department proposes below to amend the Privacy Rule by adding section 164.514(h)(2)(v) to prohibit a covered entity from imposing an unreasonable identity verification requirement on an individual attempting to exercise the right of access, and includes examples of such measures.

The Department assumes a prohibition against ''unreasonable measures'' for requesting access would not result in adverse unintended consequences for individuals, but acknowledges that covered entities may have concerns about potential implementation burdens associated with this proposal. The Department solicits comment on its assumptions, and seeks examples of unreasonable measures that individuals and covered entities believe could reduce an individual's ability to participate in the coordination of his or her own healthcare. The Department also requests comment on burdens that covered entities believe may result from this proposed change.

ii. Timeliness

As noted above, the Privacy Rule generally requires covered entities to respond to requests by individuals to exercise their right of access no later than 30 days after receipt by either providing access or a written denial that meets certain requirements.[103] If the covered entity is unable to provide access or a written denial within 30 days, it may extend the allowable time by no more than an additional 30 days if the entity provides to the individual, within the initial 30-day time limit, a written statement of the reason for the delay and the expected completion date.[104]

The Department believes that entities can provide individuals access to their information within a time limit shorter than 30 days. Therefore, to strengthen the individual's right of access to their PHI in a designated record set, the Department proposes to modify section 164.524(b)(2)(i) and (ii) of the Privacy Rule to require that access be provided ''as soon as practicable,'' but in no case later than 15 calendar days after receipt of the request, with the possibility of one 15 calendar-day extension. Where another federal or state law (*i.e.,* statute or regulation) requires a covered entity to provide an individual with access to the PHI requested in less than 15 calendar days, that shorter time limit would be deemed practicable within the meaning of the Privacy Rule under proposed new section 164.524(b)(2)(iii). The Department proposes, in new section 164.524(b)(2)(ii)(C), to also require covered entities to establish written policies for prioritizing urgent or other high priority access requests (especially those related to health and safety) so as to limit the need to use 15 calendar-day extensions for such requests.

At least eight states have statutory requirements to provide patients with copies of their health records in less time than the Privacy Rule's current 30-day limits, and at least five states require the opportunity to view or inspect the record in fewer than 30

[101] OCR previously addressed such unreasonable measures in guidance. *See* 2016 Access Guidance, available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.*

[102] The Department would redesignate section 164.524(b)(1) as section 164.524(b)(1)(i) and move the second sentence of such provision, as redesignated, to section 164.524(b)(1)(ii).

[103] 45 CFR 164.524(b)(2(i).

[104] *See* 45 CFR 164.524(b)(2)(ii)(A) and (B).

days.[105] These access laws primarily apply to health care providers, including hospitals and other health facilities, but not to health plans. Among these states, the requirements to provide copies range from 10 to 15 days.

The Department is strongly persuaded by these examples and by comments from entities operating in states with 10 to 15-day access provisions that, when mandated, covered entities are able to adapt to shorter access time limits. A majority of states do not impose time limits on health care entities that are as short as 15 days, so access to PHI in those states will be markedly improved. Additionally, these shorter timelines would better support the Department's initiatives to improve health care price transparency to empower and assist consumers with making more informed health care decisions. In support of these goals, the Administration has proposed and finalized other rules to require health insurance issuers and plans, as well as hospitals, to make health care prices more readily available to consumers in real-time. For example, in November 2019, CMS, along with the Internal Revenue Service, Department of the Treasury; and the Employee Benefits Security Administration, Department of Labor, proposed rules regarding transparency in coverage to give consumers real-time, personalized access to cost-sharing information. The proposed rules include a proposal for non-grandfathered health insurance plans and issuers in the individual and group markets to provide an estimate of participants', beneficiaries', and enrollees' cost-sharing liability for all covered health care items and services through an online self-service tool, or in paper form, upon request. The rule also would require issuers and plans 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, including personal health application developers (and other application developers that are not providing the application on behalf of or at the direction of a covered entity), to have access to health insurance coverage information.[106] In addition, CMS finalized a rule containing price transparency requirements for hospitals.[107] This rule provides that hospitals must publish on the web standard charges for certain items and services that could be delivered by the hospital to a patient, as well as display the price for bundled ''shoppable'' services that patients would likely schedule in advance, thereby informing the patient's selection of a hospital for scheduled procedures.[108] While many health plans have already provided pricing calculators as an online tool where individuals may access individualized estimates of out-of-pocket costs, not all individuals have equal access to or the ability to utilize internet resources. The proposed Privacy Rule modification would help address this gap in access by applying time limits to providing both electronic and non-electronic PHI the individual may need, such as health conditions and recommended treatment options, to conduct meaningful searches for pricing information. This proposed rule would extend and support the goals of these price transparency initiatives.

Therefore, the Department proposes to amend the individual access right provisions to require covered entities to provide copies of PHI as soon as practicable, but no later than 15 calendar days (with the possibility of one 15 calendar-day extension) or where another federal or state law requires a covered entity to provide an individual with access to the PHI requested in less than 15 calendar days, that shorter time period will be deemed practicable under the Privacy Rule. The same timeliness requirements would be applied when an individual requests direct access under proposed 45 CFR 164.524(b)(2) and when an individual requests that an electronic copy of PHI in an EHR be directed to a third party under proposed 45 CFR 164.524(d)(5).

To limit compliance complexity, the Department proposes to uniformly apply this timeliness requirement, regardless of the form or format of the PHI (*e.g.,* paper or electronic). The Department proposes to explicitly refer to calendar days as the units of time. The Department believes that the current 30-day limit is already understood to be calendar days, and the 2016 Access Guidance also uses the term ''calendar days.'' [109] Thus, the proposed addition of the reference to calendar days would not be a material change, but a clarification.

The Department also proposes to add a requirement that a covered entity may use one 15-day extension of time for providing access to requested PHI if it has established a policy to address urgent or high-priority requests. This proposal is not intended to limit the use of extensions to urgent or high-priority requests, but to provide flexibility for entities that have this type of policy. The Department does not propose to define what constitutes an urgent or high priority request, and does not intend with this proposal to encourage covered entities to require individuals to reveal the purposes for their requests for access. However, examples of urgent or high priority requests could include when an individual voluntarily reveals that the PHI is needed in preparation for urgent medical treatment, or that the individual needs documentation of a diagnosis of severe asthma to be allowed to bring medication to school.

Finally, the Department also proposes at 45 CFR 164.524(c)(3) to expressly provide that, while a covered entity may discuss aspects of the individual's access request with the individual before fulfilling the individual's request, such clarification of the request would not extend the time limit for providing access. This modification would put into regulatory language the Department's interpretation of the access deadlines in the 2016 Access Guidance [110] and help address situations described in public comments in which covered entities contact individuals for the first time near the end of the initial compliance deadline to discuss the request or obtain additional information, and then take unnecessary additional time beyond that initial deadline to fulfill the request.

Shortening and clarifying the Privacy Rule time limits for access requests would strengthen individuals' rights with respect to their health information, advance the aims of patient-directed

[105] *See e.g.,* California, Cal. Health & Safety Code 123110 (5 days to inspect; 15 days to receive a copy); Colorado, 6 Colo. Regs. 1011:1:II–5.2 (24 hours to inspect; 10 days to receive a copy); Hawaii, HRS 622.57 (10 days to receive a copy); Louisiana, LSA–R.S. 40:1165.1 (15 days to receive a copy); Montana, MCA 50–16–541(10 days, copy and inspect); Tennessee, TCA 63–2–101 (10 days to receive a copy); Texas, Tex. Health & Safety Code 241.154 (hosp.) (15 days, copy and inspect), Tex. Occupations Code 159.006 (physicians) (15 days to receive a copy), Tex. Health & Safety Code 181.102 (15 days to receive electronic copies), Tex. Admin. Code 165.2 (physicians) (15 days to receive a copy); and Washington, Wash. Rev. Code 70.02.080 (15 days, copy and inspect).

[106] *See* 84 FR 65464 (November 27, 2019).

[107] Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS 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, 84 FR 65524 (November 27, 2019).

[108] *Ibid.*

[109] *See* 2016 Access Guidance, available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.*

[110] ''These timelines apply regardless of whether . . . [t]he covered entity negotiates with the individual on the format of the response. Covered entities that spend significant time before reaching agreement with individuals on format are depleting the 30 days allotted for the response by that amount of time.'' Available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.*

health care, and enhance care coordination.

4. Addressing the Form of Access

The Privacy Rule requires a covered entity to provide the individual with access to the PHI in the form and format requested, if readily producible in that form and format, or if not, in a readable hard copy form, or other form and format as agreed to by the covered entity and individual.[111] If the individual requests electronic access to PHI that the covered entity maintains electronically, the covered entity must provide the individual with access to the information in the requested electronic form and format, if it is readily producible in that form and format, or if not, in an agreed upon alternative, readable electronic format.[112] The Department intends for the phrase ''readily producible in that form and format'' to refer to how the PHI is produced to the individual or to a third party designated by the individual to receive a copy of PHI *and* the form (*e.g.,* on paper or electronically) and format (*e.g.,* the type of electronic file, etc.) of the PHI that is transmitted. As new forms of information and communications technologies emerge, the ''form and format'' and the ''manner'' of producing or transmitting a copy of electronic PHI may become indistinguishable. For example, if a covered entity or its EHR developer business associate has chosen to implement a secure, standards-based API—such as one consistent with ONC's Cures Act certification criteria,[113] and the covered entity's Security Rule obligations—that is capable of providing access to ePHI in the form and format used by an individual's personal health application, that ePHI is considered to be *readily producible* in that form and format, and that is also the manner by which the ePHI is transmitted. Where ePHI is readily producible in the electronic form and format requested by the individual, the covered health care provider must provide that access, including when the individual requests access to the ePHI through a secure, standards-based API via the individual's personal health application.[114]

The Department is examining how best to address individuals' privacy and security interests when they use a personal health application that receives PHI from a covered entity and has outlined several approaches in the request for comment at the end of this section. The Department requests information about the costs and benefits of options for educating individuals in a manner that does not delay or create a barrier to access. The options presented are consistent with the intent expressed in the ONC Cures Act Final Rule: Although ''an actor may not prevent an individual from deciding to provide its EHI to a technology developer or application despite any risks noted regarding the application itself or the third party developer,'' ONC ''strongly encourage[s] actors to educate patients and individuals about the risks of providing other entities or parties access to their EHI.'' [115]

In addition, the Department proposes, at 45 CFR 164.524(c)(2)(iii), to provide that if other federal or state law (*e.g.,* a statute or regulation) requires an entity (which may include a business associate acting on behalf of a covered entity) to implement a technology or policy that would have the effect of providing an individual with access to his or her PHI in a particular electronic form and format (*e.g.,* if a federal law required the provision of access via secure, standards-based API), such form and format would be deemed ''readily producible'' for purposes of compliance in fulfilling requests for such PHI under 45 CFR 164.524(c)(2)(i) and (ii). This would mean, for example, that if a covered health care provider refused to provide an electronic copy of PHI in response to an individual's request for access via a secure API despite the provider's having implemented a secure API established within the provider's EHR for this purpose, the provider would be in violation of the requirement to provide the requested PHI in the form and format requested if readily producible.[116] In contrast, if the same covered health care provider required all applications to register before providing access via its secure API, imposing this requirement would not constitute a denial of access in the form and format requested, provided that the registration process did not exclude or prevent a personal health application that was capable of securely connecting to the secure API from so connecting.[117]

The Department seeks comments on related situations: Whether to require a health care provider that has EHR technology that incorporates a secure, standards-based API without extra cost, to implement the API; whether to require a health care provider that could implement such an API at little cost to do so; and how to measure the level of cost that would be considered a reasonable justification for not implementing an API.

Section 164.524(c)(2)(iii) of the current Privacy Rule, which would be redesignated as sections 164.524(c)(2)(iv) and 164.524(d)(4), allows a covered entity to provide a summary in lieu of providing access to the requested PHI, or an explanation of the PHI to which access has been provided, if the individual agrees. To ensure that individuals are able to fully exercise their right of access, the Department proposes to add new sections 164.524(c)(2)(iv)(B) and 164.524(d)(4)(ii) to require that, when a covered entity offers a summary in lieu of access, it must inform the individual that the individual retains the right to obtain a copy of the requested PHI (or direct an electronic copy of PHI in an EHR to a third party) if they do not agree to receive the summary. The proposed requirement would not apply when the covered entity offers a summary because it is denying the request for a copy on unreviewable or reviewable grounds, in which case the covered entity must implement the required procedures for such denial. For example, if a covered physician offered to provide a summary in lieu of an entire medical record requested by an individual (or in lieu of ''all PHI about the individual in a designated record set,'' if that is the request), the physician would be required to inform the individual of the

[111] *See* 45 CFR 164.524(c)(2)(i).

[112] *See* 45 CFR 164.524(c)(2)(ii).

[113] ONC has finalized significant updates to its certification criteria at 45 CFR parts 170 and 171. *See* 85 FR 25642 (May 1, 2020).

[114] *See* proposed 45 CFR 164.501 definition of personal health application: *Personal health application* means an electronic application used to access health information on an individual, which can be drawn from multiple sources, provided that such information is managed, shared, and controlled by or primarily for the individual, and not by or primarily for a covered entity. The Privacy Rule does not require a covered entity to implement an API for electronic transmission of an electronic copy of PHI to an individual. Covered entities that transmit ePHI electronically, through an API or by other means, are subject to the Security Rule requirements to ensure the confidentiality, integrity and availability of the ePHI they transmit. *See* 45 CFR 164.306, Security standards: General rules. *See* 45 CFR Subparts A and C for the complete Security Rule.

[115] 85 FR 25642, 25815 (May 1, 2020).

[116] Note that unlike the HIPAA Rules, the ONC Cures Act Final Rule defines access for the purposes of the information blocking provision as ''the ability or means necessary to make EHI available for exchange, use, or both.'' *See* 45 CFR 171.102.

[117] HIPAA does not convey authority to impose security standards on a personal health application that is not a covered entity or a business associate. However, the ONC Cures Act Final Rule at 45 CFR 171.203 provides an exception to what is considered information blocking when the actor's practice that is likely to interfere with the access, exchange, or use of electronic health information is done in order to protect the security of electronic health information. An actor whose practices met this security exception would not be subject to civil money penalties for information blocking under 45 CFR 1003.1400 of the HHS OIG proposed rule. *See* 85 FR 22979 (April 24, 2020).

right to obtain all of the PHI requested. In contrast, if a covered psychologist offered to provide a summary in lieu of requested psychotherapy notes, the psychologist would be required to follow the implementation specifications for denial of access, including providing a written denial and making other information accessible, such as mental health records that are not psychotherapy notes, as defined in the Privacy Rule.

5. Addressing the Individual Access Right To Direct Copies of PHI to Third Parties

a. Current Provisions and Issues To Address

The Privacy Rule right of access requires covered entities to transmit a copy of PHI directly to another person designated by the individual when directed by the individual.[118] Under the current regulatory provision, the request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of the PHI. The designated recipient (the ''third party'') may be a family member or caregiver, a health care provider, a researcher, or any other person or entity the individual (or their personal representative) chooses.

The access right to direct a copy of PHI to a third party is distinct from the provision that permits a covered entity to disclose PHI to a third party with an individual's valid authorization in at least four key respects: [119] (1) The mandatory versus permissive nature of the disclosure; (2) the manner in which the request is made (*e.g.,* with or without a form containing required elements); (3) the form and format of the information provided; and (4) the fees that may be charged. Under the right of access, the individual requests the desired PHI in a designated record set, for whatever purpose he or she wishes, and the covered entity that maintains the PHI is required to respond within a certain period of time and to comply with certain form and format requirements in 45 CFR 164.524, and is subject to access fee limits. In contrast, the Privacy Rule specifically designed the authorization requirements to ensure that individuals agree to the specific uses or disclosures, including the purposes for the uses or disclosures, and that they understand and know how to exercise their rights. Therefore, an authorization states the purpose for the request, describes the PHI requested in a specific and meaningful fashion, and includes a statement explaining the individual's right to revoke the authorization (among other information). The covered entity that receives the individual's valid authorization is permitted, but not required, to disclose the PHI as requested, and may charge the individual for costs beyond those that may be included in a fee for providing copies of PHI pursuant to the right of access.

The right of access does not specifically address provider-to-provider exchanges of PHI because the Privacy Rule permits such disclosures without the individual's authorization for treatment, payment, and health care operations, among other specified purposes. The Privacy Rule also does not address fees for those disclosures. However, the Department believes that some patients have been using the right to direct PHI to a third party as a means of having one covered health care provider send records to another provider. The proposed changes to the right to direct copies of PHI to third parties, such as limiting the right to electronic copies in an EHR and allowing fees for copying ePHI onto electronic media may affect those exchanges of PHI, if health care providers choose to charge fees when sending copies of PHI to other providers when previously they did not.

b. Proposals

The Department proposes to create a separate set of provisions for the right to direct copies of PHI to a third party at subsection (d) of 45 CFR 164.524. Proposed subsection (d) will better align the Privacy Rule with the HITECH Act right to direct to a third party only electronic copies of PHI in an EHR,[120] expand an individual's ability to submit an oral, electronic, or written request for a covered health care provider to transmit an electronic copy of PHI in an EHR to a designated third party in proposed 45 CFR 164.524(d)(1), and expand the access right to empower individual-directed sharing of electronic copies of PHI in an EHR (as the Department proposes to define electronic health record in 45 CFR 164.501) among covered health care providers and health plans as proposed in 45 CFR 164.524(d)(7). The Department believes that only covered health care providers would be responsible for fulfilling an individual's access request under these proposals because the Department believes other covered entities do not have an EHR as that term is defined in the HITECH Act (*i.e.,* an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff). The Department seeks comment on this assumption.

Under the first part of this proposal, at 45 CFR 164.524(d)(1), requests to direct copies of PHI to a third party will be limited to only electronic copies of PHI in an EHR. Therefore, if an individual directs a covered health care provider to transmit an electronic copy of PHI contained in an EHR (as defined in proposed 45 CFR 164.501) to a third party, the covered health care provider must provide a copy of the requested PHI to the person designated by the individual.

The *Ciox* v. *Azar* decision noted that the HITECH Act ''says nothing about a right to transmit PHI contained in any format other than an EHR.'' [121] The Department believes that the *Ciox* v. *Azar* decision precludes a proposal to require covered health care providers to provide electronic copies of PHI to third parties designated by the individual in the form and format requested by the individual. However, the Department encourages covered health care providers, when feasible, to provide copies to third parties in the electronic format requested by the individual. There are many formats in which ePHI can be saved and transmitted that are accessible, readable, and usable by a third party designated by an individual to receive the individual's PHI. For example, the portable document format (PDF) was created specifically to present readable electronic documents independent of hardware, software, and operating systems. Other electronic formats are accessible, usable, and readable because of the popularity of the format (*e.g.,* files saved in .doc and .docx format). The 2013 Omnibus Rule preamble referred to these formats as examples of electronic formats that covered entities could use when providing ePHI in response to a right of access request to ensure patients could read and use the PHI they request.[122] In addition, ONC and CMS are promoting the use of the Fast Healthcare

[118] *See* 45 CFR 164.524(c)(3)(ii). As discussed above, the Department is not enforcing the elements of this regulatory provision that apply to directing non-electronic copies of PHI or copies of PHI that are not in an EHR.

[119] *See* 45 CFR 164.508.

[120] *See* 42 U.S.C. 17935(e).

[121] See *Ciox* v. *Azar,* No. 18–cv–0040–APM, memorandum op. at 46.

[122] ''The Department considers machine readable data to mean digital information stored in a standard format enabling the information to be processed and analyzed by computer. For example, this would include providing the individual with an electronic copy of the protected health information in the format of MS Word or Excel, text, HTML, or text-based PDF, among other formats.'' *See* 78 FR 5566, 5631.

Interoperability Resources (FHIR) standard, which covered health care providers can adopt as an electronic format, to achieve interoperability and easy exchange of health information.[123]

However, in some cases, ePHI might be exported from legacy health IT systems in a proprietary format that would be unreadable for the average person. Further, many data systems offer the capability to export data in multiple formats for portability, and not all of the formats are equally accessible, usable, and readable. For example, a comma-separated value (CSV) file is a common format for sharing data between databases and spreadsheets. However, if a designated third party received PHI in a CSV file from a covered health care provider, the third party may lack the necessary context to read and use such information. Because the right to direct PHI to a third party is a part of the individual right of access, the Department encourages covered health care providers to respond to such requests in a manner that does not frustrate individuals' efforts to exercise those rights in a meaningful way or potentially require the individual to make a second request to obtain a copy of the requested information directly.

As discussed above in reference to individual access, as new forms of information and communications technologies emerge, the ''form and format'' and the ''manner'' of producing or transmitting a copy of electronic PHI may become indistinguishable. For example, if a covered entity has implemented a secure, standards-based API that is capable of providing access to ePHI in the form and format used by an individual's personal health application, that ePHI is considered to be *readily producible* in that form and format, and that is also the manner by which the ePHI may be directed to a third party.

Under the second part of this proposal, in proposed 45 CFR 164.524(d)(1), a covered health care provider would be required to respond to an individual's request to direct an electronic copy of PHI in an EHR to a third party designated by the individual when the request is ''clear, conspicuous, and specific''—which may be orally or in writing (including electronically executed requests).[124] The proposed requirement would replace the current requirement that a request to direct an electronic copy of PHI in an EHR be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of the PHI.[125]

Under these proposals, a written access request such as that contemplated in the current rule would be one means of exercising this right of access, but an oral request could also be actionable if it is clear, conspicuous, and specific. For example, an oral request that identifies the designated recipient and where to send the PHI could meet this standard. Additionally, this provision would allow an individual to use an internet-based method,[126] such as a personal health application, to submit an access request to their health care provider to direct an electronic copy of their PHI in an EHR to a third party, so long as it is ''clear, conspicuous, and specific.''

The third part of this proposal, at 45 CFR 164.524(d)(7), would create a requirement within the right of access for a covered health care provider or health plan to facilitate an individual's request to direct an electronic copy of PHI in an EHR to a third party designated by the individual, which in this case would be the covered entity facilitating the request. If an individual makes a clear, conspicuous, and specific request that his or her covered health care provider or health plan (''Requester-Recipient'') obtain an electronic copy of PHI in an EHR from one or more covered health care providers (''Discloser''), Requester-Recipient would be required to submit the individual's request to Discloser, as identified by the individual.[127] This requirement would apply when an individual is an existing or prospective new patient or a current member (or dependent) of Requester-Recipient, and is limited to directing electronic copies of PHI in an EHR back to Requester-Recipient. (The proposed rule would not require Requester-Recipient to determine whether the potential Discloser is a covered health care provider before submitting the individual's request.) Under this proposal, the individual may make the request orally if the request is clear, conspicuous, and specific. Requester-Recipient may document and submit the oral request in writing or electronically, or, if Discloser accepts oral requests for records from other health care providers or from health plans, Discloser could use its established procedures for accepting and verifying such requests.

The HITECH Act right of an individual to direct an electronic copy of their PHI in an EHR to a third party does not limit the type of entity that may be designated as a third party recipient. As such, covered entities already are potential third party recipients under the right of access, if designated as such by an individual. Under this proposal, a Requester-Recipient would be required to assist an individual in submitting their request for Discloser to direct PHI in an EHR maintained by or on behalf of the Discloser to Requester-Recipient; however, the Department does not propose to change any obligations of the Requester-Recipient once it receives the PHI. For example, the Privacy Rule does not require that a covered health care provider retain PHI it receives about individuals, and the Department does not propose to change this. While Requester-Recipient might be subject to a records retention requirement under state law, its obligations with respect to PHI it receives as a designated third party would be no different under this proposal than its existing obligations when it receives ePHI from other health care providers, *e.g.,* for treatment, payment, or health care operations (TPO) purposes. The Department believes this conclusion holds true whether the disclosure of PHI is pursuant to a valid authorization, or to a third party designated by an individual pursuant to an access request. The Department welcomes examples and comment on this assumption.

In summary, the proposed requirement offers a second mechanism (in addition to the permitted disclosure for TPO) for a covered health care provider or health plan to obtain an electronic copy of PHI in an EHR from another covered health care provider through a required disclosure initiated by an individual's exercise of the right of access. This requirement differs from the scenario in which, for example, one provider queries a health information system or health information exchange (HIE) for records from another provider pursuant to an applicable disclosure

[123] *See* 45 CFR 170.215, Application Programming Interface Standards, adopted by ONC at 85 FR 25642, 25941 and ONC's Fact Sheet, ''The ONC Cures Act Final Rule'' available at *https://www.healthit.gov/cures/sites/default/files/cures/2020-03/TheONCCuresActFinalRule.pdf; See also* 85 FR 25510, 25521, explaining that CMS-regulated entities must adopt 45 CFR 170.215 to implement and maintain a standard-based Patient Access API to support data exchange and empower patients through use of technology (''apps'').

[124] The exceptions to this right are parallel to the existing exceptions to the individual right of access in 45 CFR 164.524(a)(1) for psychotherapy notes and information compiled in anticipation of, or for use in, legal proceedings or unreviewable or reviewable grounds of denial.

[125] *See* 45 CFR 164.524(c)(3)(ii).

[126] This NPRM uses ''internet-based method'' to include online patient portals, mobile ''apps,'' and successor technologies.

[127] Discloser is an entity that maintains or previously maintained an individual's PHI, so they will have had a relationship with the patient, unless the request is made in error.

permission, such as for treatment or health care operations purposes.

The Department's proposal would require that Requester-Recipient submit such access requests to Discloser on behalf of the individual as soon as practicable, but no later than 15 calendar days after receiving the individual's direction and any information the Requester-Recipient needs to submit the access request to Discloser. For example, Discloser may need the name and birthdate of the individual, as well as the name of the Requester-Recipient, a link to a secure electronic document exchange portal, or a physical address where the Discloser may deliver electronic media. The time limit for Requester-Recipient to submit an individual's access request to Discloser would be distinct from covered entities' obligations to provide copies in response to an individual's access request, and a 15 calendar day extension would not be available to Requester-Recipient when submitting the request. Pursuant to the access right to direct an electronic copy of PHI in an EHR to a third party, Discloser would be required to provide the requested electronic copy to Requester-Recipient according to the shorter time proposed for all access requests when the individual directs the information to a third party under 45 CFR 164.524(d)(5) (''as soon as practicable, but not later than 15 calendar days after receiving the request''), provided that the request is clear, conspicuous, and specific. The proposal would permit one 15 calendar day extension under the same conditions described above with respect to the Discloser fulfilling other access requests. Thus, Requester-Recipient would be required to submit an individual's clear, conspicuous, and specific request to Discloser within 15 calendar days of receipt of the request from the individual, and Discloser would then be required to respond by providing the electronic copy to Requester-Recipient, in accordance with proposed 45 CFR 164.524(d)(7). As explained above with respect to requests to direct electronic copies of PHI in an EHR to a third party, individuals may choose to use an internet-based method, such as a personal health application, to ask Requester-Recipient to submit a request to Discloser to transmit an electronic copy of the individual's PHI in an EHR to Requester-Recipient, so long as it is ''clear, conspicuous, and specific.'' The Department welcomes comments on whether a Requester-Recipient should be permitted to refuse to submit a request for an individual in some circumstances (*e.g.,* if it already has the requested information), and whether the Department should specify in regulatory text that if a Requestor-Recipient discusses the request with the individual (*e.g.,* to clarify the request or explain how the request could be changed to be more useful in meeting the individual's health needs), such discussion does not extend the time limit for submitting the request.

The Department also seeks comments on approaches it may take to clarify that the Privacy Rule permits covered entities to use HIEs to make ''broadcast'' queries on behalf of an individual to determine which covered entities have PHI about the individual and request copies of that PHI. Section 164.506(c)(1) permits a covered entity to disclose PHI for its own health care operations purposes, including customer service activities, which could include forwarding an access request to other providers using a trusted exchange network. The Department is considering approaches to clarifying this permission to enhance the right of access and seeks comment on how to do so effectively.

The Department's proposal regarding individual-directed disclosures of PHI in an EHR among certain covered entities would strengthen and clarify the individual's ability to direct the sharing of such PHI. The proposed changes are not intended to replace or frustrate prompt transfers of PHI and ePHI that covered health care providers and health plans already make voluntarily for purposes of treatment, payment, and health care operations. Instead, as was urged by commenters on the 2018 RFI, the proposed changes would require covered entities to submit certain requests for PHI and require covered health care providers to make certain disclosures, pursuant to the exercise of the individual's right to access. This mechanism creates a new required disclosure to covered entities, but in a manner that respects individual preferences and control over the disclosure of PHI through his or her exercise of the right of access.

Finally, parallel to the proposal with respect to the individual right to obtain copies of PHI (and discussed in III.a.4), the Department proposes to require covered entities to inform individuals about their right to direct the requested electronic copies of PHI in an EHR to designated third parties when a covered entity offers to provide a summary in lieu of the requested copies of PHI in 45 CFR 164.524(d)(4)(ii). Consistent with the earlier proposal, the new requirement would not apply when the covered entity offers a summary because it is denying the request for a copy on unreviewable or reviewable grounds, in which case the covered entity must implement the required procedures for such denial.

6. Adjusting Permitted Fees for Access to PHI and ePHI

a. Current Provisions and Issues To Address

The Privacy Rule allows covered entities to charge a reasonable, cost-based fee to fulfill access requests from individuals for copies of their PHI. Section 45 CFR 164.524(c)(4) limits the allowable fees to the costs of (i) labor for copying (whether the PHI is in paper or electronic form), (ii) supplies for creating the paper copy or electronic media if requested, (iii) postage, and (iv) preparing any agreed-upon summary or explanation of the requested PHI. Section 13405(e) of the HITECH Act expands the individual right of access to include the right to direct an electronic copy of PHI in an EHR to a third party. Because the HITECH Act expressly placed the new right within 45 CFR 164.524, the long established right of access, the Department interpreted the 2013 Omnibus Rule as applying the component parts of the existing access right to the new type of access right. This interpretation applied the limitation on fees that covered entities may charge individuals exercising the access right. However, the Department first explained its interpretation in the 2016 Access Guidance, not the 2013 Omnibus Rule. As a result, the *Ciox* v. *Azar* court found that the Department had improperly imposed the fee limitations in the access right to direct a copy of PHI to a third party without notice and comment rulemaking. This NPRM proposes to place modified fee limitations in regulatory text and requests public comment on all aspects of the proposal.

b. Proposal

The Department proposes to modify the access fee provisions to establish a fee structure with two elements based on the type of access request. The first element describes categories of access for which covered entities cannot charge a fee. The second element describes the allowable costs that may be included when an access fee is permitted. The modified fee provisions will be separately located within the enumerated sections for the individual right to inspect and obtain copies of PHI and for the right to direct electronic copies of PHI in an EHR to third parties, as summarized below.

For the individual right to inspect PHI and to obtain copies of PHI about the individual, fees would be:

(1) Always free of charge (*i.e.,* no fee permitted) in proposed 45 CFR 164.524(c)(4)(ii), when:

(a) an individual inspects PHI about the individual in person, which may include recording or copying PHI in a designated record set with the individual's own device(s) or resource(s).

(b) an individual uses an internet-based method to view or obtain a copy of electronic PHI maintained by or on behalf of the covered entity. This includes, for example, access obtained by an individual through the covered entity's certified health IT (*e.g.,* the ''view, download, and transmit'' criterion at 45 CFR 170.315), or by a personal health application connecting to secure standards-based APIs,[128] consistent with applicable federal or state law. The Department intends that such access would be provided without charging a fee to the individual or the personal health application developer.

(2) A reasonable, cost-based fee, in proposed 45 CFR 164.524(c)(4)(i), provided that the fee includes only the cost of:

(a) Labor for copying the PHI requested by the individual in electronic or non-electronic (*e.g.,* paper, film) form;

(b) Supplies for making non-electronic copies;

(c) Actual postage and shipping for mailing non-electronic copies; and

(d) Preparing an explanation or summary of electronic or non-electronic PHI, if agreed to by the individual as provided in paragraph (c)(2)(iii) when an individual requests an electronic or non-electronic copy of PHI about the individual through a means other than an internet-based method.

For the right to direct an electronic copy of PHI in an EHR to a third party, the fees would be:

Under proposed 45 CFR 164.524(d)(6), a reasonable, cost-based fee for an access request to direct a covered health care provider to transmit an electronic copy of PHI in an EHR to a third party through other than an internet-based method, provided that the fee includes only the cost of:

(a) Labor for copying the PHI requested by the individual in electronic form; and

(b) Preparing an explanation or summary of the electronic PHI, if agreed to by the individual as provided in paragraph (d)(4).

This category would apply to requests for a copy of PHI that cannot be fulfilled through an automated process. For example, requests to copy PHI in an EHR onto electronic media and mail it to a physical address would fall within this category.

A summary of how different types of access and recipients of the PHI would affect the proposed allowable access fees is outlined in the chart below.

Type of access	Recipient of PHI	Allowable fees
In-person inspection—including viewing and self-recording or -copying.	Individual (or personal representative).	Free.
Internet-based method of requesting and obtaining copies of PHI (*e.g.,* using View-Download-Transmit functionality (VDT), or a personal health application connection via a certified-API technology).	Individual	Free.
Receiving a non-electronic copy of PHI in response to an access request.	Individual	Reasonable cost-based fee, limited to labor for making copies, supplies for copying, actual postage & shipping, and costs of preparing a summary or explanation as agreed to by the individual.
Receiving an electronic copy of PHI through a non-internet-based method in response to an access request (*e.g.,* by sending PHI copied onto electronic media through the U.S. Mail or via certified export functionality) [129].	Individual	Reasonable cost-based fee, limited to labor for making copies and costs of preparing a summary or explanation as agreed to by the individual.
Electronic copies of PHI in an EHR received in response to an access request to direct such copies to a third party.	Third party as directed by the individual through the right of access.	Reasonable cost-based fee, limited to labor for making copies and for preparing a summary or explanation agreed to by the individual.

The proposed approach, described in further detail below, also would allow covered entities to recoup their costs for handling certain requests to send copies of PHI to third parties, while ensuring that covered entities do not profit from disclosures of PHI made at the individual's request.

(1)(a) No fees permitted when an individual inspects PHI in person, including taking notes, photographs, or using other personal resources to view or capture the information.

As noted above, the current Privacy Rule permits a covered entity to impose a reasonable, cost-based fee for providing copies of PHI that may include only the cost of labor for copying the PHI requested; supplies for creating the copy (*e.g.,* paper, electronic media); postage for mailing the copy to the individual, where applicable; and, if agreed to by the individual, preparation of an explanation or summary of the PHI. The Rule contains no provision permitting fees to be charged for inspection of PHI by the individual who is the subject of the PHI. The Department believes that a covered entity does not incur labor costs for copying, and is unlikely to incur costs for supplies, when providing the individual the opportunity to inspect PHI in person and use his or her own personal resources to capture the information. Therefore, the Department proposes to expressly provide that the covered entity may not charge a fee to an individual who exercises the right to inspect their PHI in person.

Based on its beliefs regarding likely costs, the Department proposes to expressly require that covered entities allow an individual to exercise the access right to inspect their PHI in person without charging a fee.[130] Inspecting PHI may include viewing the information on a patient portal, which could be made available in person for the individual at the point of care in conjunction with a health care appointment or at a medical records office.

The Department requests comment on any new costs that covered entities would likely incur when providing individuals with opportunities to

[128] *See e.g.,* 85 FR 25642, 25645 (May 1, 2020), discussing ONC adoption of API certification criteria at 45 CFR 170.213 and 215.

[129] *See e.g.* 45 CFR 170.315(b)(10) Data export functionality, as added by ONC Final Rule, 85 FR 25642 (May 1, 2020).

[130] This proposal is consistent with the Department's interpretation of this issue in guidance. *See also* FAQ #2035, available at *https://www.hhs.gov/hipaa/for-professionals/faq/2035/can-an-individual-be-charged-a-fee-if-the-individual/index.html.*

inspect their PHI in this manner in person at the covered entity's facility.

(1)(b) No fees permitted when an individual uses an internet-based method to view and capture or obtain an electronic copy of PHI maintained by or on behalf of the covered entity.

The Department believes that access through an internet-based method likely occurs without involvement of covered entity workforce members, and thus believes that the covered entity likely incurs no allowable labor costs or expenses. The Department requests comment on its view of the costs of providing access through an internet-based method, including any internet-based methods described in the ONC Cures Act Final Rule.

Based on its views regarding costs, and to further the policy goal of removing unnecessary barriers to individuals' exercise of the right of access, the Department proposes to prohibit covered entities from charging a fee to provide access through an internet-based method, as described below. While covered entities currently use patient portals and APIs to provide individuals and/or their designated third party recipients with electronic access, the Department proposes that the term ''internet-based method'' would apply to portals and APIs, as well as similar successor technologies. The Department does not intend free access to apply to situations where the individual is simply using an online portal to submit a request for copies of PHI to be sent to him or her in a manner that would require the covered entity to incur allowable costs for supplies, postage, or labor for copying.

(2)(a) Access requests by an individual for a non-electronic copy of PHI through other than an internet-based method would remain subject to the individual access fee limitations.

When providing copies of PHI to an individual, covered entities would remain subject to the current access fee limits.[131] This would include only labor for copying PHI in non-electronic form, supplies for creating the non-electronic copy, actual postage for mailed copies, and the costs of preparing a requested summary or explanation of the PHI.

(2)(b) Access requests by an individual for an electronic copy of PHI through other than an internet-based method would be a reasonable, cost-based fee that is limited to the costs of: (i) Labor for making electronic copies of the PHI, and (ii) preparing a summary or explanation as agreed to by the individual.

The Department understands that such methods may require special effort on the part of the covered entity, which may include, for example, copying PHI onto electronic media and mailing it to the individual or, under some circumstances, using the export functionality of certified EHR technology to transmit ePHI.[132] The costs of electronic media and postage would not be allowed for providing electronic copies of PHI by any method. Pursuant to section 13405(e) of the HITECH Act, ''any fee that the covered entity may impose for providing [an] individual with a copy of such information (or a summary or explanation of such information) if such copy (or summary or explanation) is in an electronic form shall not be greater than the entity's labor costs in responding to the request for the copy (or summary or explanation).'' [133] Therefore, the Department is proposing to limit the fees covered entities are permitted to charge for electronic copies of PHI in an EHR based on a plain reading of this statutory requirement.

For the right to direct the transmission of an electronic copy of PHI in an EHR to a third party:

A reasonable, cost-based fee that is limited to the costs of: (i) Labor for making electronic copies of the PHI, and (ii) preparing a summary or explanation as agreed to by the individual.

In response to the *Ciox* v. *Azar* [134] decision and comments received in response to the 2018 RFI, the Department proposes in 45 CFR 164.524(c)(3)(ii) to limit the right of an individual to direct copies of PHI to a third party to only electronic copies of PHI in an EHR (as defined in proposed 45 CFR 164.501). The Department also proposes to limit the allowable fees for such copies to the costs of labor for making such electronic copies.

Section 13405(e) of the HITECH Act created a new way for an individual to exercise the right of access by choosing to send a copy of PHI to a third party, and thus changed the assumptions previously expressed in the 2000 Privacy Rule that disclosures at the individual's initiation are made only to the individual, while disclosures to third parties are always initiated by others. For example, the 2000 Privacy Rule preamble contrasted the limited fees to provide PHI ''for individuals'' based on the individual's request with fees allowed for ''the exchange of records not requested by the individual'' [135] (*i.e.,* requests made by other persons). The HITECH Act expanded the types of records exchanges that could be requested by the individual pursuant to the right of access, with the result that the identity of the recipient of PHI no longer signifies whether the PHI was provided ''for'' the individual (*i.e.,* at the individual's request through their exercise of the right of access). In addition, the same policy rationales expressed in the 2000 Privacy Rule for limiting fees for individual requests for access, to ensure that the right of access ''is within reach of all individuals,'' [136] apply when the individual requests to direct a copy of PHI to a third party: In both cases, the individual is choosing where to send their own PHI and often, if not always, will be responsible for paying the fee themselves. Finally, by placing the right to direct an electronic copy of PHI in an EHR within the right of access, which had included access fee limitations since the 2000 Privacy Rule, the Department believes the HITECH Act contemplated that access fee limitations would apply, along with other aspects of the existing access right.

Under this proposal, the allowable fees would include, for example, the labor involved in transferring electronic copies of PHI from an EHR onto electronic media when requested by the individual, but would exclude the costs of the electronic media, the labor involved in shipping or mailing the media, and the costs of shipping or postage. Additionally, as under the current rule, a covered entity would be permitted to charge for the costs of preparing a summary or explanation of the requested PHI to be directed to a third party as agreed to by the individual in advance. With these proposed changes, individuals would rely on a valid authorization to send non-electronic copies of PHI in an EHR, or electronic copies of PHI that is not in an EHR, to third parties. Covered entities responding to requests based on an authorization would not be subject to the access fee limitations; however, the fees would remain limited by the Privacy Rule's provisions on the sale of PHI [137] and by applicable state law.

[131] *See* 45 CFR 164.524(c)(4).

[132] *See e.g.,* 45 CFR 170.315(b)(10) and 85 FR 25642, 25691 (May 1, 2020). The ONC Cures Act Final Rule added this requirement but did not specify an export format such as an internet-based method of access. Therefore, at times special effort by covered entity workforce member may be required to copy the exported EHI.

[133] *See* 42 U.S.C. 17935(e)(2),

[134] No. 18–cv–0040–APM (D.D.C. January 23, 2020).

[135] *See* 65 FR 82462, 82754 (December 28, 2000).

[136] *See Id* at 82577.

[137] By default, this change would treat disclosures based on requests to direct non-electronic and non-EHR copies of PHI to third parties the same as other

Under the Privacy Rule's provisions on the sale of PHI at 45 CFR 164.502(a)(5)(ii)(B)(*2*)(*viii*) and 45 CFR 164.502(a)(5)(ii)(A), covered entities generally must limit fees for disclosures pursuant to an authorization to a ''reasonable, cost-based fee to cover the cost to prepare and transmit the protected health information for such purpose or a fee otherwise expressly permitted by other law'' or must state in the authorization that the disclosure will result in remuneration to the covered entity as provided in 45 CFR 164.508(a)(4).

Although covered entities would be restricted from recouping some costs that are allowed under the current rule, the effect of limiting the right to direct PHI to a third party to only electronic copies of PHI in an EHR would significantly reduce covered entities' burdens by increasing the number of requests based on an authorization. For example, many states have laws permitting health care entities to impose fees for providing copies of medical records that may be higher than the Privacy Rule allows. The states, for example, may permit covered entities to charge for costs other than supplies, labor for copying, and postage, or may establish a per page fee in excess of what the Privacy Rule allows. However, under the current Privacy Rule, when an individual exercises his or her access right, including when directing an electronic or non-electronic copy of PHI to any third party, covered entities are not permitted to impose higher fees for copies of PHI that may be permitted by state law.[138]

The Department anticipates that no fees would be charged when an individual uses an internet-based method to direct an electronic copy of PHI in an EHR to any third party, when an individual uses such a method to direct a covered health care provider or health plan to submit an access request to another covered health care provider, or when an individual submits a request through a health care provider or health plan to other providers and plans using such method. The rationale for this understanding is the same as discussed above in relation to the individual right to access or obtain copies of PHI available via an internet-based method—that there are no associated costs incurred by the covered entity for responding to the specific request. The Department requests comment on whether the assumption that no costs will be incurred to provide access using an internet-based method applies to each of the internet-based access scenarios described in this paragraph.

As a consequence of the proposed limits on the right to direct transmission of electronic copies of PHI in an EHR, covered entities would be permitted to charge less restricted fees when fulfilling requests to send non-electronic copies of PHI in an EHR, or electronic copies of PHI that is not in an EHR, to third parties, because these requests would no longer be within the right of access.[139] Instead, such disclosures to third parties (whether to an individual's family member, covered entity, researcher, or any other person) would be accomplished through an individual's valid authorization, with the only Privacy Rule limitation on the fees for such copies being the Privacy Rule's provisions on the sale of PHI.[140]

The Department does not propose to change how covered entities currently charge for disclosing records to health plans and providers. It is the Department's understanding that frequently there is no charge for permitted disclosures of PHI to another covered entities for core health care activities such as treatment, payment, or health care operations. This proposal is not intended to cause covered entities to begin charging fees for such disclosures, but to recognize individuals as the center of their own health care and empower individual-initiated transfers of electronic copies of PHI in an EHR.

7. Notice of Access and Authorization Fees [141]

To increase an individual's awareness of the cost of copies of PHI, and to make the access fee requirements more uniform, the Department proposes to add a new subsection 525 to 45 CFR 164 to require covered entities to provide advance notice of approximate fees for copies of PHI requested under the access right and with an individual's valid authorization. Readily available public information about access fees would also serve to promote compliance with the Privacy Rule because covered entities will want to avoid posting fee schedules that show noncompliance with fee limitations,[142] or that publicly misrepresent their business practices, and individuals will be empowered to insist on covered entities' compliance as well. Specifically, covered entities would be required to post a fee schedule online (if they have a website) and make the fee schedule available to individuals at the point of service, upon an individual's request. The notice must include: (i) All types of access available free of charge and (ii) fee schedule for: (A) Copies provided to individuals under 45 CFR 164.524(a), with respect to all readily producible electronic and non-electronic forms and formats for such copies; (B) copies of PHI in an EHR and directed to third parties designated by the individual under 45 CFR 164.524(d), with respect to all readily producible electronic forms and formats for such copies; and (C) copies of PHI sent to third parties with the individual's valid authorization under 45 CFR 164.508, with respect to all available forms and formats for such copies.

With respect to fee schedule availability at the point of service, the Department would expect that a covered health care provider would make the fee schedule available upon request, in paper or electronic form, at the point of care or at an office that is responsible for releasing medical records, as well as orally (*e.g.,* over the phone), as applicable. For both covered health care providers and health plans, the point of service also could include a customer service call center that handles requests for records, or any location at which PHI is made available for individuals to inspect, as required under 45 CFR 164.524.

Additionally, the Department proposes to require that covered entities provide an individualized estimate to an individual of the approximate fees to be charged for the requested copies of PHI, upon request. The Department would expect that the covered entity would provide the individualized estimate upon request and within the initial time (or in many cases sooner) in which the covered entity has to fulfill the access

requests for disclosures pursuant to a valid authorization. See discussion of the limitations on requests to direct certain copies of PHI to a third party and related requirements, *infra. See also* 45 CFR 164.502(a)(5)(ii)(A) and 164.508(a)(4).

[138] *See* 78 FR 5566, 5636 (January 25, 2013).

[139] By default, this would change the status of requests to direct non-electronic and non-EHR copies of PHI to third parties by relegating such requests to disclosures under the authorization standards. See discussion of the limitations on requests to direct certain copies of PHI to a third party and related information requirements, *infra.*

[140] 45 CFR 164.501(a)(5)(ii)(A) and 164.508(a)(4).

[141] This NPRM uses ''access and authorization fees'' to mean fees for copies of PHI provided pursuant to the individual's right of access and for disclosures made pursuant to a valid authorization, respectively.

[142] In addition to the access fees limits contained in 45 CFR 164.524, the Privacy Rule limits the fees that may be charged for uses and disclosures of PHI based on an authorization. Under the Privacy Rule's provisions on the sale of PHI, covered entities generally must limit fees for disclosures pursuant to an authorization to a ''reasonable, cost-based fee to cover the cost to prepare and transmit the protected health information for such purpose or a fee otherwise expressly permitted by other law'' or must state in the authorization that the disclosure will result in remuneration to the covered entity. *See* 45 CFR 164.502(a)(5)(ii)(B)(*2*)(*viii*); 45 CFR 164.502(a)(5)(ii)(A); 45 CFR 164.508(a)(4).

request (prior to any extension of time that may be allowed for providing the copies) and prior to providing the requested PHI, to allow for a meaningful decision by the individual regarding the scope of the request or the form and format requested. If more time is needed to provide the requested copies after providing an individualized estimate, a covered entity may notify the individual of its need for a 15-day extension.

The Department also proposes in 45 CFR 164.525 to require covered entities to provide, upon an individual's request, an itemization of the charges for labor for copying, supplies, and postage, as applicable, which constitute the total fee charged to the individual for copies of PHI.

The Privacy Rule does not prohibit a covered entity from requiring individuals to pay a fee for copies of PHI ''upfront'' before receiving such copies. The Department does not propose to amend the Privacy Rule to require covered entities to fulfill the requests of individuals (by providing copies of PHI) before fees are paid. However, because the Department believes that providing individuals with access to their health information is an important component of delivering and paying for healthcare, the Department continues to encourage covered entities that charge fees for copies of PHI to waive fees or provide flexibility in payment (such as delaying charges or accepting payment in installments, without delaying the provision of copies) for individuals who are unable to pay upfront due to an emergency or a lack of resources.[143] The Department also encourages covered entities to waive access fees in cases where the individual cannot pay the fee due to a demonstrated financial hardship, including when the requesting individual is a Medicaid beneficiary, homeless, otherwise financially disadvantaged, or experiencing financial strain due to some other type of emergency situation.

Finally, an individual's request for a fee estimate under this proposal would not automatically extend the time permitted for covered entities to provide copies of PHI under the right of access; however, a covered entity would have the ability to inform the individual if one 15-day extension is needed.

8. Technical Change to General Rules for Required Business Associate Disclosures of PHI

The Department proposes to insert clarifying language in 45 CFR 164.502(a)(4)(ii), which currently requires business associates to provide copies of PHI to covered entities, individuals, or individuals' designees, to satisfy the covered entity's obligations under the right of access. To clarify when a business associate must disclose PHI and to whom, the proposal would specify that a business associate is required to disclose PHI to the covered entity so the covered entity can meet its access obligations. However, if the business associate agreement provides that the business associate will provide access to PHI in an EHR directly to the individual or the individual's designee, the business associate must then provide such direct access. This proposed clarification is consistent with the preamble discussion on this topic in the 2013 Omnibus Rule [144] and subsequent guidance,[145] and is not intended to be a substantive change.

9. Request for Comments

The Department seeks comment on the foregoing proposals, including any benefits or unintended consequences, and the following considerations in particular:

a. Whether the Department's proposed definition of EHR is too broad, given the context of the HITECH Act, such that the definition should be limited to clinical and demographic information concerning the individual.

b. Whether an electronic record can only be an EHR if it is created or maintained by a health care provider, or whether there are circumstances in which a health plan would create or maintain an EHR.

c. Whether the Department should instead define EHRs to align with the scope of paragraphs (1)(i) and (2) of the definition of designated record set.[146]

d. Whether the proposed definition of EHR includes PHI outside of an electronic designated record set, whether it should, and examples of such PHI.

e. Whether the proposed interpretation of ''health care clinicians and staff'' as it relates to the proposed EHR definition is appropriate, too broad, or too narrow, and in what respects.

f. Should ''health care clinicians and staff'' be interpreted to mean all workforce members of a covered health care provider? What are the benefits or adverse consequences of such an interpretation? Does the same interpretation apply regardless of whether the provider has a direct treatment relationship with individuals, and why or why not?

g. Are there other health care industry participants that have access to or maintain EHRs that should be explicitly recognized in the definition of EHR or that OCR should consider when establishing such a definition?

h. Whether EHR should be defined more broadly to include all ePHI in a designated record set, and benefits or drawbacks of doing so.

i. Should the definition of EHR for Privacy Rule purposes be aligned with other Department authorities or programs related to electronic health information? If so, which ones and for what purposes? [147]

j. Any other effects, burdens, or unintended consequences of the proposed definition of EHR or of including a definition for EHR in the Privacy Rule.

k. What types of activities should be encompassed in the terms ''managed,'' ''shared,'' and ''controlled'' in the proposed definition of personal health application, and whether other terms would improve the clarity of the definition.

l. State laws or other known legal restrictions that might affect the ability of individuals to take photos of or otherwise capture copies of their PHI in a designated record set.

m. The frequency with which covered entities currently receive requests to inspect PHI in person, and estimated annual costs to covered health care providers and health plans of fulfilling such requests.

n. Whether a time limit shorter than 15 calendar days for a covered entity to submit, or respond to, an individual's access request would be appropriate. The Department seeks comment on time limits for covered entities to respond to access requests, requests to direct electronic copies of PHI in an EHR to a third party, and requests to submit a request to another provider on behalf of the individual. The Department welcomes data on the burdens and

[143] *See* 2016 Access Guidance, available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.*

[144] *See* 78 FR 5566, 5598–5599 (January 25, 2013).

[145] *See https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html?language=es.*

[146] *See* 45 CFR 164.501, definition of ''Designated record set.''

[147] *See, e.g.,* 84 FR 55766 (October 19, 2019). *Electronic health record* means a repository that includes electronic health information that—(1) Is transmitted by or maintained in electronic media; and (2) Relates to the past, present, or future health or condition of an individual or the provision of health care to an individual. *https://www.federalregister.gov/d/2019-22028/p-535.*

benefits such a time limit would impose.

o. Whether a covered health care provider should be required to inform an individual who requests that PHI be transmitted to the individual's personal health application of the privacy and security risks of transmitting PHI to an entity that is not covered by the HIPAA Rules. What are the benefits or burdens of different approaches? For example: Accepting the individual's judgment without requiring covered entities to provide education, notice, or warning; requiring a covered entity to provide a warning verbally and/or electronically at the time the individual requests transmission of PHI to a personal health application; providing education about the application developer's privacy and security policies and practices through an automated attestation and warning process; or adding information about risks to PHI disclosed to a personal health application in the covered entity's NPP.

p. The Department also invites comment on whether to apply any potential education, notice, or warning requirement to only health care providers or also to health plans. Whether the Department should consider requiring a covered health care provider or health plan to provide any specific educational or advisory language to individuals who may choose to share their PHI with other individuals through applications that are not regulated by the Privacy Rule.

q. Whether the Department should specify in regulatory text that if a Requestor-Recipient discusses the request with the individual (*e.g.,* to clarify the request or explain how the request could be changed to be more useful in meeting the individual's health needs), such discussion does not extend the time limit for submitting the request, and the benefits or drawbacks of such a provision.

r. Whether any federal or state law time limit shorter than 15 calendar days that applies to disclosures of PHI to a third party (*e.g.,* public health agency) should be deemed a ''practicable'' time limit under the Privacy Rule right of access.

s. Whether and how a covered entity should be required to implement a policy for prioritizing urgent or otherwise high priority access requests, so as to minimize the use of the 15-calendar-day extension. Would there be unintended adverse consequences of such a requirement—*e.g.,* would covered entities begin to require individuals to state the purposes for their access requests even though the Privacy Rule does not make the right of access contingent on the purpose for the request? If a covered entity did impose such a requirement, would this constitute an unreasonable measure that impedes the individual from obtaining access?

t. Any benefits or drawbacks of the proposal to require a covered entity to act on an oral access request to either direct an electronic copy of PHI in an EHR to a third party or direct a covered entity to submit such a request, provided the oral communication is clear, conspicuous, and specific.

u. Whether there would be unintended consequences for the covered entity that has received PHI as a result of a request that was made to another covered entity by an individual.

v. ''Clear, conspicuous, and specific'' is a statutory standard [148] that the Department proposes to use in place of the existing regulatory requirement that the request be signed and in writing and clearly identify the designated third party. The Department requests comment on how to interpret the phrase ''clear, conspicuous, and specific,'' including when the request is verbal.

w. Whether the Department should specify any bases for a Requester-Recipient to deny an individual's request to submit an access request to a Discloser, for example, if the requested disclosure is prohibited by state or other law or if the Requester-Recipient already has the information.

x. Whether there are certain types of individual requests to submit an access request to a Discloser that would place an undue burden on the Requester-Recipient, such as submitting large numbers of requests to multiple Disclosers, or other factors affecting the potential burden on or benefit to a Requester-Recipient.

y. Whether a covered health care provider or health plan that uses an HIE to make a broadcast query to identify other HIE participants that have PHI about that individual, and that requests the PHI on behalf of an individual, should be considered to be making a permissible disclosure of PHI for customer service or other administrative or management activities that are part of the covered health care provider or health plan's health care operations.[149] Are there unintended consequences for covered entities or individuals of such an interpretation of health care operations?

z. Information from individuals and covered entities about how covered entities currently respond to ''imperfect'' requests to send PHI to a third party (*e.g.,* requesting information that is not part of the access right; all the necessary elements of a right of access request are not included when an individual directs electronic PHI in an EHR to a designated third party; invalid authorizations, etc.) and the efforts made by covered entities to enhance individuals' abilities to efficiently obtain the requested information.

aa. Whether the term ''internet-based method'' or alternative terms adequately describe online patient portals, mobile applications, APIs, and other related technologies. If there are unintended consequences associated with using such broad terminology, are there ways in which any unintended adverse effects could be minimized?

bb. Should the Privacy Rule prohibit covered entities from charging fees for copies of PHI when requested by certain categories of individuals (*e.g.,* Medicaid beneficiaries or applicants for or recipients of Social Security Disability Insurance (SSDI)), or when the copies are directed to particular types of entities (*e.g.,* entities conducting clinical research)?

cc. Whether the Privacy Rule should prohibit covered entities from denying requests to exercise the right of access to copies of PHI when the individual is unable to pay the access fee. If so, how should a covered entity determine when an individual is unable to pay?

dd. The fees (if any) that covered entities currently charge when sending records to another provider or covered entity at the request of an individual.

ee. What fees, if any, are charged for disclosures among covered entities made at the request of the entities?

ff. How covered entities currently treat access requests that involve converting non-electronic PHI into an electronic format, the fees that are charged for such requests, and how that compares to fees charged for similar requests for copies of PHI made by a third party with an individual's valid authorization.

gg. How the proposals to narrow the access right to direct PHI to third parties to electronic copies of PHI in an EHR will affect fees for copies of PHI.

hh. How covered entities currently calculate reasonable, cost-based fees for copies of PHI under the right of access. For example, OCR's 2016 Access Guidance offered three illustrative methods for calculating allowable access fees: (1) Actual labor costs for copying, plus supplies and postage; (2) average labor costs for copying, plus supplies and postage; and (3) a flat fee of $6.50 for electronic copies of ePHI, inclusive of labor, supplies, and any

[148] *See* 42 U.S.C. 17935(e).

[149] *See* 45 CFR 164.501 (definition of ''Health care operations,'' paragraph (6)).

applicable postage. The Department requests comment on the extent to which entities use each of these methods. For entities using the average costs option (2), the Department requests comment on what data is being used to calculate the average. It also seeks comment on how covered entities calculate fees for ''hybrid'' access requests—that is, requests for copies of PHI that encompass both electronic and non-electronic PHI.

ii. Comment on whether the Department should specify one or more of the three methods listed above, or another method, in the regulatory text as the exclusive acceptable method of calculating access fees. This NPRM does not propose to require any particular method of calculation; however, the Department requests comment on the benefits and burdens of doing so. The Department also requests comment on the reasonableness of the $6.50 flat fee for electronic copies of PHI maintained electronically, and whether another flat rate would be more appropriate. Finally, the Department requests comment on whether other methods of calculating fees should be required in regulation or offered as options in guidance.

jj. Whether the Department should establish in regulation a separate required timeframe for covered entities to respond to individuals' requests for access fee estimates or an itemized list of charges, and what timeframe(s) would be appropriate, and whether the time to respond to a request for access should be tolled pending an individual's confirmation that it desires the requested information given the fee estimate.

kk. Whether there should be a legal consequence to covered entities for the bad faith provision of an incorrect estimate of fees for access and authorization requests, and if so, what actions should be considered evidence of bad faith sufficient to subject a covered entity to potential penalties.

ll. More information from covered entities and individuals about their experiences with records requests (including when made at the direction of the individual or with an individual's valid authorization) and any unintended consequences that may result from the Department's proposals.

mm. What are commonly available electronic forms and formats that covered entities and business associates generally provide to individuals or third parties? How many requests per month for electronic copies of PHI on electronic media do covered entities and business associates receive from individuals? How many requests per month are received for electronic copies provided through internet-based methods? How long does it take to fulfill each type of request?

nn. Do individuals or third parties ever receive requested PHI in unreadable electronic forms and formats? What are those forms and formats, and do covered entities or business associates provide another form and format if they are told the first copy of PHI they provided is unreadable or unusable?

B. Reducing Identity Verification Burden for Individuals Exercising the Right of Access (45 CFR 164.514(h))

1. Current Provision and Issues To Address

Section 45 CFR 164.514(h) of the Privacy Rule generally requires a covered entity to take reasonable steps to verify the identity of a person requesting PHI before disclosing the PHI to help ensure that unauthorized persons do not obtain an individual's PHI.[150]

As OCR has explained in guidance,[151] the Department's view is that the Privacy Rule does not mandate any particular form of verification (such as viewing an individual's driver's license at the point of service), but instead generally leaves the type and manner of the verification to the discretion and professional judgment of the covered entity, provided the verification processes and measures do not create barriers to, or unreasonably delay, the individual from obtaining access to their PHI. Verification may be done orally or in writing and, in many cases, the type of verification may depend on how the individual is requesting and/or receiving access, such as in person, by phone (if permitted by the covered entity), by faxing or emailing the request on the covered entity's supplied form, by secure internet portal, or by other means. For example, if the covered entity requires that access requests be made on its own supplied form, the form could ask for basic information about the individual that would enable the covered entity to verify that the person requesting access is the subject of the information requested or is the individual's personal representative. For covered entities providing individuals with access to their PHI through internet portals, the Department's view is that the portals should be set up with appropriate authentication controls, as required by 45 CFR 164.312(d) of the HIPAA Security Rule, to ensure that the person seeking access is the individual who is the subject of the PHI (or their personal representative).

Despite OCR's guidance explaining the Department's interpretation of the verification and individual access provisions in 45 CFR 164.514(h) and 164.524,[152] the Department has received complaints and heard anecdotal accounts of covered entities imposing burdensome verification requirements on individuals seeking to obtain their PHI pursuant to the individual right of access. For example, some covered entities require individuals to receive their PHI in person, or even to go through the process (and potential added expense) of obtaining a notarization on a written request, to exercise their right of access.

2. Proposal

To address these ongoing challenges and barriers to an individual's access to their health information, the Department proposes to modify paragraph (2)(v) of 45 CFR 164.514(h) to expressly prohibit a covered entity from imposing unreasonable identity verification measures on an individual (or his or her personal representative) exercising a right under the Privacy Rule. In addition, the Department proposes to clarify within the regulatory text that unreasonable verification measures are those that require an individual to expend unnecessary effort or expense when a less burdensome verification measure is practicable for the particular covered entity. Unreasonable measures would include requiring individuals to obtain notarization of requests to exercise their Privacy Rule rights and requiring individuals to provide proof of identity in person when a more convenient method for remote verification is practicable for the covered entity. The Department would consider the application of the practicability standard for verification measures to encompass considerations related to an entity's fulfillment of its Security Rule obligations including its size, complexity and capabilities; its technical infrastructure, hardware, and software security capabilities; the costs of security measures related to verification and implementing measures that may be more convenient for individuals; and the probability and criticality of potential risks to ePHI in the covered entity's systems.[153] This modification is not intended to prevent

[150] *See* 45 CFR 164.514(h). Disclosures under 45 CFR 164.510 are excepted from this requirement. *See* 45 CFR 164.514(h)(1)(i).

[151] *See* 2016 Access Guidance, available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.*

[152] *Id.*

[153] *See* 45 CFR 164.306(b)(2).

covered entities from taking reasonable measures to verify the identity and authority of the individual or entity making the request.

As explained above, the Department proposes to clarify that a covered entity that implements a requirement for individuals to submit a request for access in writing would not be permitted to do so in a way that imposes unreasonable burdens on individuals. The proposed change to prohibit a covered entity from implementing unreasonable identity verification requirements complements the first proposal to ensure that an individual is afforded as much flexibility as reasonable when accessing his or her own records. In contrast, a covered entity that is responding to an individual's request to direct an electronic copy of ePHI in the covered entity's EHR to a third party must do so if the oral or written request is clear, conspicuous, and specific. The Department assumes that a covered entity holding records of an individual in an EHR has necessarily established a treatment relationship with such individual, and therefore, imposing additional verification requirements is unnecessary. The Department seeks comments on this assumption.

Consistent with the verification provisions described above, unreasonable measures for submitting an access request in writing would be measures that impede the individual from obtaining access when a measure that is less burdensome for individuals is practicable for the particular covered entity. For example, requiring individuals to complete a form with only the limited information needed for the entity to provide access would be considered reasonable because it only requests information necessary for verification and does not require the individual to expend unnecessary effort. In contrast, requiring individuals to fill out a form with the extensive information contained in a HIPAA authorization form may impose an unreasonable burden to individuals. In addition, while covered entities are encouraged to provide individuals with the option to submit access requests through online portals, it generally would be unreasonable for a covered entity to require that requests for access be made only through the covered entity's online portal, depending on factors such as the covered entity's analysis of security risks to ePHI.[154] Unreasonable measures also would include applying onerous or infeasible registration requirements for personal health applications (or other applications that are not being provided on behalf of or at the direction of the covered entity) that would create a barrier to or unreasonably delay registration beyond what is necessary for compliance with the HIPAA Security Rule, such as requiring a third party that does not meet the definition of a business associate to enter into a business associate agreement with the covered entity. Another example would be preventing an individual's personal health application from registering with an endpoint (*e.g.,* API) that the covered entity makes public, absent an identified security risk to the ePHI in the covered entity's (or its business associate's) EHR systems.

The Department's view is that, under the Privacy Rule access requirements, covered entities generally must allow every application that wants to register with the API to provide access for an individual, the ability to do so, assuming that it is practicable for the covered entities and absent any Security Rule concerns.[155] Therefore, a covered entity or its business associate that makes available a secure, standards-based API but denies registration, and therefore individual access, to a designated personal health application, or other application that is not being provided on behalf of or at the direction of a covered entity, may be in violation of the Privacy Rule requirements for provision of access of individuals to PHI. For example, a health care provider may not deny an application from registering solely because the application does not have a business associate relationship and agreement with the covered entity or because the application offers another service to patients that competes with a service the health care provider offers.

The Department recognizes that due to the variety of circumstances of individuals and entities, a given measure to complete identity verification or request access, such as using an online portal, may be convenient for some individuals and burdensome for others, and practicable for some entities but not for others. Due to this variability, the Department does not propose to require that covered entities implement any particular measure, nor require covered entities to analyze and adopt the least burdensome measure possible for each individual. Further, the Department does not intend to impede the ability of covered entities to comply with any applicable federal or state law provisions that provide greater privacy or security protections related to verification of identity to access medical records, provided that the identity verification measures used and the manner in which they are implemented do not impose unreasonable burdens on an individual's exercise of the right of access.[156] Rather, the Department would expect covered entities to avoid imposing measures that would require unnecessary effort or expense by an individual and to provide individuals with some flexibility (*e.g.,* by accepting verification and access requests by more than one practicable measure).

3. Request for Comments

The Department requests comments on the above proposal, including:

a. Please describe any circumstances in which individuals have faced verification barriers to exercising their Privacy Rule rights, as well as examples of verification measures that should be encouraged as convenient and practicable, in comparison to those that should be prohibited as per se unreasonable. Please also describe any circumstances related to unreasonable verification measures imposed on third parties to whom an individual directs a copy of PHI.

b. What verification standard should apply when a covered health care provider or health plan submits an individual's access request to another covered health care provider or health plan? Specifically, should the covered entity that holds the requested PHI be required to verify the identity and authority of the covered entity that submitted the request, but be permitted to rely on the requesting entity's verification of the identity of the individual (or personal representative)?

[154] See proposed 45 CFR 164.514(h)(v), which would require a covered entity to examine risks pursuant to 45 CFR 164.308(b)(2).

[155] The ONC Cures Act Final Rule provides exceptions aligned to the HIPAA Rules to information blocking requirements to prevent harm, for privacy and security. This discussion is consistent with those provisions. *See* 85 FR 25642 (May 1, 2020), 45 CFR 171 Subpart B.

[156] For example, Privacy Act guidelines for federal agencies state, ''A requester need not state his [or her] reason for seeking access to records under the Privacy Act, but an agency should verify the identity of the requester in order to avoid violating subsection (b) [of that Act.] *https://www.justice.gov/opcl/individuals-right-access. See* OMB Guidelines, 40 FR 28948, 28957–58 (July 9, 1975), available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/inforeg/implementation_guidelines.pdf. See also* 5 U.S.C. 552a(i)(1) (imposing criminal penalties for disclosure of information to parties not entitled to receive it); 5 U.S.C. 552a(i)(3) (imposing criminal penalties for obtaining records about an individual under false pretenses); *cf., e.g.,* 28 CFR 16.41(d) (DOJ regulation regarding the verification of identity). *See also* OMB guidance on Privacy Act implementation available at *https://www.whitehouse.gov/omb/information-regulatory-affairs/privacy/.*

c. How could or should covered entities consider the costs of implementation when evaluating whether a verification method is practicable?

d. Whether the proposal would support individuals' access rights by reducing the verification burdens on individuals, and any potential unintended adverse consequences.

e. Whether a different identity verification standard should apply when an individual requests access, as compared to when a personal representative requests access on the individual's behalf.

f. Examples of state law identity verification requirements that apply when a covered entity provides PHI to an individual or personal representative, or fulfills an individual's request to direct a copy of PHI to a third party. Please provide input on whether any state law identity verification requirements create a barrier to or unreasonably delay an individual's exercise of the right of access in a manner that should be considered inconsistent with the Privacy Rule.

C. Amending the Definition of Health Care Operations To Clarify the Scope of Care Coordination and Case Management (45 CFR 160.103)

1. Current Provision and Issues To Address

The Privacy Rule expressly permits certain uses and disclosures of PHI, without an individual's valid authorization, for treatment and certain health care operations, among other important purposes.[157] The definitions of both treatment and health care operations include some care coordination and case management activities. For example, the Privacy Rule definition defines treatment to include ''the provision, coordination, or management of health care.'' [158] The definition of health care operations includes, among other activities, ''. . . population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination . . . and related functions that do not include treatment.'' [159]

The preamble to the 2000 Final Privacy Rule states that certain activities ''may be considered either health care operations or treatment, depending on whether population-wide or patient-specific activities occur, and if patient-specific, whether the individualized communication with a patient occurs on behalf of a health care provider or a health plan. For example, a telephone call by a nurse in a doctor's office to a patient to discuss follow-up care is a treatment activity. The same activity performed by a nurse working for a health plan would be a health care operation.'' [160] Therefore, the Privacy Rule contemplates that health plans would—as part of health care operations—conduct the types of activities described in this NPRM as care coordination and case management not only at the population level across multiple enrolled individuals but also at the individual level for unique patients including providing for their care across different settings.[161]

Despite this guidance published in the preamble to the 2000 Privacy Rule,[162] some covered entities appear to interpret the existing definition of health care operations to include only *population-based* care coordination and case management, which would have the effect of excluding individual-focused care coordination and case management by health plans. Since health plans do not perform treatment functions as defined by HIPAA, such an interpretation could limit a health plan's ability to perform such individual-level care coordination or case management activities.

While the 2018 RFI did not specifically request comment on the definitions of treatment or health care operations, both of which include care coordination activities, some covered entities expressed uncertainty regarding whether the use or disclosure of PHI for a particular care coordination or case management activity is permitted as part of treatment, health care operations, both, or neither. Some covered entities reported that, due to uncertainty about which provisions apply in certain circumstances, they do not request or disclose PHI even when doing so would support coordinated care and the transformation of the health care system to value based care.

2. Proposal

The Department proposes to clarify the definition of health care operations in 45 CFR 164.501 to encompass all care coordination and case management by health plans, whether individual-level or population-based. The proposal would provide clarity to covered entities and individuals regarding which Privacy Rule standards apply to which care coordination and case management activities, and thereby facilitate those beneficial activities. The clarification also would complement and enhance the proposal in this NPRM to modify the minimum necessary standard to promote uses and disclosures for care coordination and case management for treatment or health care operations by covered health care providers and health plans. The Department believes that, as drafted, the placement of commas separating the list of activities following the term ''population-based activities'' permits the interpretation that the term ''population-based activities'' modifies (*i.e.,* places a condition on) all of the activities listed between the semi-colons, including case management and care coordination, although the Department has not placed that interpretation on the definition of health care operations. In order to clearly convey that the activities listed are each separate types of health care operations, the Department proposes to change the commas into semi-colons. The new definition proposed in paragraph (1) of the definition of ''Health care operations'' in 45 CFR 164.501 would read as follows:

> . . . population-based activities relating to improving health or reducing health care costs; protocol development; case management and care coordination; contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.

The Department believes this change in punctuation would clarify that health care operations encompasses all care coordination and case management activities by health plans and covered health care providers, whether population-based or focused on particular individuals, and thus would increase the likelihood of these entities' using and disclosing PHI for such beneficial activities.

3. Request for Comments

The Department requests comments on the benefits and costs of clarifying the definition of health care operations, including information on how, if at all, this clarification would affect covered

[157] *See* 45 CFR 164.506. 45 CFR 160.103 defines ''Disclosure'' as ''release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information''; The term ''Use'' is defined as ''with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information with an entity that maintains such information.''

[158] *See* 45 CFR 164.501, definition of ''Treatment.''

[159] *See* 45 CFR 164.501, definition of ''Health care operations.''

[160] 65 FR 82462, 82627 (December 28, 2000).

[161] This NPRM describes such activities as ''population-based'' and ''individual-level'' care coordination and case management, respectively.

[162] 65 FR 82462, 82627 (December 28, 2000).

entities' decision-making regarding uses and disclosures of PHI for these purposes, and on any potential unintended adverse consequences.

D. Creating an Exception to the Minimum Necessary Standard for Disclosures for Individual-Level Care Coordination and Case Management (45 CFR 164.502(b)(2))

1. Current Provision and Issues To Address

The Privacy Rule generally requires that covered entities use, disclose, or request only the minimum PHI necessary to meet the purpose of the use, disclosure, or request.[163] This minimum necessary standard requires covered entities to evaluate their practices and enhance safeguards as needed to limit unnecessary or inappropriate use and disclosure of PHI.[164] While the standard is an important privacy protection that is consistent with foundational federal information privacy policy,[165] the Department believes that there is room for flexibility in the application of the standard without sacrificing key privacy protections.

The Privacy Rule's minimum necessary requirements are designed to be sufficiently flexible to accommodate the various circumstances of any covered entity and to avoid creating unnecessary barriers to information sharing for permitted purposes. Accordingly, the minimum necessary standard gives a covered entity that receives a request for PHI from another covered entity (and certain non-covered entities) the ability to rely on the requestor's assessment of what it needs, if such reliance is reasonable under the circumstances.[166] For example, a covered health care provider may determine that it is reasonable to rely on a health plan's representations that the plan is requesting the minimum necessary PHI to conduct a medical necessity determination for payment purposes. The disclosing provider is not required to make its own independent assessment of what is the minimum necessary PHI that can be disclosed to meet the request.[167] As another example, a health plan may rely on the representations of a public health authority, including a person or entity acting under a grant of authority from, or under a contract with, a public health authority, requesting PHI that the information requested is the minimum necessary for the stated purposes, such as preventing or controlling disease, provided that the authority is authorized by law to collect or receive information for the requested purposes.[168]

The minimum necessary standard also includes important exceptions to facilitate the provision of health care to individuals. Most importantly, the minimum necessary standard does not apply to disclosures to, or requests by, a health care provider for treatment purposes [169]—an exception intended to avoid creating barriers or delays in providing patient care. For example, a hospital that discloses PHI to an inpatient rehabilitation facility to coordinate patient care is making a disclosure to a health care provider for treatment that is not subject to the minimum necessary standard, regardless of whether the facility is covered by the HIPAA Rules. However, while disclosures of PHI to health care providers for treatment, including for case management and care coordination, are excluded from the minimum necessary standard, uses of PHI for treatment must adhere to the minimum necessary standard.[170] With respect to uses of PHI, the covered entity's policies and procedures must identify the persons or classes of persons within the covered entity who need access to the PHI to carry out their job duties, the categories or types of PHI needed, and conditions appropriate to such access.[171]

The Privacy Rule also permits certain uses and disclosures of PHI for care coordination and case management that are considered health care operations activities, and thus are subject to the minimum necessary standard.[172] For example, the Privacy Rule permits a covered health care provider or health plan to use or disclose only the minimum necessary PHI for population-based case management, such as to identify all patients or enrollees with diabetes and send them information about a recommended healthy diet to facilitate diabetes self-management.[173]

Finally, under the Privacy Rule, because health plans generally do not perform treatment functions, any care coordination or case management activity conducted by a health plan generally is a health care operation subject to the minimum necessary standard.[174] Thus, the current rule imposes greater restrictions on disclosures to and requests by health plans than on disclosures to and requests by covered health care providers when conducting care coordination or case management activities related to an individual.

In the 2018 RFI, the Department requested public input on whether it should expand the exceptions to the minimum necessary standard to include uses and disclosures for additional activities related to care coordination and case management.[175] For example, the Department asked whether the exceptions to the minimum necessary standard should be expanded to include payment and health care operations activities such as population-based care coordination and case management activities, claims management, review of health care services for appropriateness of care, utilization reviews, or formulary development.[176] Comments varied widely, even within the general categories of commenters (*e.g.,* health care providers or consumers).

Many commenters supported expanding the exceptions to the minimum necessary standard for care coordination and case management. These commenters stated that such an expansion would allow providers to better coordinate and manage patient care across systems and delivery models. Some health care professionals who supported additional exceptions expressed concern that their interpretation of ''necessary'' might not be correct, and that they would be ''punished'' under the existing standard for an impermissible use or disclosure of PHI. Some commenters reported that this uncertainty about compliance requirements creates fears that may result in less information sharing, and

[163] *See* 45 CFR 164.502(b)(1).

[164] ''Use'' in this context refers to internal utilization and sharing of PHI within a covered entity or business associate. *See* 45 CFR 160.103.

[165] *See* Advisory Committee on Automated Personal Data Systems, Report: ''Records, Computers and the Rights of Citizens,'' ASPE (1973) available at *https://aspe.hhs.gov/report/records-computers-and-rights-citizens. See also,* ''Guidelines for the Protections of Privacy and Transborder Flow of Personal Data,'' Organization for Economic Cooperation & Development (1981, revised in 2013), available at *http://www.oecd.org/sti/ieconomy/privacy.htm.*

[166] *See* 45 CFR 164.514(d)(3)(iii)(B).

[167] *See* 45 CFR 164.514(d)(3)(iii)(B) stating that a covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when: . . . ''(B) The information is requested by another covered entity''.

[168] *See* 45 CFR 164.514(d)(3)(iii)(A) and 45 CFR 164.512(b)(1)(i). *See also* definition of ''Public health authority'', 45 CFR 164.501.

[169] *See* 45 CFR 164.502(b)(2)(i).

[170] *See* 45 CFR 160.103 definition of ''Use'' as ''the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.''

[171] *See* 45 CFR 164.514(d)(2)(i).

[172] *See* 45 CFR 164.501, definition of ''Health care operations.''

[173] *See* 45 CFR 164.502(b)(1)–(2), identifying when the minimum necessary standard applies and does not apply.

[174] *See* 45 CFR 164.501, definition of ''Health care operations.''

[175] *See* 83 FR 64302 (December. 14, 2018).

[176] *Ibid.*

therefore less efficient and effective care.

In contrast, over half of the responsive commenters opposed adding exceptions to the minimum necessary standard. Many commenters expressed strong concerns that a broader exception could undermine patient privacy or lead to unspecified harm to patients, some specifically noting that the minimum necessary standard is the only requirement for covered entities to consider what information is reasonably needed for their purpose before making a request, use, or disclosure. Others asserted that if health care operations activities were excepted from the standard, there would be no clear boundaries and covered entities likely would disclose entire patient records to each other, when convenient, without effective limit. In addition, some covered health care provider commenters expressed fear of an increase in requests for large volumes of data that would overwhelm their capacity.

2. Proposal

To consistently promote permissible disclosures of PHI for care coordination and case management, the Department proposes to add an express exception to the minimum necessary standard for disclosures to, or requests by, a health plan or covered health care provider for care coordination and case management.[177] The exception would apply only to those care coordination and case management activities that are at the individual level, in recognition of the concerns expressed by commenters that this proposal would weaken patient privacy by permitting additional PHI to flow for these purposes.

Health plans and covered health care providers would continue to be responsible for meeting the minimum necessary requirements that apply to: (1) Disclosures of PHI for health care operations other than individual-level care coordination and case management; (2) disclosures of PHI for care coordination and case management to most entities other than health care providers and health plans, such as social services agencies or transitional supportive housing authorities; (3) uses of PHI for care coordination and case management, whether as part of treatment or health care operations; and (4) uses, requests, and disclosures of PHI for other purposes, including all population-based activities, when applicable.[178] In addition, covered entities would continue to be able to agree to and honor an individual's request not to use or disclose information for these purposes, as provided in the Privacy Rule and the ONC Cures Act Final Rule information blocking exception for respecting an individual's request.[179]

This proposal would relieve covered entities from the requirement to make determinations about the minimum information necessary when the request is from, or the disclosure is made to, a covered health care provider or health plan to support individual-level care coordination and case management activities. The proposal would also remove the disincentive to disclose and request PHI to support care coordination and case management based on uncertainty about applicable permissions and fear of being subject to penalties for noncompliance resulting from such uncertainty. For example, when a health plan requests a disclosure for care coordination or case management to facilitate an individual's participation in the plan's new wellness program, a requesting health plan or covered health care provider would be relieved of the responsibility for determining the minimum necessary amount of PHI for the purpose and the disclosing health plan or covered health care provider would be relieved of the responsibility of assessing whether reliance on the health plan's determination of the minimum necessary PHI for its purpose is reasonable under the circumstances. As another example, when a covered health care provider contacts a health plan to coordinate potential mental health treatment referrals for a patient, the provider would not need to consider what information is the minimum necessary to disclose to the health plan for this purpose. In fact, the ONC Cures Act Final Rule would prohibit a health care provider from limiting a permissible disclosure to what the provider believes to be the minimum necessary information when the Privacy Rule specifically excepts the disclosure from the minimum necessary standard. However, the provider still could honor an individual's request for restrictions on disclosures of PHI,[180] consistent with the ONC Cures Act Final Rule privacy sub-exception for respecting an individual's request not to share information.[181]

This proposed exception would enable health plans and covered health care providers to more easily and efficiently request and disclose PHI for care coordination and case management for individuals, and would complement the proposal in this NPRM to create an express permission for covered entities to disclose PHI for care coordination and case management, which is described below.

3. Request for Comments

The Department requests comments on the above proposal, and the following considerations in particular:

a. Would the proposed exceptions improve the ability of covered entities to conduct care coordination and case management activities? Why or why not? Please provide any cost or savings estimates that may apply both on the entity level and across the health care system.

b. Please provide examples of particular care coordination or case management activities that would be furthered or impeded by this proposal.

c. Please describe any unintended negative consequences of the proposed changes for the privacy of PHI or the health information rights and interests of individuals. Would there be any negative impact, in particular, on certain populations (*e.g.,* people with disabilities, older adults, rural dwellers, persons experiencing mental health conditions and/or substance use disorders or other illnesses, or others)?

d. Would the proposed changes have similar or different effects on the activities of health plans versus health care providers? Are there unintended consequences for other ancillary providers including social services agencies, community based organizations, and HCBS providers? Please describe.

e. What alternative regulatory modifications or clarifying guidance might achieve the same or greater improvements in care coordination or case management?

f. A health care provider that refused to disclose PHI would not be considered to be information blocking when a state or federal law requires one or more preconditions for providing access, exchange, or use of electronic health information and the precondition has not been satisfied.[182] This proposed modification would remove one of the minimum necessary policy ''preconditions'' for refusing to respond

[177] *See* proposed 45 CFR 164.502(b)(2)(vii).

[178] *See* 45 CFR 164.502(b); 164.514(d).

[179] *See* 45 CFR 164.522(a); 171.202(e).

[180] *See* 45 CFR 164.522.

[181] *See* 45 CFR 171.201(e).

[182] As noted elsewhere in this preamble, the ONC Cures Act Final Rule defines information blocking, in part, as a practice that, if ''conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. *See* 45 CFR 171.103 *Information blocking and* § 171.202 Privacy exception (b) *Sub-exception—precondition not satisfied.*

to a request for an individual's PHI without violating the information blocking prohibition. How would the information blocking provisions in the ONC rule interact with these modifications, and are there any adverse unintended consequences that might result, such as covered entities requesting and receiving far more than the minimum amount of PHI necessary for individual-level care coordination and case management and using PHI for other unrelated purposes?

g. Some disclosures for payment purposes with respect to an individual's health care are related to care coordination and case management (*e.g.,* review of health care services for appropriateness of care). Disclosures for payment purposes are subject to the minimum necessary standards. Should all or certain individual-level payment activities be included in the proposed exception?

h. Please provide additional examples of circumstances in which it should be considered reasonable, or unreasonable, to rely on the representations of another entity that it is requesting the minimum necessary PHI.

E. Clarifying the Scope of Covered Entities' Abilities To Disclose PHI to Certain Third Parties for Individual-Level Care Coordination and Case Management That Constitutes Treatment or Health Care Operations (45 CFR 164.506)

1. Current Provisions and Issues To Address

Section 45 CFR 164.506 sets forth the permissible uses and disclosures of PHI to carry out TPO. Section 45 CFR 164.506(b)(1) permits, but does not require, covered entities to obtain an individual's consent to use or disclose their PHI for TPO purposes,[183] while 45 CFR 164.506(c) describes the implementation specifications for TPO uses and disclosures, including 45 CFR 164.506(c)(1), which expressly permits a covered entity to use and disclose PHI for its own TPO. OCR guidance provides an example of how this Privacy Rule provision permits covered health care providers to disclose PHI to public or private-sector entities that provide health-related social and community based services as part of the disclosing provider's treatment activities: [184]

A health care provider may disclose a patient's PHI for treatment purposes without having to obtain the authorization of the individual. Treatment includes the coordination or management of health care by a health care provider with a third party. Health care means care, services, or supplies related to the health of an individual. Thus, health care providers who believe that disclosures to certain social service entities are a necessary component of, or may help further, the individual's health or mental health care may disclose the minimum necessary PHI to such entities without the individual's authorization. For example, a provider may disclose PHI about a patient needing mental health care supportive housing to a service agency that arranges such services for individuals.[185]

The guidance explains the circumstances in which the Privacy Rule permits a covered health care provider to disclose PHI about an individual to a third party when the third party is part of the broader health treatment plan, or participating in the coordination of care, for an individual.[186] Such a treatment disclosure generally is subject to the minimum necessary standard, where the disclosure is made to a third party entity that is not a health care provider, even though the entity is providing health-related services.[187]

Under the Privacy Rule, a covered health care provider is able to make a disclosure for treatment purposes of an elderly or disabled patient by disclosing PHI to a home and community based services (HCBS) [188] provider if it is for the coordination or management of treatment by the health care provider.[189] For example, a health care provider may disclose the minimum necessary PHI to a senior center or adult day care provider to help coordinate necessary health-related services for an individual, such as arranging for a home aide, to help the older adult or disabled person with their prescibed at-home or post-discharge treatment protocol. Likewise, a disclosure could also facilitate care coordination and case management as part of a covered health plan's health care operations, such as when a health plan discloses the PHI of a senior citizen to a senior wellness center as part of the plan's wellness program in which the senior citizen is enrolled.

Despite the guidance on this topic, OCR has heard that many covered entities make disclosures to third parties that are commonly referred to as social services agencies and community based organizations, and to HCBS providers, only after obtaining a valid authorization from the individual. Similarly, some covered entities never disclose PHI to these health-related service providers, even when a treating provider specifies the service as part of a treatment plan or when it would enable the covered health care provider's treatment of the individual across a care continuum (*e.g.,* from inpatient to home or HCBS setting). Some covered entities may not be aware that the Privacy Rule contemplates disclosures of PHI to third party organizations without authorization for care coordination and case management, including when required by law.[190] Other covered entities may be uncertain about the scope of the permission to disclose, and may fear that they will inadvertently violate the HIPAA Rules, as the current regulatory provisions permitting disclosures for treatment do not expressly list these types of entities as permissible recipients of PHI.

The 2018 RFI requested comments on whether the Department should modify the Privacy Rule to clarify the scope of and eliminate any confusion about a covered entitity's ability to disclose PHI to third parties, such as social services agencies, community based organizations, and HCBS providers,[191] as necessary for a disclosing health care provider to carry out a treatment plan, or for a disclosing health plan to conduct care coordination and case management as health care operations. Health care associations, information technology (IT) vendors, health plans, and health care providers commented on this topic.

Some supportive commenters urged the Department to clarify the permissions for covered entities by modifying the regulation text to reduce any confusion on the part of covered entities about their ability to disclose

[183] A consent that a covered entity chooses to obtain consistent with 45 CFR 164.506(b) is different from an authorization obtained under 45 CFR 164.508, which is required for certain uses and disclosures of PHI.

[184] The disclosure of patient information for treatment and other purposes may be subject to other laws, including 42 CFR part 2 for substance use disorder records.

[185] *See* HHS Office for Civil Rights, Frequently Asked Questions on Mental Health, Disclosures for Care Coordination (2018), available at *https://www.hhs.gov/hipaa/for-professionals/faq/3008/does-hipaa-permit-health-care-providers-share-phi-individual-mental-illness-third-party-not-health-care-provider-continuity-care-purposes/index.html.* A consent that a covered entity chooses to obtain consistent with 45 CFR 164.506(b) is different from an authorization obtained under 45 CFR 164.508, which is required for certain uses and disclosures of PHI.

[186] *Ibid.* However, the disclosure of patient information for treatment and other purposes may be subject to other laws, including 42 CFR part 2 for substance use disorder records.

[187] *See* 45 CFR 164.502(b)(2)(i).

[188] Information about HCBS is available at *https://www.medicaid.gov/medicaid/hcbs/index.html.* Some HCBS providers also may be health care providers within the definition at 45 CFR 160.103, in which case the disclosing provider could disclose PHI for the receiving HCBS provider's treatment purposes. *See* 45 CFR 164.506(c)(2).

[189] *See* 45 CFR 164.506(c).

[190] *See* 45 CFR 164.506(c) and 164.512(a).

[191] The Department intends to include other types of organizations that are similar to these named examples.

PHI to the types of entities that typically partner with providers and (in some cases) health plans to improve those covered entities' own treatment- or health care operations-based care coordination and case management for the individual. Most commenters also stated that such a regulatory change should include a definition of social services agencies with examples of the types of services contemplated. Several commenters recommended that the Department permit disclosures of PHI with these organizations only with an individual's consent.

Some health plan commenters stated that an express regulatory permission for covered entities to disclose PHI to social services agencies for care coordination and case management purposes would be helpful, but recommended placing some limits on the permission, such as only permitting disclosures with patient consent. Several health plans described the care coordination and case management activities they would like to provide to their plan members, including working closely with community based organizations and/or multi-disciplinary teams to address the social determinants of health, without first receiving the individual's valid authorization; and coordinating comprehensive wraparound services, including clinical and behavioral health care, social services, and patient advocates to support certain populations, such as people experiencing SMI or SUD. The Department finds the comments by health plans to be persuasive in demonstrating the need to propose an express permission to disclose PHI for individual-level care coordination and case management activities that constitute health care operations.

Not all commenters supported addressing disclosures to third parties including social services agencies, community based organizations, and HCBS providers through rulemaking. Some correctly stated that covered health care providers already are permitted to make such disclosures, and therefore the commenters did not believe a change in the regulation was needed. Others specifically opposed expanding disclosures to any law enforcement entity that may be part of a multi-disciplinary team, expressing concern that law enforcement intrusions into health records can deter patients from seeking needed care, especially if law enforcement has broad access to SUD treatment information.

2. Proposal

The Department proposes to modify 45 CFR 164.506(c) to add a new subsection 164.506(c)(6). This new subsection would expressly permit covered entities to disclose PHI to social services agencies, community based organizations, HCBS providers, and other similar third parties that provide health-related services to specific individuals for individual-level care coordination and case management, either as a treatment activity of a covered health care provider or as a health care operations activity of a covered health care provider or health plan. Under this provision a health plan or a covered health care provider could only disclose PHI without authorization to a third party that provides health-related services to individuals; however, the third party does not have to be a health care provider. Instead, the third party may be providing health-related social services or other supportive services—*e.g.,* food or sheltered housing needed to address health risks. Section 45 CFR 164.501 of the Privacy Rule defines treatment as ''the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.'' Section 45 CFR 164.501 paragraph (1) of the current Privacy Rule definition of health care operations also refers to case management and care coordination.[192] This express permission would allow a covered entity to disclose PHI to these third party entities that provide or coordinate ancillary and other health-related services when the covered entity determines that the disclosure is needed to provide health-related services to specific individuals for individual-level care coordination and case management activities that constitute treatment or health care operations, as applicable.[193] For example, a covered entity could disclose the PHI of a senior individual experiencing chronic illness to a senior center attended by the individual to check on his or her health periodically, and to ask the senior center to give reminders about effective disease self-management.

The Department notes that there may be instances in which some disclosures for care coordination and case management, for treatment or health care operations, will be made to business associates engaged by a covered entity, such as a health plan, to provide health-related services to an individual, or that relate to an individual's health care, on behalf of the plan. In such cases, the covered entity must have a HIPAA compliant business associate agreement in place prior to disclosing the PHI for this purpose. In other cases, the entity receiving the PHI will be providing health-related services on its own behalf, and not performing covered activities or functions for or on behalf of the disclosing covered entity. In the latter situation, a business associate agreement is not required, because the entity receiving the PHI does not meet the definition of a business associate.[194]

The express permission for disclosures to these third party entities is being proposed primarily to facilitate the treatment and health care operations of the disclosing covered entities in cases where a disclosure will serve the health care or health-related needs of individuals. The Department's understanding is that, in general, the third party entities receiving PHI under this proposed permission would not be covered entities and thus, the PHI disclosed to them would no longer be protected by the HIPAA Rules. However, because some of these third party recipients of PHI may be health care providers or covered health care providers under HIPAA,[195] which can perform care coordination and case management for their own treatment activities (and, with respect to covered health care providers, for health care operations), the Department does not propose to limit the regulatory text of the permission to disclosures made by a covered health care provider or health plan as part of *the discloser's own* treatment and health care operations. For example, under this proposal a covered health care provider could expressly disclose PHI for the case management and care coordination activities of another health care provider or health plan. Such disclosures are permitted under the current rule at 45 CFR 164.506(c)(2) and (c)(4); however, the Privacy Rule currently does not

[192] This NPRM includes a proposal to change the punctuation in paragraph (1) of the definition of health care operations at 45 CFR 164.501 to make clear that care coordination and case management are not limited to ''population-based activities.'' *See* proposed 45 CFR 164.501.

[193] *See* proposed 45 CFR 164.506(c)(6).

[194] *See* the definition of ''Business associate'' at 45 CFR 160.103. Whether the Privacy Rule permits a particular disclosure for health care operations is determined separately from whether a business associate agreement is required. These provisions of the rule operate independently, such that disclosures for health care operations may be made to an entity that is neither a covered entity nor a business associate of the covered entity. *See, e.g.,* 65 FR 82462, 82491 (December 28, 2000).

[195] *See* the definitions of ''Health care provider'' and ''Covered entity'' at 45 CFR 160.103.

address the applicability of this permission to case management and care coordination. The Department requests comment on whether such limiting language would be appropriate.

Although the Department believes that such disclosures generally are permitted under the existing Privacy Rule for treatment or certain health care operations, this additional, express regulatory language would provide greater regulatory clarity, and help ensure that covered entities are able to disclose PHI to coordinate care for individuals with social services agencies, community based organizations, and HCBS providers or other similar third parties that are providing health-related services to those individuals. The Department acknowledges that some RFI commenters expressed concerns about expressly permitting such disclosures without individuals' authorization or consent. In response, the Department notes that, similar to its proposal to except certain care coordination and case management disclosures from the minimum necessary standard, it also proposes to limit the scope of this permission to disclosures by covered entities for care coordination and case management for individuals (whether as treatment or health care operations, depending on whether the covered entity is a health care provider or a health plan, respectively), rather than population-based activities. The Department believes that the limitation to individual-level activities will ensure that the disclosures made under this permission would be akin to disclosures for treatment, which individuals expect to occur without their needing to provide an authorization or consent. The existing Privacy Rule right to request restrictions on disclosures for treatment, payment, and health care operations purposes under 45 CFR 164.522(a) also remains available for individuals to request more limited disclosures.

The Department believes this change would facilitate and encourage greater wraparound support and more targeted care for individuals, particularly where it would be difficult to obtain an individual's authorization or consent in advance, because the individual cannot easily be contacted (*e.g.,* when an individual is homeless). This improved care coordination and case management could lead to better health outcomes while retaining existing limits on population-based disclosures. At this time, the Department proposes to place examples of the third party recipient entities in regulatory text but does not propose definitions of care coordination and case management that such third parties must conduct to be appropriate recipients of PHI for these purposes. The Department believes the robust description and discussion of stakeholder definitions for ''care coordination and case management'' affords the regulated community sufficient information with which to determine whether a recipient is engaged in the contemplated activities.

3. Request for Comments

The Department requests comments on the above proposal, and the following considerations in particular:

a. Whether the proposal to create an express permission to disclose PHI to certain third parties for individual level treatment and health care operations would help improve care coordination and case management for individuals, and any potential unintended adverse consequences.

b. Whether the proposal poses any particular risks for individuals related to permitting disclosures without authorization for individual-level care coordination and case management activities that are health care operations (*i.e.,* those that are conducted by health plans) in addition to individual-level care coordination and case management activities that constitute treatment (*i.e.,* those that are conducted by health care providers).

c. Would the proposed change remove perceived barriers to disclosure of PHI, as appropriate, to social services agencies, community-based organizations, and HCBS providers to better enable care coordination and case management? Are there other entities the Department should identify in regulatory text as examples of appropriate recipients of PHI under the proposed permission?

d. Should the proposed change be limited to care coordination and case management for a particular individual as proposed, or should it also include population-based efforts?

e. Would this permission to disclose PHI for case management and care coordination to the entities described above interact with the ONC information blocking requirement to create any unintended adverse consequences for individuals' privacy? Please explain.

f. Should the Department specify the types of organizational entities to be included as recipients of PHI in this express permission in regulation text, as well as limitations or exclusions, if any, that should be placed on the types of entities included? If yes, what types of organizational entities should be included or excluded?

g. Should the Department limit the proposed permission to disclose PHI to circumstances in which a particular service provided by a social services agency, community-based organization, or HCBS provider is specifically identified in an individual's care plan and/or for which a social need has been identified via a screening assessment? Should the Department require, as a condition of the disclosure, that the parties put in place an agreement that describes and/or limits the uses and further disclosures allowed by the third party recipients?

h. To what extent are social services agencies, community-based organizations, and HCBS providers covered health care providers under HIPAA? How many are non-covered health care providers? Are any such entities covered under HIPAA as health plans?

F. Encouraging Disclosures of PHI When Needed to Help Individuals Experiencing Substance Use Disorder (Including Opioid Use Disorder), Serious Mental Illness, and in Emergency Circumstances (45 CFR 164.502 and 164.510–514)

Support from family members, friends, and caregivers is key to helping people experiencing substance use disorder (SUD) or serious mental illness (SMI).[196] However, individuals' family members and caregivers cannot help if they are not informed. Therefore, to encourage covered entities to share information in individuals' best interests, without fear of HIPAA penalties, the Department proposes to amend five provisions of the Privacy Rule to replace ''the exercise of professional judgment'' standard with a standard permitting certain disclosures based on a ''good faith belief'' about an individual's best interests. Further, to better enable covered entities to prevent and lessen harm to individuals or the public, the Department proposes to

[196] *See* Substance Abuse and Mental Health Administration, *Mental Health and Substance Use Disorders,* which defines these terms as follows: Serious mental illness is defined by someone over 18 having (within the past year) a diagnosable mental, behavior, or emotional disorder that causes serious functional impairment that substantially interferes with or limits one or more major life activities. Substance use disorders occur when the recurrent use of alcohol and/or drugs causes clinically significant impairment, including health problems, disability, and failure to meet major responsibilities at work, school, or home. For minors, the term ''Serious Emotional Disturbance'' refers to a diagnosable mental, behavioral, or emotional disorder in the past year, which resulted in functional impairment that substantially interferes with or limits the child's role or functioning in family, school, or community activities. Available at *https://www.samhsa.gov/find-help/disorders.*

replace the Privacy Rule provision that currently permits a covered entity to use or disclose an individual's PHI based on a ''serious and imminent threat'' with a ''serious and reasonably foreseeable threat'' standard. These provisions and the proposed amendments are discussed in detail below.

1. Current Provisions and Issues To Address

Disclosures to Personal Representatives

Under 45 CFR 164.502(g) of the Privacy Rule, a personal representative is a person with authority under applicable law (*e.g.,* state law) to act on behalf of an individual in making decisions related to health care.[197] In general, the Privacy Rule treats a personal representative in the same way it treats the individual; thus, for example, a personal representative is able to exercise the individual's right to obtain PHI about the individual.[198] In many circumstances, the parent or guardian of an unemancipated minor child is treated as the minor's personal representative under applicable law. In addition, to address circumstances in which state or other applicable law does not treat a parent as an unemancipated minor's personal representative, the provision at 45 CFR 164.502(g)(3)(ii)(C) permits, but does not require, covered entities to provide access under 45 CFR 164.524 to a parent, guardian or other person acting in *loco parentis* who is not a personal representative under applicable law, if the action is consistent with state or other applicable law, and the decision to disclose is based on the professional judgment of a licensed health care professional.

Uses and Disclosures Requiring an Opportunity for the Individual To Agree or Object

Under 45 CFR 164.510, covered entities, including health care providers, generally must provide an individual with the opportunity to agree or object before using or disclosing the individual's PHI for inclusion in a facility directory or disclosing PHI to family members, caregivers, or others involved in care or payment for care. However, individuals are not always able to agree or object to such uses or disclosures, particularly in emergency situations.

Accordingly, 45 CFR 164.510(a)(3) permits a covered health care provider to disclose facility directory information, including name, location within the provider's facility, general condition, and religious affiliation to clergy and others, such as family members, who ask for the individual by name, when the individual cannot agree or object due to incapacity or an emergency treatment circumstance, if: (A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and (B) the disclosure is in the individual's best interests, as determined by the covered health care provider, in the exercise of professional judgment.

A similar rationale applies to 45 CFR 164.510(b), which recognizes that family members and other caregivers have a legitimate need to obtain the information that will permit them to continue to participate in the individual's care when it is in the individual's best interests, particularly in emergency circumstances. Currently, 45 CFR 164.510(b)(2)(iii) permits a covered entity to disclose relevant PHI about an individual who is present and has decision-making capacity, if the covered entity can reasonably infer, based on the exercise of professional judgment, that the individual does not object to the disclosure. Further, 45 CFR 164.510(b)(3) permits a covered entity to disclose relevant PHI about an individual who cannot agree or object due to incapacity or an emergency circumstance to family members and other caregivers involved in the individual's care or payment for care, if the covered entity, based on professional judgment, determines that the disclosure is in the best interests of the individual.

Identity Verification

Section 164.514(h)(2)(iv) of title 45 CFR generally requires covered entities to establish and use written policies and procedures reasonably designed to verify the identity and authority of the requestor of PHI.[199] However, certain circumstances surrounding the disclosure itself may accomplish the verification without having to collect additional documents or rely on a pre-established procedure.[200] Therefore, 45 CFR 164.514(h)(2)(iv) provides that a covered entity's obligation to verify a requestor's identify is met if the covered entity relies on an exercise of professional judgment pursuant to 45 CFR 164.510, or acts on a good faith belief in making a disclosure pursuant to 45 CFR 164.512(j) to prevent or lessen certain serious and imminent threats.

Uses and Disclosures To Avert a Serious Threat to Health or Safety

Section 164.512(j) of title 45 CFR permits covered entities, ''consistent with applicable law and standards of ethical conduct,'' to rely on a good faith belief to use or disclose PHI when necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.[201] The permission is intended to accommodate, and be consistent with, a ''duty to warn'' third parties of a threat as established in case law (and, in some states, statutory requirements).[202] Certain conditions apply, including that the recipient of the PHI must be reasonably able to prevent or lessen the threat, or the use or disclosure must be necessary for law enforcement to identify or apprehend the subject individual.[203] In the case of a disclosure to law enforcement, additional conditions include that the individual made a statement admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim, or that circumstances demonstrate that the subject individual escaped from a correctional institute or lawful custody, as defined in the Privacy Rule.[204]

[197] 45 CFR 164.502(g)(3)(i) lists exceptions to this general rule, specifying that such a person may not be a personal representative with respect to information pertaining to a health care service if: (A) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative; (B) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting in loco parentis, and the minor, a court, or another person authorized by law consents to such health care service; or (C) A parent, guardian, or other person acting in loco parentis assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

[198] *See* 45 CFR 164.502(g)(1).

[199] *See* 65 FR 82462, 82546 (December 28, 2000).

[200] *Ibid.*

[201] *See* 45 CFR 164.512(j)(1)(i)(A). To ''lessen'' a threat could mean, for example, to reduce the severity of the threat, or the likelihood of the anticipated harm occurring.

[202] *See* 65 FR 82462, 82538 (December 28, 2000). *See also* state law requirements compiled at *http://www.ncsl.org/research/health/mental-health-professionals-duty-to-warn.aspx.* To the extent that state or other law requires a disclosure (*e.g.,* as part of a statutory duty to warn), the Privacy Rule would permit the disclosure under its permission for uses and disclosures of PHI required by law. *See* 45 CFR 164.512(a). However, not all states have enacted such requirements, and those that do apply a variety of different standards. In contrast, HIPAA's disclosure permission applies a uniform permissive standard to covered entities nationwide.

[203] *See* 45 CFR 164.512(j)(1)(ii).

[204] *Ibid. See also* 164.501, definition of ''Correctional institution,'' including description of ''lawful custody.''

Relevant Guidance Encouraging Disclosures of PHI To Help Individuals Experiencing Opioid Use Disorder or Mental Illness

On October 27, 2017, in response to the nation's opioid crisis, OCR issued guidance titled *How HIPAA Allows Doctors to Respond to the Opioid Crisis.*[205] The guidance addresses the HIPAA permission for covered health care providers to share PHI with an individual's friends, family, and others involved in the individual's care or the payment for that care when the individual has overdosed and is unable to agree or object to uses and disclosures of PHI. The guidance clarifies that ''a provider may use professional judgment to talk to the parents of someone incapacitated by an opioid overdose about the overdose and related medical information, but generally could not share medical information unrelated to the overdose without permission.'' [206]

The guidance further clarifies when a covered health care provider may rely on another permission, 45 CFR 164.512(j), in an overdose situation:

> For example, a doctor whose patient has overdosed on opioids is presumed to have complied with HIPAA if the doctor informs family, friends, or care-givers of the opioid abuse after determining, based on the facts and circumstances, that the patient poses a serious and imminent threat to his or her health through continued opioid abuse upon discharge.[207]

Although the guidance focuses primarily on overdose situations, the HIPAA provisions apply equally to the disclosure of PHI during other health emergencies or dangerous situations. The full text of the guidance is available at *https://www.hhs.gov/sites/default/files/hipaa-opioid-crisis.pdf?language=es.*

In addition to guidance addressing the opioid epidemic, OCR has issued guidance to assist individuals experiencing SMI, their families, and other caregivers as required by the Cures Act.[208] Section 11001 of the Cures Act includes a ''sense of Congress'' that clarification was needed regarding the Privacy Rule's existing permitted uses and disclosures of PHI by health care professionals to communicate with caregivers of adults with SMI to facilitate treatment. Section 11003 directed the Secretary, acting through the Director of OCR, to issue clarifying guidance explaining the circumstances under the Privacy Rule in which a health care provider or other covered entity may disclose PHI, such as in the exercise of professional judgment regarding the best interests of a patient when the patient is incapacitated or in an emergency situation, and the circumstances in which HIPAA permits disclosures of PHI to a patient's family and other caregivers. In response to the requirements in the Cures Act, OCR created new web pages for health care professionals and consumers containing all of its guidance and materials related to mental and behavioral health information.[209]

Despite issuing extensive guidance, OCR continues to hear that some covered entities are reluctant to disclose information to persons involved in the care of individuals experiencing these health issues, even when the Privacy Rule permits such disclosures. For example, since the guidance was published and as recently as July 11, 2018, a patient advocate testified before the Federal Commission for School Safety (FCSS) that, despite OCR's efforts to disseminate guidance, providers continue to ''stonewall'' families when asked to disclose PHI and routinely withhold medical information from family members, out of concerns of potentially violating HIPAA.[210]

The Department has similarly heard anecdotal accounts that some health care providers are reluctant to disclose needed health information about an incapacitated patient to even their closest friends and family, due to concerns about potential penalties under HIPAA. OCR understands that this reluctance to disclose, even when the Privacy Rule permits disclosure, creates particular difficulties, and potential risks for patients and others, when a patient is unable to agree or object to the disclosure due to incapacity related to SMI, SUD, or another cause.

In addition, in the wake of the incidents of mass violence in recent years, such as shootings and acts of terrorism, the Department has heard anecdotes claiming that HIPAA impedes health care providers from disclosing PHI, even when such disclosure could prevent or lessen a serious and imminent threat of harm or violence. According to these accounts, the reluctance to disclose persists even though the HIPAA Rules permit disclosure in such circumstances.

In the 2018 RFI, the Department solicited public input to determine whether and how to modify the Privacy Rule to help combat the opioid crisis, treat SMI, and promote family involvement in the care of individuals experiencing these health situations. It also sought comment on how the Department could amend the Privacy Rule to increase disclosures of PHI by covered health care providers with family members and other caregivers experiencing difficulties obtaining health information about their minor and adult children or parents, spouses, and other individuals when needed to coordinate their care or otherwise be involved in their treatment. Noting anecdotal information suggesting that some covered entities are reluctant to involve the caregivers of individuals facing health crises for fear of violating the Privacy Rule, the Department asked for examples of circumstances in which the Privacy Rule has presented real or perceived barriers to family members attempting to access information.

Many commenters asked the Department to align the Privacy Rule with 42 CFR part 2 (Part 2), which requires certain federally funded SUD treatment programs (called ''Part 2 programs'') and downstream recipients (called ''lawful holders'') of their patient-identifying information to maintain the confidentiality of records related to the diagnosis and treatment of SUD.[211] Part 2 modifications are outside the scope of this rulemaking, and nothing in this Privacy Rule NPRM would change the part 2 compliance obligations of covered entities who are subject to part 2. Further, this NPRM does not affect covered entities' obligations to comply with applicable state laws that restrict the disclosure of sensitive information, including SUD or other sensitive health issues.

[205] Guidance on Responding to an Opioid Overdose, HHS Office for Civil Rights (October 27, 2017), available at *https://www.hhs.gov/sites/default/files/hipaa-opioid-crisis.pdf?language=es.*

[206] *Ibid.*

[207] *Ibid.*

[208] Available at *https://www.hhs.gov/sites/default/files/hipaa-privacy-rule-and-sharing-info-related-to-mental-health.pdf.*

[209] ''Information Related to Mental and Behavioral Health, including Opioid Overdose,'' HHS Office for Civil Rights (2017), available at *https://www.hhs.gov/hipaa/for-professionals/special-topics/mental-health/index.html* and *https://www.hhs.gov/hipaa/for-individuals/mental-health/index.html.*

[210] ''Final Report on the Federal Commission on School Safety,'' Department of Education (December 18, 2018), p. 136, available at *https://www2.ed.gov/documents/school-safety/school-safety-report.pdf.*

[211] The Part 2 regulations are authorized by section 290dd–2 of Title 42 US Code, which provides that ''Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance use disorder education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b).''

On March 27, 2020, Congress enacted the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) which requires greater alignment of the part 2 regulations with the HIPAA Rules.[212] On July 15, 2020, the Department, through the Substance Abuse and Mental Health Services Administration (SAMHSA), published a final rule revising the part 2 regulations to facilitate such activities as quality improvement and claims management in a manner that more closely aligns part 2 with some of the disclosure permissions of the Privacy Rule.[213] The Department will implement the CARES Act requirements concerning the part 2 regulations in a future rulemaking.

Nearly all commenters who identified as family members of patients agreed that in many cases more information related to an individual's SMI or SUD should be disclosed to family caregivers, and shared personal stories about the devastating consequences—such as suicide, missed appointments, homelessness, and lack of continuity in treatment and medication—that occurred because of a lack of information disclosure. A few commenters suggested that HIPAA should preempt all state laws that restrict disclosures of mental and behavioral health information to family members or coordinating health and social services agencies. A few other commenters expressed concern that the inability to disclose PHI related to mental health to social services agencies largely impacts poor individuals and minorities.

Commenters who identified as patients or privacy advocacy groups almost universally opposed modifying the Privacy Rule to expand permitted disclosures of information related to SMI and opioid use disorder or other SUDs. Many commenters expressed fear of family members and employers having access to this information, citing potentially adverse consequences, including fear of discrimination, abuse, and retaliation. Many health care providers expressed concern about the chilling effect that increased disclosures would have on individuals seeking treatment for opioid use disorders and stated that the Privacy Rule is already flexible enough to permit the amount of disclosure needed to address the opioid epidemic. Many suggested issuing clarifying guidance on existing regulatory permissions as a preferred approach to increasing disclosures of PHI. A few pointed to the need to leverage technology, such as consent management and data segmentation, pursuant to the health information certification standards[214] published by ONC, as a means to help providers protect sensitive records while accessing information necessary for care.

As the Department noted in the 2018 RFI, the Privacy Rule generally defers to state law with respect to the circumstances in which a parent or guardian is treated as the personal representative of an unemancipated minor child, and under which information may not be disclosed to parents. Many commenters recognized state law, not the Privacy Rule, as the source of the more restrictive provisions (*e.g.,* state laws that restrict access to an unemancipated adolescent's mental health information). Nevertheless, some commenters suggested that HIPAA presented a barrier, especially in cases where a teenager or school-aged child experienced mental illness. Accordingly, some covered entities, professional organizations, advocacy organizations, and parents supported increasing parental access to minors' PHI. Some commenters were particularly supportive of increasing disclosures of PHI involving SUD, SMI, and other behavioral health concerns. However, some commenters raised concerns about abusive parents or guardians gaining access to a minor child's PHI, and some appreciated that the Privacy Rule currently permits a covered entity to deny access to a personal representative suspected of abuse or neglect. In addition, some commenters expressed concern that increasing parental access would inhibit a child from seeking the health care he or she needs, especially with respect to sensitive health conditions.

The Department received a few comments related to adult children being able to access the records of their parents. For example, one commenter suggested that the Department create a ''relative caregiver'' category with a right to access the medical records of elderly parents; another commenter provided a similar suggestion to address the care of individuals experiencing dementia. In contrast, several commenters raised concerns about impinging on the individual autonomy of their adult parents or other adults, and stressed the importance of protecting privacy for older adults.

2. Proposals

The Department believes more can be done to encourage health care providers to disclose PHI when families and other caregivers of individuals are attempting to assist with health related emergencies, SUD (including opioid disorder) or SMI, and other circumstances in which individuals are incapacitated or otherwise unable to express their privacy preference. To address these concerns, the Department proposes several modifications to the Privacy Rule to encourage covered entities to use and disclose PHI more broadly in scenarios that involve SUD, SMI, and emergency situations, provided that certain conditions are met. In particular, the Department proposes to amend five provisions of the Privacy Rule to replace ''exercise of professional judgment'' with ''good faith belief'' as the standard pursuant to which covered entities would be permitted to make certain uses and disclosures in the best interests of individuals. The professional judgment standard presupposes that a decision is made by a health care professional, such as a licensed practitioner, whereas good faith may be exercised by other workforce members who are trained on the covered entity's HIPAA policies and procedures and who are acting within the scope of their authority. The Department also proposes a presumption that a covered entity has complied with the good faith requirement, absent evidence that the covered entity acted in bad faith. Together, these proposed modifications would improve the ability and willingness of covered entities to make certain uses and disclosures of PHI as described below.

The Department acknowledges prior comments expressing concern that a good faith standard offers individuals less privacy protection. However, covered entities still must take into account the facts and circumstances surrounding the disclosures, such as an individual's prior expressed privacy preferences and knowledge of any abusive relationship between the person to whom the covered entity would disclose PHI and the individual. Similarly, the Department would treat disclosures for any improper purpose as ''bad faith'' disclosures. Examples of bad faith could include knowledge that information will be used to harm the individual or will be used for crime, fraud (including defrauding the individual), or personal enrichment. As another example, a provider who is sued for malpractice and demands a signed statement of satisfactory care

[212] *See* Public Law 116–136, 134 Stat. 286 (March 27, 2020). Section 3221 of Public Law 116–136 amended 42 U.S.C. 290dd–2.

[213] *See* 85 FR 42986 (July 15, 2020).

[214] *See* 45 CFR parts 170 and 171.

from an incapacitated individual's family member in exchange for disclosing the individual's PHI to the family member has likely acted in bad faith. Finally, the Department encourages covered entities to ascertain the privacy preferences of individuals who are at known risk of experiencing episodes of incapacity before such individuals become incapacitated, where possible. *Replacing professional judgment with good faith in sections 45 CFR 164.502(g)(3)(ii)(C), 164.510(a)(3), 164.510(b)(2)(iii), 164.510(b)(3), 164.514(h)(2)(iv).*

The Department's proposal to replace ''professional judgment'' with a standard based on the good faith belief of the covered entity in the five provisions listed above should improve care coordination by expanding the ability of covered entities to disclose PHI to family members and other caregivers when they believe it is in the best interests of the individual, without fear of violating HIPAA. The requirement under the current rule to exercise ''professional judgment'' could be interpreted as limiting the permission to persons who are licensed or who rely on professional training to determine whether a use or disclosure of PHI is in an individual's best interests. While professional training and experience naturally inform a health care provider's good faith belief about an individual's best interests, a good faith belief does not always require a covered entity or its workforce member to possess specialized education or professional experience. Rather, a good faith belief may be based on, for example, knowledge of the facts of the situation (including any prior expressed privacy preferences of the individual, such as those in an advance directive), or the representations of a person or persons who reasonably can be expected to have knowledge of relevant facts.

At the same time, as illustrated by the following scenarios, a standard of ''good faith'' anticipates that a covered entity or workforce member would exercise a degree of discretion appropriate for its role when deciding to use or disclose PHI, and to comply with any other conditions contained in the applicable permissions. For example, ''good faith'' would permit a licensed health care professional to draw on experience to make a good faith determination that it is in the best interests of a young adult patient, who has overdosed on opioids, to disclose information to a parent who is involved in the patient's treatment and who the young adult would expect, based on their relationship, to participate in or be involved with the patient's recovery from the overdose. In this circumstance, the professional's good faith belief should be informed by professional judgment, but the professional would be assured that the Department would not second-guess the decision made for the patient's best interests by, for example, requiring the professional to prove that the decision was consistent with his or her professional training.

Likewise, front desk staff at a physician's office who have regularly seen a family member or other caregiver accompany an adult patient to appointments could disclose information about upcoming appointments when the patient is not present, based on the staff's knowledge of the person's involvement and a ''good faith'' belief about the patient's best interests. The extent of the disclosure of PHI would be limited to the level of involvement of the family member or caregiver of which the staff is aware, consistent with the covered health care provider's policies and procedures for disclosures of PHI by workforce members. In contrast, front desk staff would not be permitted to decide whether to provide access to records under the individual right of access at 45 CFR 164.524 to a parent who is not their minor child's personal representative, because the applicable permission at 45 CFR 164.502(g)(3)(2)(C) requires that the decision be made by a licensed health care professional.

The Department understands that these proposals may raise concerns about unintended consequences where a covered health care provider is asked to disclose sensitive information to family members or other caregivers about individuals at risk of, or experiencing, abuse by the requesting family members or caregivers. The Department assumes that health care providers would incorporate relevant concerns about an individual's risk of abuse as a key factor in whether a disclosure of PHI is in an individual's best interest. Disclosures to suspected abusers are not in the best interests of individuals and health care providers' workforce members should feel confident that this proposal would not negate their ability to consider all relevant factors when making decisions about disclosing PHI to an individual's family and other caregivers related to their involvement in the individual's care or payment for care.

The following examples illustrate the operation of a good faith standard in each provision this proposal would modify:

• *Parent or guardian who is not the individual's personal representative.* The Department proposes to amend 45 CFR 164.502(g)(3)(ii)(C) to permit a covered entity to disclose the PHI of an unemancipated minor to a parent or guardian who is not the personal representative of the individual under HIPAA if consistent with state or other applicable law and a licensed health care professional has a good faith belief that disclosing PHI is in the best interests of the individual. For example, the proposed change would permit a covered health care provider to disclose PHI of an un-emancipated minor experiencing SUD in a state or jurisdiction where applicable law does not treat the minor's parent as a personal representative, when the provider believes that disclosing information to the parent could improve the care and treatment of the minor. This proposed good faith standard would remove an impediment to disclosures of PHI to a parent or guardian of a minor experiencing SUD or SMI where the parent or guardian is not recognized as the personal representative of the minor under state law. At the same time, this proposal would not preempt state laws that prohibit the disclosure of sensitive information because this proposal would permit, but not require, the disclosure under HIPAA. As such, a covered entity could comply with both HIPAA and a more restrictive state law by limiting disclosures in accordance with the state law.

• *Facility Directories.* The Department proposes to amend 45 CFR 164.510(a)(3)(i)(B) to permit a covered entity to include an individual's name in a facility directory and to disclose, for directory purposes, the individual's location and general condition, when the individual is unable to agree or object and the covered entity has a good faith belief that the disclosure is in the best interests of the individual. For example, this change would facilitate a hospital's disclosure of directory information about an individual who is incapacitated and unable to identify family members or other caregivers involved in his or her care who are trying to locate the individual. The Department does not propose to change 45 CFR 164.510(a)(3)(i)(A), which requires that a disclosure under 45 CFR 164.510(a)(3) be consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider.

• *Emergency contacts.* The Department proposes to amend 45 CFR 164.510(b)(2)(iii) to permit covered entities to disclose relevant information to a person involved in the individual's care or payment for care when the covered entity reasonably infers, based

on a good faith belief, that the individual does not object. For example, under this proposal an acute care facility that lacks a written designation of an emergency contact but possesses knowledge of an incapacitated patient's designated emergency contact could disclose PHI to that contact, based on a good faith belief that the patient does not object to the disclosure. In contrast, a disclosure of PHI by a covered entity with knowledge of an individual's advance directive that documents an objection to disclosure to a particular person would be inconsistent with a good faith belief that the individual does not object.

• *Emergencies and incapacity.* The Department proposes to amend 45 CFR 164.510(b)(3) to permit covered entities to disclose relevant information about the individual to family members and other caregivers who are involved with the individual's care or payment for care, or who require notification related to the individual, when the individual cannot agree to the disclosure because of absence, incapacity, or emergency circumstances, and the covered entity has a good faith belief that the disclosure is in the best interests of the individual. This change would, for example, facilitate a health care provider's disclosure of PHI to a caregiver of a patient who is incapacitated by an overdose, mental health crisis, or other health emergency. The Privacy Rule does not define incapacity, but the Department has provided examples and explained that a formal determination is not necessary.[215]

• *Verifying requestor's identity.* The Department proposes to amend 45 CFR 164.514(h)(2)(iv) to provide that a covered entity would satisfy its obligations to verify a requestor's identity if the covered entity acts on a good faith belief in making a disclosure of relevant PHI under 45 CFR 164.510, 164.512(j), and 164.514(h)(2)(iv). These disclosures are already limited in scope to the information relevant to assisting the individual with his or her health care or payment for care (45 CFR 164.510) or to the minimum amount of information necessary for the purpose (45 CFR 164.512(j)). This proposal would, for example, improve the ability of a covered hospital to disclose PHI of an individual experiencing an emergency to a person who represents that he or she is a family member or caregiver of the individual, without requiring the family member or caregiver to present documentation of the relationship with the individual, if the hospital has a good faith basis for believing the requestor and the requestor's identity. As stated in the preamble to the 2000 Privacy Rule:

> ''Requiring written proof of identity in many of these situations, such as when a family member is seeking to locate a relative in an emergency or disaster situation, would create enormous burden without a corresponding enhancement of privacy, and could cause unnecessary delays in these situations. The Department therefore believes that reliance on professional judgment provides a better framework for balancing the need for privacy with the need to locate and identify individuals. . . . As with many of the requirements of this final rule, health care providers are given latitude and expected to make decisions regarding disclosures, based on their professional judgment and experience with common practice, in the best interest of the individual.'' [216]

A hospital may not have a good faith basis for believing the requestor's representations about the requestor's identity and relationship with the individual if, for example, a workforce member receives a request from an unfamiliar and unverified email address or the requestor is unknown and not named as a contact in an individual's record. Additionally, this proposal would not remove a covered entity's obligation(s) under other applicable laws, such as laws requiring providers to obtain documentation of a relationship before disclosing information, including laws governing requests for access to medical records by a person who claims to be an individual's personal representative.

The Department also proposes to amend the Privacy Rule at 45 CFR 164.502 by adding a new paragraph (k), which would apply a presumption of compliance with the ''good faith'' requirement when covered entities make a disclosure based upon a belief that the disclosure is in the best interests of the individual with regard to those five provisions.

Changing ''Serious and Imminent'' to ''Serious and Reasonably Foreseeable''

As noted above, 45 CFR 164.512(j)(1)(i)(A) permits covered entities to use or disclose PHI, consistent with applicable law and standards of ethical conduct, if the covered entity has a good faith belief that the use or disclosure is necessary to prevent or lessen a ''serious and imminent threat'' to the health or safety of a person (including the individual) or the public.[217] The recipient of the PHI must be reasonably able to prevent harm or lessen the threat, or the use or disclosure must be necessary for law enforcement to identify or apprehend an individual.[218]

To clarify that the Privacy Rule permits covered entities to address threats of harm, the Department proposes to amend the Privacy Rule at 45 CFR 164.512(j)(1)(i)(A) to replace the ''serious and imminent threat'' standard with a ''serious and reasonably foreseeable threat'' standard. The Department seeks to prevent situations in which covered entities decline to make uses and disclosures they believe are needed to prevent harm or lessen threats of harm due to concerns that their inability to determine precisely how imminent the threat of a harm is may make them subject to HIPAA penalties for an impermissible use or disclosure. The proposed modification would permit covered entities to use or disclose PHI without having to determine whether the threatened harm is imminent (which may not be possible in some cases); instead, they may determine whether it is reasonably foreseeable that the threatened harm might occur. The Department further proposes to add a new paragraph (5) to define ''reasonably foreseeable'' using a reasonable person standard.[219] This standard involves consideration of whether a similarly situated covered entity could believe that a serious harm is reasonably likely to occur, and does not require a determination that a

[215] *See e.g., https://www.hhs.gov/hipaa/for-professionals/faq/2090/when-does-mental-illness-or-another-mental-condition-constitute-incapacity-under-privacy-rule.html.*

[216] 65 FR 82462, 82719 (December 28, 2000).

[217] 45 CFR 164.512(j)(1)(i)(A). 45 CFR 164.512(j), unlike the provisions above that currently permit uses and disclosures based on professional judgment, already permits a covered entity to disclose PHI based on a good faith belief.

[218] *See* 45 CFR 164.512(j)(1)(ii)(A)–(B). This condition additionally requires the individual who is the subject of the PHI to have admitted participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim of the crime, or the individual who is the subject of the PHI has escaped from a correctional institute or lawful custody.

[219] *See, e.g.,* Rest. 2d Torts, section 283. In describing the standard of the ''reasonable man'' in the context of negligence in tort law, the authors note benefits of the standard that also apply to the proposal in this NPRM: ''The chief advantage of this standard of the reasonable man is that it enables the triers of fact who are to decide whether the actor's conduct is such as to subject him to liability for negligence, to look to a community standard rather than an individual one, and at the same time to express their judgment of what that standard is in terms of the conduct of a human being. The standard provides sufficient flexibility, and leeway, to permit due allowance to be made for such differences between individuals as the law permits to be taken into account, and for all of the particular circumstances of the case which may reasonably affect the conduct required, and at the same time affords a formula by which, so far as possible, a uniform standard may be maintained.''

majority of covered entities could have such a belief. However, the ''reasonably foreseeable'' standard would not permit the application of assumptions unwarranted by the individual's diagnosis and specific circumstances. For example, the assumption that a person with a diagnosis of depression or anxiety is a threat to themselves or others merely by virtue of that diagnosis is unfounded. Likewise, assuming that an individual on the autism spectrum who displays certain behaviors frequently associated with mental illness has co-occurring mental illness without any such diagnosis is unfounded.

The Department recognizes that some covered health care providers, such as licensed mental and behavioral health professionals, have specialized training, expertise, or experience in assessing an individual's risk to health or safety (*e.g.,* through a violence or suicide risk assessment). Therefore, the reasonably foreseeable standard would include an express presumption that such a covered health care provider has met the reasonably foreseeable standard when it makes a disclosure related to facts and circumstances about which the covered health care provider (or member of the provider's workforce) has specialized training, expertise, or experience.

Threats to public health or safety would include, for example, mass shootings, the use of explosive devices to attack a crowd, or other acts of terrorism. These examples are intended to highlight for covered health care providers their ability to use or disclose PHI to lessen the threat of, or prevent harm due to, potential mass violence and are not intended to limit the scope or type of serious and reasonably foreseeable threats covered by this provision. That is, a covered entity (or a member of a covered entity's workforce) need not have such specialized training, expertise, or experience in order to meet the reasonably foreseeable standard.

The Department does not propose to change the existing ''presumption of good faith belief'' at 45 CFR 164.512(j)(4), which explains the circumstances in which a covered entity is presumed to have acted in good faith with regard to a belief that a use or disclosure is necessary to prevent harm or lessen a threat.[220] Therefore, with the proposed modification, a covered entity that reports a threat to health or safety could potentially benefit from two presumptions under the Privacy Rule: (1) A presumption that the serious harm the covered entity identified was reasonably foreseeable, and (2) a presumption that the covered entity believed the use or disclosure was necessary to prevent harm or lessen the threat.

The Department expects that the proposed modification would improve the timeliness of disclosures that would have occurred, but for the covered entity's uncertainty regarding whether a threatened harm is ''imminent.'' As such, this proposed change would improve covered entities' ability to disclose PHI to persons who are reasonably able to lessen the threat and to prevent harm to the individual, other persons, or the public—with sufficient time for such persons to act.

Thus, for example, adopting a ''serious and reasonably foreseeable threat'' standard could further enable a health care provider to timely notify a family member that an individual is at risk of suicide, even if the provider cannot predict that a suicide attempt is likely to occur ''imminently.'' For an individual who poses a threat to public safety, a ''serious and reasonably foreseeable threat'' standard may afford a health care provider sufficient time to notify a person, such as a law enforcement official, who is in a position to avert a serious harm that may occur and ensure the safety of the individual and others.

By referencing mental and behavioral health professionals in the proposed definition of reasonably foreseeable, the Department does not mean to imply that individuals with mental or behavioral health conditions are more likely than other individuals to commit acts of violence. As the Department has stated previously,[221] mental illness is not proven to be an effective predictor of gun violence, and individuals who are experiencing mental illness are more likely to be the victims of violent crime than perpetrators.[222] The Department does not intend with this proposal to perpetuate false and harmful stereotypes about individuals with SMI or SUD, but rather to ensure that HIPAA is not a barrier in instances when entities believe a disclosure of PHI is necessary to prevent harm to the individual or to others.[223] Further, the Department believes that licensed mental and behavioral health professionals are among the health care providers that are most likely to have specialized training, expertise, or experience for which it is reasonable to establish a higher level of deference to their belief that a threat exists and that serious harm is reasonably foreseeable. The Department requests comment on this proposal.

The Department also proposes non-substantive revisions to 45 CFR 164.512(j) to refer to preventing a harm or lessening a threat, rather than preventing or lessening a threat. These proposed revisions are intended to clarify the standard, not change it; however, the Department requests comment on whether any unintended adverse consequences may result from the revisions.

Finally, the Privacy Rule does not preempt other law that is more protective of the individual's privacy.[224] As such, this proposal would not relieve covered entities of stricter restrictions on disclosure under state law or other Federal laws. However, the proposal would help ensure that HIPAA is not a barrier to disclosures needed to prevent harm.

3. Request for Comments

The Department requests comments on the above proposal, and the following considerations in particular:

a. Would the proposed change in standard from ''professional judgment'' to ''good faith belief'' discourage individuals from seeking care?

b. Should the Department apply the good faith standard to any or all of the other nine provisions in the Privacy Rule that call for the exercise of professional judgment? Are there circumstances in which it would be inappropriate to apply a presumption of compliance across the other nine provisions?

c. Should 45 CFR 164.510(b)(3) be revised to permit a covered entity to disclose the PHI of an individual who has decision making capacity to the individual's family member, friend, or other person involved in care, in a manner inconsistent with the individual's known privacy preferences (including oral and written expressions), based on the covered entity's good faith belief that the use or disclosure is in the individual's best interests, in any situations outside of an emergency circumstance? Put another way, are there examples in which the totality of the facts and circumstances should or would outweigh an individual's preferences, but do not rise

[220] *See* 45 CFR 164.512(j)(4). The provision states the presumption of good faith belief applies ''if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.''

[221] *See* HIPAA Privacy Rule and the National Instant Criminal Background Check System Proposed Rule, 79 FR 784 (January 7, 2014), and Final Rule, 81 FR 382 (January 6, 2016).

[222] *See* 79 FR 784, 788 (January 7, 2014) and 81 FR 382, 386 (January 6, 2016).

[223] *Ibid., Id.* at 387.

[224] *See* 45 CFR 160.203.

to the level of posing a serious and reasonably foreseeable threat under 45 CFR 164.512(j)? Are there examples related to individuals who have regained capacity after having been formerly incapacitated, such as where an individual recovering from an opioid overdose leaves the hospital against medical advice or leaves a residential treatment program?

d. When should overriding an individual's prior expressed preferences constitute bad faith on the part of the covered entity, which would rebut the presumption of compliance? Are there instances in which overriding an individual's prior expressed preferences would not constitute bad faith on the part of the covered entity?

e. Would the proposed ''serious and reasonably foreseeable threat'' standard discourage individuals from seeking care?

f. Would the proposed standard improve a covered entity's ability to prevent potential harm, such that the benefits of the change would outweigh potential risks? Please provide examples.

g. How often do mental and behavioral health professionals perceive that HIPAA constrains their ability to report such threats? Please provide specific examples, when available, including relevant state law.

h. Are there potential unintended consequences related to granting extra deference to a covered health care provider based on specialized risk assessment training, expertise, or experience when determining that a serious threat exists or that serious harm is reasonably foreseeable? Are there unintended consequences related to specifying mental and behavioral health professionals as examples of such providers?

i. As an alternative to the existing proposal, should the Department establish a specific permission for mental and behavioral health professionals to disclose PHI when in the view of the professional, the disclosure could prevent serious and reasonably foreseeable harm or lessen a serious and reasonably foreseeable threat to the health or safety of a person or the public? What would be potential unintended consequences of such an alternative?

G. Eliminating Notice of Privacy Practices Requirements Related to Obtaining Written Acknowledgment of Receipt, Establishing an Individual Right To Discuss the NPP With a Designated Person, Modifying the NPP Content Requirements, and Adding an Optional Element (45 CFR 164.520)

1. Current Provision and Issues To Address

The Privacy Rule, at 45 CFR 164.520, requires a covered health care provider that has a direct treatment relationship with an individual to make a good faith effort to obtain a written acknowledgment of receipt of the provider's NPP. If the provider is unable to obtain the written acknowledgment, the provider must document its good faith efforts and the reason(s) for not obtaining an individual's acknowledgment, and maintain such documentation for six years.[225]

The Department has heard anecdotally and in public comments on the 2018 RFI that the acknowledgment requirements impose paperwork burdens that are perceived as unnecessary and that create confusion for individuals (who may erroneously believe they are signing an authorization or waiver of some kind), as well as front office staff (who may erroneously believe that individuals must sign the acknowledgment to obtain care).

In the 2018 RFI, the Department asked whether it should eliminate the signature and recordkeeping requirements in 45 CFR 164.520 to reduce administrative burden on covered health care providers and free up time and resources for providers to spend on treatment, including care coordination. In addition, the 2018 RFI asked providers to suggest alternative ways to document that they provided an NPP to an individual if the written acknowledgment were no longer required. The Department also asked whether and how to modify other NPP requirements to alleviate covered entity burdens without compromising transparency about providers' privacy practices or an individual's awareness of his or her rights. In particular, the Department requested feedback on how to improve the NPP content and dissemination requirements.

Most commenters stated that the acknowledgment requirement was unduly burdensome, but did not provide cost estimates. Many covered entities and associations that commented reported experiencing a large administrative burden to document the good faith effort to obtain the acknowledgment in cases where the patient is unconscious or otherwise incapacitated or cannot sign the acknowledgment due to communication barriers.

Covered entities and large associations agreed with the Department's concern in the 2018 RFI that some individuals may mistakenly believe that their signature or written acknowledgment of the NPP is required to receive treatment. Commenters of all types reported their observations of individuals not reading the NPP when presented with it. Commenters also noted that physician offices frequently provide the NPP form to patients as part of a large bundle of paperwork at the time of the visit. Some commenters perceived the bundling of the NPP and acknowledgment with other paperwork as diminishing the likelihood that individuals pay attention to NPP content.

Associations and health systems/hospitals supported eliminating the requirement of a written acknowledgment of receipt of the NPP and believed the expected benefits would outweigh any adverse consequences. Professional associations, hospitals, and physicians commented that the signed NPP acknowledgment or the documentation of good faith efforts to obtain the written acknowledgment was of little or no use, and was an unnecessary burden.

In contrast, a number of commenters opposed removing the requirement relating to the written acknowledgment of receipt of the NPP, asserting that the acknowledgment helps to ensure that individuals are aware of their HIPAA rights. These commenters expressed concern that eliminating the written acknowledgment requirement would make it difficult or even impossible to track whether an individual was actually given the NPP and made aware of his or her rights under HIPAA.

Some commenters suggested alternative policy solutions or other actions that the Department could take to improve consumer awareness of the NPP, such as requiring providers to post the NPP electronically and increasing consumer education about the contents of the NPP.

Regarding NPP content, ONC, in collaboration with OCR, developed several model NPPs, which are publicly available on the OCR website.[226] These

[225] *See* 45 CFR 164.520(e); 45 CFR 164.530(j)(2).

[226] *See* ''Model Notices of Privacy Practices,'' HHS Office for Civil Rights (2013), available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/model-notices-privacy-practices/index.html* and *https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/npp_fullpage_hc_provider.pdf.*

models use plain language and approachable designs that were tested with consumer focus groups. The 2018 RFI sought comment on whether covered entities use the model NPPs, whether the model NPPs should contain more specific information, and whether an entity that uses a model NPP should be deemed compliant with the NPP content requirements.

Some commenters stated that they use the model NPP as a reference when creating their own forms, or modify a model to conform to state law and other organizational requirements. Some professional associations supported creating a safe harbor for entities using a model NPP, but several commenters pointed out potential challenges that such a safe harbor could create. For example, some commenters stated that a safe harbor would lead to greater confusion, with some entities having to incorporate provisions from state or local law into model NPP language. Others stated that utilizing the model NPP form would lead to longer and harder-to-understand notices. Most commenters urged that, rather than creating a safe harbor, the Department instead focus on developing consumer-focused educational materials.

Additional issues to address in connection with the NPP would arise from the NPRM's proposal to limit the individual right to direct PHI to a third party only to an electronic copy of ePHI in an EHR. Covered entities may receive requests from individuals to direct to third parties copies of PHI that are not ePHI in an EHR and therefore are outside the scope of the access right to direct a copy of PHI to a third party. The current NPP content does not address these limitations. For example, an individual submits a request to her health plan to direct ePHI in a designated record set to a third party, but that ePHI is not in an EHR. As another example, an individual requests that a paper copy, rather than an electronic copy, of PHI in an EHR be sent to a third party. Neither of these requests would be included in the individuals' right of access to direct an electronic copy of their PHI in an EHR to a third party. In addition, the Department is aware that many requests to send PHI to a third party may be for a ''complete medical record'' that exists in multiple forms and formats (electronic and in paper),) which are hybrid in nature. The current NPP content requirements do not help the individual understand how to obtain such records.

2. Proposal

To alleviate paperwork burdens and reduce confusion for individuals and covered health care providers, the Department proposes to eliminate the requirements for a covered health care provider with a direct treatment relationship to an individual to obtain a written acknowledgment of receipt of the NPP and, if unable to obtain the written acknowledgment, to document their good faith efforts and the reason for not obtaining the acknowledgment.[227] The proposal also would remove the current requirement to retain copies of such documentation for six years.[228]

To ensure that individuals are able to understand and make decisions based on the information in the NPP, the Department proposes at 45 CFR 164.520(b)(1)(iv)(G) to replace the written acknowledgment requirements with an individual right to discuss the NPP with a person designated by the covered entity. In addition, the Department proposes at 45 CFR 164.520(b)(1)(i) to modify the content requirements of the NPP to help increase patients' understanding of an entity's privacy practices and their rights with respect to their PHI. First, the Department proposes to modify the required header of the NPP to specify to individuals that the notice provides information about (1) how to access their health information; (2) how to file a HIPAA complaint; and (3) individuals' right to receive a copy of the notice and to discuss its contents with a designated person.

Second, the required header would specify whether the designated contact person is available onsite and must include a phone number and email address the individual can use to reach the designated person. This header content requirement would apply to all covered entities, and not just covered health care providers with direct treatment relationships with individuals, ensuring consistency in how NPP content is presented to individuals. Providing this information at the beginning of the NPP would improve patients' awareness of their Privacy Rule rights, what they can do if they suspect a violation of the Privacy Rule, and how to contact a designated person to ask questions.

Further, consistent with the proposed header language, and to ensure that individuals are fully informed of their access rights, the Department proposes at 45 CFR 164.520(b)(1)(iv)(C) to modify the required element of an NPP that addresses the access right, to describe how an individual can exercise the right of access to obtain a copy of their records at limited cost or, in some cases, free of charge, and the right to direct a covered health care provider to transmit an electronic copy of PHI in an EHR to a third party. Finally, the Department proposes to add an optional element to the NPP to include information to address instances in which individuals seek to direct their PHI to a third party, when their PHI is not in an electronic health record or is not in an electronic format. This optional element would help make individuals aware that they retain the right to obtain the PHI directly and give it to a third party or they can request to send a copy of PHI directly to a third party using a valid authorization. The Department believes these proposals to remove the acknowledgment of the NPP requirements would eliminate a significant documentation and storage burden for health care providers. The Department also believes the proposals would help individuals better understand how to exercise their rights, including what they can do if they suspect a violation of the Privacy Rule, and who to contact with specific questions.

Based on public comments on the 2018 RFI, the Department does not propose to create a safe harbor to deem those entities that use the model NPP compliant with the NPP content requirements. Instead, the Department requests comment on ways the model NPP could be changed to improve consumer understanding. For example, the Privacy Rule requires that the NPP contain a description, including at least one example, of the types of uses and disclosures the covered entity is permitted to make for health care operations (as well as for treatment and payment), and the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required.[229] The model NPP explains that the health care operations permission allows uses and disclosures of PHI to ''run [the] organization,'' which is further described as disclosing an individual's health information to run the practice, improve care, and contact the individual. The model NPP also includes an example of health care operations as ''us[ing] health

[227] *See* 45 CFR 164.520(c)(2)(ii).

[228] *See* 45 CFR 164.520(e).

[229] *See* 45 CFR 164.520(b)(1)(ii)(A) and (D).

information . . . to manage your treatment and services.'' [230]

Based on the Department's experience, many individuals are not aware of the scope of activities that constitute health care operations, and thus the description and example currently in the model NPP may not provide sufficient detail to inform the individual of how their health information may be used and disclosed for health care operations purposes. To that end, the Department requests recommendations for how best to impart to individuals how health information can be used and disclosed under the health care operations permission in the model NPP.

Finally, consistent with public feedback, the Department will continue to consider how to best educate and conduct outreach to inform individuals about their Privacy Rule rights and entities' privacy practices.

3. Request for Comments

The Department requests comments on the above proposal, and the following considerations in particular:

a. Would the proposed changes to the NPP requirements have any unintended adverse consequences for individuals or regulated entities?

b. Would the revised NPP content requirements improve individuals' understanding of, and ability to exercise, their rights under the Privacy Rule?

c. Are there ways that OCR can improve the model NPPs to be more informative and easier to understand?

d. Should the model NPP's description of health care operations be modified? If so, please provide suggested language for modifying the description in the model NPP to reflect how your organization uses PHI for health care operations purposes.

e. Are there specific examples that should be included in a model NPP to explain to individuals how PHI can be used or disclosed for health care operations?

f. Specific examples of amounts spent and any other costs incurred by a covered entity to comply with the requirements relating to the acknowledgement of receipt of the NPP, when the covered entity fulfills the requirements using paper-based or electronic forms, signatures, or document filing systems.

[230] *See* ''Full Page Model Notice of Privacy Practices'', HHS Office for Civil Rights (2013), available at *https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/npp_fullpage_hc_provider.pdf.*

H. Permitting Disclosures for Telecommunications Relay Services for People Who are Deaf, Hard of Hearing, or Deaf-Blind, or Who Have a Speech Disability (45 CFR 164.512)

1. Current Provisions and Issues To Address

Telecommunications Relay Service (TRS) facilitates telephone calls between individuals who are deaf, hard of hearing, or deaf-blind, or who have a speech disability, and others. [231] TRS is a federally mandated service that federally regulated common carriers (*e.g.,* operators of all landline and mobile telephone services) are required to provide individuals, in the general public, who are deaf, hard of hearing, or deaf-blind, or who have a speech disability.[232] The Federal Communications Commission (FCC), pursuant to the Americans with Disabilities Act (ADA) [233] certifies TRS programs, which are available in all 50 states, the District of Columbia, Puerto Rico, and U.S. territories. States and other government entities typically compensate telephone companies to provide TRS services.[234]

TRS facilitates such telephone communication by using a communications assistant [235] who transliterates conversations (or, in some cases, interprets using ASL). The communications assistant relays information, which may include PHI, between a person who uses text or video and another person, who may be communicating by voice or who may also use TRS.[236] Several forms of TRS are available.[237] All TRS providers must comply with standards for operators established by the FCC pursuant to Title IV of the ADA, including protecting the confidentiality of all relayed communications.[238]

OCR has a longstanding FAQ on the use of TRS by a covered entity to communicate with an individual who is deaf, hard of hearing, or deaf-blind, or who has a speech disability. The FAQ states that a covered entity is permitted to disclose an individual's PHI to a TRS communications assistant when communicating with the individual, without the need for a business associate agreement with the TRS provider.[239] The FAQ explains that the Privacy Rule permits disclosures to TRS communications assistants under 45 CFR 164.510(b) because individuals have an opportunity to agree or object to disclosures of PHI to a TRS communications assistant at the beginning of a call, and the individuals are identifying the communications assistant as involved in their care if they do not object. The FAQ also explains that the TRS provider is not acting for or on behalf of the covered entity when it provides such relay services, and therefore is not a business associate.

Since the FAQ was created, the Department has become aware that advances in technology now allow people who are deaf, hard of hearing, or deaf-blind, or who have a speech disability to communicate with the help of a TRS communications assistant in a seamless manner, with immediate connection and instantaneous transliteration of text or interpretation of ASL to voice and vice versa, such that the other party to the call may not know that a person is using a TRS communications assistant. In addition, TRS is used to not only connect patients and providers, but also to assist communications between workforce members of covered entities and business associates. For these reasons, the original assumption that individuals would always have the opportunity to agree or object to a use or disclosure of PHI to a communications assistant no longer holds when it is a workforce member of the covered entity or business associate, rather than an individual (*e.g.,* patient or beneficiary), who needs the TRS services to assist in making communications. Further,

[231] *See* ''Consumer Guide, Telecommunications Relay Service,'' FCC (2017), available at *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

[232] *See* 47 U.S.C. 225(b).

[233] Public Law 101–336, 104 Stat. 327 (July 26, 1990), and its amendments.

[234] *See* ''Consumer Guide, Telecommunications Relay Service,'' *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

[235] A communications assistant is ''[a] person who transliterates or interprets conversation between two or more end users of TRS.'' 47 CFR 64.601(a)(12).

[236] *See generally,* FCC's 2017 ''Consumer Guide, Telecommunications Relay Service,'' available at *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

[237] TRS types include Text-to-Voice, Voice Carry Over, Hearing Carry Over, Speech-to-Speech Relay, Shared Non-English Language Relay, Captioned Telephone Service, IP Captioned Telephone Service, internet Protocol Relay Service, and Video Relay Service. *Id.* at 2.

[238] Except in very limited circumstances specified in FCC regulations, TRS communications assistants are not permitted to keep notes of the contents of a call after a call, unless the caller requests that the communications assistant retain such information in order to facilitate the completion of subsequent calls. In no case may the communications assistant retain such information after the completion of the subsequent call(s). *See* 47 CFR 64.604(a)(2).

[239] *See* HHS Office for Civil Rights Frequently Asked Questions, available at *https://www.hhs.gov/hipaa/for-professionals/faq/500/is-a-relay-service-a-business-associate-of-a-doctor/index.html.*

stakeholders have requested that the Department specifically address the use of TRS by members of the covered entity or business associate workforce to share PHI with other workforce members or outside parties as needed to perform their duties. These stakeholders have shared anecdotal accounts in which a covered entity or business associate refuses to allow a workforce member to use this essential service because of concerns about violating the Privacy Rule if they do not have a business associate agreement with the TRS provider.

2. Proposal

The Department proposes to expressly permit covered entities (and their business associates, acting on the covered entities' behalf) to disclose PHI to TRS communications assistants to conduct covered functions by adding a new paragraph (m) to 45 CFR 164.512.[240] This proposed permission would cover all disclosures to TRS communications assistants relating to any covered functions performed by, for, or on behalf of covered entities and clarify for covered entities that a business associate agreement is not needed with a TRS communications assistant.

The Department also proposes to add a new subsection (v) to paragraph (4) of the definition of business associate at 45 CFR 160.103 to expressly exclude TRS providers from the definition of business associate. The proposed exclusion would apply regardless of whether the workforce member is an employee, contractor, or business associate of the covered entity. This proposal would ensure that covered entities and business associates do not bear the burdens of analyzing whether they need business associate agreements with TRS providers and, potentially, establishing such agreements.

Together, these modifications would help ensure that workforce members and individuals who are deaf, hard of hearing, or deaf-blind, or who have a speech disability are able to communicate easily using TRS for care coordination and other purposes.

3. Request for Comments

The Department requests comments on this proposal, including the following questions:

a. Would the proposed change achieve the anticipated effects?

b. Are there any potential unintended, adverse consequences of the proposal?

c. Please share data related to the number of covered entity and business associate workforce members who are deaf, hard of hearing, or deaf-blind, or who have a speech disability and currently utilize TRS to perform their duties.

d. Please provide data on the amount of time and other resources covered entities and business associates have spent on determining whether they need a business associate agreement with a TRS provider, or actually entering into business associate agreements with TRS providers.

I. Expanding the Permission To Use and Disclose the PHI of Armed Forces Personnel To Cover all Uniformed Services Personnel (45 CFR 164.512(k))

1. Current Provision and Issues To Address

The original Privacy Rule [241] established an express permission for covered entities to use and disclose the PHI of Armed Services personnel, under certain conditions, to avoid the burden and obstacles of obtaining individuals' authorizations when the balance of privacy interests and social values weighed toward permitting the use or disclosure of PHI without authorization for specialized purposes. Currently, a covered entity may use and disclose the PHI of Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, provided the conditions at 45 CFR 164.512(k) are met. The appropriate military command authorities and the purposes for which the PHI may be used or disclosed must be identified through **Federal Register** notices.[242]

Like the Secretaries of the Armed Services, the Secretaries of HHS and the Department of Commerce are responsible for ensuring the medical readiness of the Uniformed Services personnel in the U.S. Public Health Service (USPHS) Commissioned Corps and the National Oceanic and Atmospheric Administration (NOAA) Commissioned Corps, respectively. Pursuant to 42 U.S.C. 204a(a)(1), while on active duty, the ongoing medical standards require USPHS personnel to be medically fit to deploy in response to urgent and emergent public health crises, as well as for any necessary military mission, and for duty in various environments. These medical standards include physical, dental, and mental health requirements. The NOAA Commissioned Corps has a similar standard, requiring personnel to meet U.S. Coast Guard medical standards to maintain individual medical readiness for deployment on aircraft and shipboard missions. Further, when personnel in the Uniformed Services are no longer fit for duty, they are entitled to retirement pay and compensation, and once separated they are entitled to receive veterans' benefits. In order to confirm the medical fitness of personnel, the USPHS and NOAA Commissioned Corps must have access to personnel's medical records.

In addition, the USPHS Commissioned Corps and NOAA Commissioned Corps routinely align their policies and practices with those of the Armed Forces. Members of the USPHS and NOAA Commissioned Corps may be assigned to the Armed Services and must meet medical readiness standards consistent with the various military missions of the Armed Services. In times of war, the President may declare the USPHS and the NOAA Commissioned Corps to be a military service.

However, the members of the USPHS and NOAA Commissioned Corps are not members of the Armed Services, and thus covered entities currently are not permitted to use and disclose the PHI of such Commissioned Corps personnel for the same purposes as for Armed Forces personnel unless the member is actively assigned to the Armed Services. The Department proposes to expand the existing permission at 45 CFR 164.512(k)(1) in recognition that ensuring the health and well-being of Uniformed Services personnel is essential, whether such personnel are serving in the continental United States or overseas or whether such service is combat-related. In all environments, operational or otherwise, the Uniformed Services must be assured that personnel are medically qualified to perform their responsibilities and medically ready for deployment at all times.

Although the issue was not raised in the 2018 RFI, the Department received a joint comment in response to the 2018 RFI from the Directors of the Commissioned Corps of NOAA and USPHS suggesting that the current permission for covered entities to use and disclose the PHI of Armed Forces personnel be broadened to also include non-armed Uniformed Services personnel. The Directors of the NOAA and USPHS Commissioned Corps stated that the existing rule limits the ability of the NOAA and USPHS Commissioned Corps to facilitate health care coordination and case management for Commissioned Corps personnel,

[240] The terms ''Telecommunications Relay Service'' and ''Telecommunications Relay Service Communications Assistant'' have the same meaning used in 47 CFR part 64.

[241] *See* 65 FR 82462, 82704, 82817 (December 28, 2000).

[242] *See* 45 CFR 164.512(k)(1)(i).

which is important for ensuring that personnel meet medical readiness standards, and thus for fulfilling the Commissioned Corps' respective missions. The commenters also stated that the permission is important because personnel and the broader population are put at risk when personnel do not disclose medical conditions to Commissioned Corps leaders and are deployed on a Commissioned Corps mission.

2. Proposal

The Department agrees that expanding the Armed Forces permission may facilitate coordinated care and enhance USPHS and NOAA Commissioned Corps' readiness. Therefore, to improve care coordination and case management for individuals serving in the Uniformed Services, the Department proposes in 45 CFR 164.512(k)(1) to expand to all Uniformed Services personnel the current Armed Forces permission for covered entities to use and disclose PHI for mission requirements and veteran eligibility.

3. Request for Comments

The Department requests comments on this proposal, including on whether the proposed change would achieve the anticipated effects and any potential unintended consequences.

IV. Public Participation

The Department seeks comment on all issues raised by the proposed regulation, including any unintended adverse consequences. Because of the large number of public comments normally received on **Federal Register** documents, the Department is not able to acknowledge or respond to them individually. In developing the final rule, the Department will consider all comments that are received by the date and time specified in the **DATES** section of the Preamble.

Because mailed comments may be subject to security delays due to security procedures, please allow sufficient time for mailed comments to be timely received in the event of delivery delays. Any attachments submitted with electronic comments on *www.regulations.gov* should be in Microsoft Word or Portable Document Format (PDF). Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

V. Regulatory Impact Analysis

The Department has examined the impact of the proposed rule as required by Executive Order 12866 on Regulatory Planning and Review, 58 FR 51735 (October 4, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review, 76 FR 3821 (January 21, 2011); Executive Order 13132 on Federalism, 64 FR 43255 (August 4, 1999); Executive Order 13175 on Consultation and Coordination with Indian Tribal Governments, 65 FR 67249 (November 6, 2000); Executive Order 13771 on Reducing Regulation and Controlling Costs, 82 FR 9339 (January 30, 2017); the Congressional Review Act, Public Law 104–121, sec. 251, 110 Stat. 847 (March 29, 1996); the Unfunded Mandates Reform Act of 1995, Public Law 104–4, 109 Stat.48 (March 22, 1995); the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (September 19, 1980); Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking, 67 FR 53461 (August 16, 2002); the Assessment of Federal Regulation and Policies on Families, Public Law 105–277, sec. 6545, 112 Stat. 2681 (October 21, 1998); and the Paperwork Reduction Act of 1995, Public Law 104–13, 109 Stat. 163 (May 22, 1995).

A. Executive Orders 12866 and 13563 and Related Executive Orders on Regulatory Review

Executive Order 12866 directs 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 is supplemental to, and reaffirms the principles, structures, and definitions governing regulatory review as established in, Executive Order 12866.

This proposed rule is deregulatory. The Department has estimated that the effects of the proposed requirements for regulated entities would result in new costs of $996 million within 12 months of implementing the final rule. The Department estimates these first year costs would be partially offset by $880 million of first year cost savings, followed by net savings of $825 million annually in years two through five, resulting in overall net cost savings of $3.2 billion over five years.

The Department estimates that the private sector would bear approximately 60 percent of the costs, with state and federal health plans bearing the remaining 40 percent of the costs. All of the costs savings experienced from the first year through subsequent years would benefit covered entities. As a result of the economic impact, the Office of Management and Budget (OMB) has determined that this proposed rule is an economically significant regulatory action within the meaning of section 3(f)(1) of E.O. 12866. Accordingly, OMB has reviewed this proposed rule.

The Department presents a detailed analysis below.

1. Summary of the Proposed Rule

This NPRM proposes to modify the Privacy Rule to improve individuals' access to their PHI, increase permissible disclosures of PHI, and improve care coordination and case management by:

- Adding definitions for electronic health records (EHRs) and personal health applications.
- Modifying the provisions on the individuals' right of access to protected health information (PHI) by: Strengthening the individual's right to inspect their PHI, which includes allowing individuals to take notes or use other personal resources to view and capture copies of their PHI in a designated record set; shortening covered entities' response time to 15 calendar days (from the current 30 days); clarifying what constitutes a readily producible form and format when providing requested copies of PHI, which may be ePHI transmitted via a personal health application, while requiring covered entities to inform individuals about their right to obtain or direct copies of PHI to a third party when a summary or explanation is offered; requiring covered health care providers and health plans to respond to certain record requests from other covered health care providers and health plans made at the direction of an individual; clarifying when ePHI must be provided to the individual free of charge; amending the fee structure for certain requests to direct ePHI to a third party; and requiring covered entities to post fee schedules on their websites (if they have a website) for common types of requests for copies of PHI, and, upon request, provide individualized estimates of fees for copies and an itemized list of actual costs for requests for copies.
- Reducing the identity verification burden on individuals exercising their access right.
- Amending the definition of health care operations to clarify the scope of care coordination and case management activities encompassed in the term.
- Creating an exception to the minimum necessary standard for disclosures to, or requests from, a health plan or covered health care provider for individual-level care coordination and case management activities.

• Clarifying the scope of covered entities' ability to disclose PHI to social services agencies, community-based organizations, home and community based service (HCBS) providers, and other similar third parties that provide health-related services, to facilitate individual-level care coordination and case management activities that constitute treatment- or health care operations.

• Replacing the privacy standard that permits covered entities to make decisions about certain uses and disclosures based on their ''professional judgment'' with a standard permitting covered entities to use or disclose PHI in some circumstances based on a good faith belief that the use or disclosure is in the best interests of the individual. The proposed standard would presume a covered entity's compliance with the good faith requirement; the presumption could be overcome with evidence that a covered entity acted in bad faith.

• Expanding the ability of covered entities to use or disclose PHI to avert a serious threat to health or safety when a harm is ''serious and reasonably foreseeable,'' instead of the current standard which requires a ''serious and imminent'' threat to health or safety.

• Eliminating the requirement to obtain an individual's written acknowledgment of receipt of a direct treatment provider's Notice of Privacy Practices and modifying the content requirements of the Notice of Privacy Practices to clarify for individuals their rights with respect to their PHI and how to exercise those rights.

• Expressly permitting disclosures to Telecommunications Relay Services (TRS) communications assistants and modifying the definition of business associate to exclude TRS providers.

• Expanding the Armed Forces permission to use or disclose PHI to all Uniformed Services, which would include the U.S. Public Health Service (USPHS) Commissioned Corps and the National Oceanic and Atmospheric Administration (NOAA) Commissioned Corps.

The proposed changes to the Privacy Rule offer some estimated costs, and numerous and substantial estimated cost savings and expected benefits which the Department is unable to quantify, but are described in depth below. These include improved care coordination and health outcomes; improved harm reduction; greater adherence to treatment for persons experiencing health emergencies, SUD, and SMI; improved understanding of individuals' rights and covered entities' privacy practices; improved access to care; quicker, more convenient access to PHI by individuals; improved access to PHI by health care providers and health plans; reduction in access fee disputes, resulting in improved ability to collect of fees for copies of PHI; increased certainty about allowable fees; increased adoption and utilization of EHR technology; improved employment conditions and opportunities for workforce members of HIPAA covered entities and business associates who are deaf, hard of hearing, or deaf-blind, or who have a speech disability; and improved compliance with non-discrimination laws that require accessibility for individuals with disabilities.

The Department has identified three general categories of costs arising from these proposals which mostly relate to activities by HIPAA covered entities, particularly health care providers and health plans: (1) Administrative activities (first-year and ongoing); (2) revising or creating policies and procedures, the NPP, and an access fee schedule; and (3) revising training programs for workforce members.

The Department estimates that the first-year costs will total $996 million. These costs are attributable to covered entities revising or developing new policies and procedures, at a cost of $696 million; revising training programs for workforce members, at a cost of $224 million; and additional administrative tasks, at a cost of $76 million. For years two through five, estimated annual costs of $55 million are attributable to ongoing administrative costs, primarily related to improvements to the right of access to PHI.

The Department estimates annual cost savings of $880 million per year, over five years, attributable to eliminating the NPP acknowledgment requirements (cost savings of $537 million) and clarifying the minimum necessary standard ($343 million).

The Department estimates net costs for covered entities totaling $116 million in the first year followed by net savings of $825 million annually in years two through five, resulting in overall cost savings of $3.2 billion over five years. Covered entities would experience an average net savings of approximately $1,065 per entity in years two through five after expending costs of $150 per entity in the first year.[243]

[243] The Department recognizes that some of the proposed changes would affect certain covered entities more than others, resulting in significantly different costs and savings. The tables summarizing estimated costs and cost savings account for these differences (Cost-Benefit Analysis, subsections f–j and Tables 10–17).

TABLE 1—ESTIMATED FIVE-YEAR COSTS AND COST-SAVINGS, UNDISCOUNTED, IN MILLIONS

	Amount
Costs:	
Revise Training	$224
Revise Policies and Procedures	696
Administrative Costs	297
Capital Costs	1
Total Costs	1,218
Cost Savings:	
Eliminate Notice of Privacy Practices Acknowledgment	2,685
Clarify Minimum Necessary Standard	1,715
Total Cost Savings	4,400
Net Total (negative = savings)	−3,182

The Department estimates that the proposed adjustments to costs that can be charged to individuals for copies of PHI in an EHR on electronic media would result in a transfer of those expenses from individuals to covered entities in a total estimated amount of $1.4 million. The Department also estimates that the proposed changes to the right to direct the transmission of copies of PHI to a third party and to allowable access fees would result in an annual transfer of $43 million in costs incurred by covered entities to individuals for directing copies of PHI to third parties. The net result of these proposals likely would be a transfer of an estimated $41.6 million in costs from covered entities to individuals and some third party recipients of PHI in the form of higher fees for copies of PHI.

2. Need for the Proposed Rule

The Privacy Rule balances protecting the privacy of individuals' PHI with facilitating the use and disclosure of PHI for important public interest purposes, such as facilitating efficient care coordination and case management. This proposed rule would improve on this balance with modifications to promote the transformation to value-based health care and reduce regulatory burdens by removing unhelpful or unnecessary requirements. Based on public comments on the 2018 RFI and OCR's experience administering and enforcing the Privacy Rule, the Department has identified areas where the Privacy Rule could be modified to improve the flow of PHI for such purposes in a manner that would continue to protect individuals' privacy. These include changes strengthening the individual's ability to gain access to his or her own PHI; enhancing the

disclosure of PHI between covered entities; improving health care providers' ability to disclose needed PHI to patients' family members, friends, caregivers, and others in a position to prevent harm; supporting the rights of workforce members who need accommodations to communicate and share PHI; including all branches of the Uniformed Services in applicable disclosure permissions; and technical amendments for business associates to provide individuals with access to copies of PHI.

a. Individual Right of Access

Individual access to PHI is a core right established by the Privacy Rule. Delays or lack of access inhibit care coordination and may contribute to worse health outcomes for individuals. Individuals frequently face barriers to obtaining timely access to their PHI, in the form and format requested, and at a reasonable, cost-based, and transparent fee. A recent cross-sectional study of medical records request processes conducted in 83 top-ranked US hospitals found numerous indications of noncompliance with the access right.[244]

To address multiple barriers to individual access, the Department proposes to: Add definitions of EHR and personal health application; expressly provide that the right to inspect PHI in person includes the right of an individual to take notes and photographs of, and use other personal resources to capture, PHI; clarify what constitutes a readily producible form and format for copies of PHI, while requiring covered entities to inform individuals about access rights when offering a summary in lieu of providing or directing copies; shorten the time limits for covered entities to respond to access requests; empower individuals to use the right of access to direct the disclosure of PHI among their health care providers and health plans; adjust and clarify the fees covered entities may impose; and require covered entities to provide individuals with notice of the fees charged for copies of PHI. Additionally, the Department proposes to limit the scope of the right to direct the transmission of copies of PHI to a third party to electronic copies of PHI in an EHR, consistent with the *Ciox* v. *Azar* decision.[245]

i. Defining Electronic Health Record and Personal Health Application

The Department proposes to add a definition of EHR for the purpose of clarifying the scope of the individual right to direct an electronic copy of PHI in an EHR to a third party. For purposes of harmonizing the proposed regulatory changes and the right of the individual to obtain an electronic copy, the Department interprets the EHR as health information ''created, gathered, managed, and consulted by authorized health care clinicians and staff.'' The definition would be tied to clinicians with direct treatment relationships with individuals and consistent with the defined terms in the current rule. The proposed definition would improve understanding of whether certain aspects of a covered entity's electronic records are or are not part of an EHR to enable a covered entity to assess whether such electronic PHI is subject to the HITECH Act right of access requirements to respond to requests from an individual to direct electronic copies of PHI in an EHR to designated third parties. Although covered health care providers have substantial flexibility in determining the composition of an EHR, an EHR may vary across different health care providers. The definition is intended to provide a clear standard by which health care providers would be able to identify what PHI is subject to HITECH Act requirements for electronic PHI in an EHR. As noted earlier, the Department proposes that only covered health care providers would provide such access because only providers would maintain EHRs as defined in proposed 45 CFR 164.501, and that an EHR would also include billing records.

The Department also proposes to add a new definition for the term ''Personal health application'' that is similar to the HITECH Act definition of personal health record (PHR),[246] but is intended to specifically address health applications, which may or may not be PHRs.[247] Adding this definition would clarify the intended scope of proposed changes to the right of access, such as clarifying that an individual may use an internet-based method such as a personal health application to obtain access without charge.

ii. Strengthening the Right To Inspect and Obtain Copies of PHI

The individual right of access under the Privacy Rule includes a right to ''inspect and obtain a copy of'' PHI in a designated record set.[248] The Department proposes to strengthen the access right to inspect and obtain copies of PHI to generally enable an individual to take notes, videos, and photographs, and use other personal resources to capture PHI in a designated record set, as part of the right to inspect PHI in person.

iii. Timeliness

Timely access to an individual's own PHI can be a key component to patient-directed care (see discussion of harms due to lack of timeliness above in section III.A.3.a.). The Department proposes to modify the Privacy Rule to require that access be provided as soon as practicable, but no later than 15 calendar days after receipt of the request, with the possibility of one 15 calendar-day extension, provided certain conditions are met. Where another federal or state law (*i.e.,* statute or regulation) requires a covered entity to provide individuals with access to the PHI requested in less than 15 calendar days, that shorter time period would be deemed practicable under 45 CFR 164.524 (b)(2)(i) and (d)(5). The Department also proposes to add a new condition requiring a covered entity to establish a written policy to prioritize urgent or other high-priority access requests (especially those for health and safety and to support individual decisions about treatment options), to limit the need to use a 15 calendar-day extension for such requests. This would reduce by half the time within which entities must provide access to PHI, consistent with existing requirements in several large states, improvements in health IT, and consumers' needs and expectations. The proposal would also prohibit covered entities from delaying the right to inspect PHI that is readily available at the point of care in conjunction with a health care appointment.

The Department lacks sufficient data to correlate shorter required access times with health care costs. The Department examined state health expenditure data[249] and noted that of

[244] Lye CT, Forman HP, Gao R, et al. ''Assessment of US Hospital Compliance With Regulations for Patients' Requests for Medical Records.'' JAMA Network Open. October 5, 2018, 1(6):e183014, available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2705850.*

[245] No. 18–cv–0040–APM (D.D.C. January 23, 2020).

[246] *See* the HITECH Act definition of personal health record, ''[A]n electronic record of PHR identifiable health information (as defined in section 17937(f)(2) of this title) on an individual that can be drawn from multiple sources and that is managed, shared, and controlled by or primarily for the individual.'' 42 U.S.C. 17921(11). *See also* proposed 45 CFR 164.501, definition of ''Personal health application.''

[247] The same software could be a personal health application under the proposed Privacy Rule definition and also be a personal health record under the HITECH Act for other purposes, to the extent it meets both definitions.

[248] *See* 45 CFR 164.524(a).

[249] *See* ''Kaiser Family Foundation, Health Care Expenditures, per Capita, by State of Residence,'' available at *https://www.kff.org/other/state-*

the eight states with shorter access time limits than the Privacy Rule,[250] six rank in the lowest third for health care expenditures; however, there is a lack of granularity to this data upon which to draw clear conclusions about the potential ongoing burden to covered entities. The Department has estimated that the proposed changes would increase costs on an ongoing basis and welcomes data about these estimates, as detailed in the cost-benefits analysis.

Finally, the Department also proposes to expressly provide that while a covered entity may discuss aspects of the individual's access request with the individual before fulfilling the individual's request, such discussions to clarify the scope of the request would not extend the time limit for providing access. This modification would help address the issue raised in individual complaints and comments on the 2018 RFI that covered entities may contact individuals for the first time nearly 30 days after receiving a request for access to discuss the request or obtain additional information, and then take additional time beyond the 30-day period to fulfill the request.

iv. Addressing the Form and Format of Access

The Department proposes to clarify that ''readily producible'' includes access through APIs and personal health applications and to add a set of parallel requirements related to the form of access that applies to both the individual right to obtain copies of PHI and the access right to direct the transmission of electronic copies of PHI in an EHR to a designated third party. As new forms of information and communications technologies emerge, the ''form and format'' and the ''manner'' of producing or transmitting a copy of electronic PHI may become indistinguishable. For example, if a covered entity or its EHR developer business associate has chosen to implement a secure, standards-based API—such as one consistent with ONC's Cures Act certification criteria,[251] and the covered entity's Security Rule obligations—that is capable of providing access to ePHI in the form and format used by an individual's personal health application, that ePHI is considered to be *readily producible* in that form and format, and that is also the manner by which the ePHI is transmitted.

Additionally, when a covered entity offers a summary in lieu of providing or directing the requested copies of PHI, the Department would require the covered entity to inform the individual of the right to obtain or direct the requested copies if the individual does not agree to the offered summary. This requirement would not apply when the covered entity denies the access request for a copy on unreviewable or reviewable grounds, in which case the covered entity must implement the required procedures for such denial.

v. Addressing the Individual Access Right to Direct Copies of PHI to Third Parties

The Department proposes to implement the *Ciox* v. *Azar* decision by codifying in regulation the HITECH Act right to direct the transmission to a third party of only electronic copies of PHI in an EHR in 45 CFR 164.524(d)(1). Under this proposal, if an individual directs a covered health care provider to transmit an electronic copy of PHI in an EHR to a third party, the covered health care provider would be required to provide a copy of the requested PHI to the person designated by the individual. The Department believes this proposal is consistent with the plain meaning of section 13405(e) of the HITECH Act, which extended a right to a copy of PHI in an EHR ''in an electronic format'' as part of the Privacy Rule right of access. As a result, requests to direct to a third party non-electronic copies of PHI in a designated record set (whether from an EHR or other source) and electronic copies of PHI that is not in an EHR, would no longer fall within the right of access. Individuals would continue to have the right to directly obtain the types of PHI that are outside of the scope of the access right to direct electronic copies of PHI in an EHR to a third party, and also could request that a copy of the PHI be sent to a third party by submitting a valid authorization. To address the potential impact on individual rights as a result of these changes the Department proposes an optional element for the Notice of Privacy Practices (NPP) as described in the NPP sections of the NPRM.

The Department proposes to extend the right to direct copies of PHI to a third party by adding an express right to request that covered health care providers and health plans submit an access request to covered health care providers for electronic copies of PHI in an EHR on behalf of the individual. Under this proposal, if an individual is a current or prospective new patient of a covered health care provider, or an enrolled member or dependent of a health plan, and the individual makes a clear, conspicuous, and specific request that their health care provider or health plan submit an access request for electronic copies of PHI in an EHR to another covered health care provider, the first health care provider or health plan (''Requester-Recipient'') would be required to submit the request on behalf of the individual as soon as practicable, but no later than 15 calendar days after receiving the individual's direction and any information needed to make the access request. The requirement would be limited to requests to send the electronic PHI back to the covered entity that submitted the request on behalf of the individual.

A covered health care provider that receives an individual's access request (''Discloser'') for an electronic copy of PHI maintained in an EHR by or on behalf of the Discloser, from a health care provider or health plan Requester-Recipient that is clear, conspicuous, and specific (*e.g.,* clearly identifies the Requester-Recipient, the scope of the requested PHI and where to transmit it), would be required to transmit the requested electronic copy to the Requester-Recipient, consistent with obligations under the access right to direct a copy of PHI to a third party. The Department reconfirms the clarification provided in the preamble to the 2000 Privacy Rule and OCR's 2016 Access Guidance that a covered entity may accept an electronic copy of a signed request by the individual or personal representative (*e.g.,* PDF), as well as an electronically executed request (*e.g.,* via a secure web portal or using secure, standards-based API technology) that includes an electronic signature of the individual or personal representative.[252]

These proposed changes would empower individuals' ability to direct the transmission of PHI in an EHR through a health care provider or health plan. The costs for implementing these changes generally would be one-time expenditures for updating policies and

indicator/health-spending-per-capita/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (*citing CMS,* National Health Care Expenditure Data, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsStateHealthAccountsResidence.html.*

[250] California, Colorado, Hawaii, Louisiana, Montana, Tennessee, Texas, and Wyoming (New York's shorter time limit is published as agency guidance).

[251] ONC has finalized significant updates to its certification criteria at 45 CFR parts 170 and 171. *See* 85 FR 25642 (May 1, 2020).

[252] *See* 65 FR 82462, 82660 (December 28, 2000) (''We intend email and electronic documents to qualify as written documents. Electronic signatures are sufficient, provided they meet standards to be adopted under HIPAA. In addition, we do not intend to interfere with the application of the Electronic Signature in Global and National Commerce Act.''); *see also* OCR's 2016 Access Guidance, available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html#newlyreleasedfaqs.*

procedures to ensure compliance with the proposed requirement to submit requests for individuals to health care providers within 15 calendar days of receipt of the request from the individual as would be required under the proposed changes. The Department anticipates that some covered entities are already relying on the individual right to direct the transmission of copies to a third party [253] as a means of obtaining electronic copies of PHI in an EHR [254] and are facilitating individuals' access rights by transmitting requests within 15 calendar days in compliance with applicable state laws, so these changes would create certainty without significantly increasing burdens for these covered entities. Additionally, despite problems that are addressed by this proposal, many covered entities that receive requests from another covered entity for copies of PHI are fulfilling such requests, so no additional burden would be created for these disclosing entities when the electronic copy requested by the individual is submitted by and transmitted to their current health care provider or health plan.

vi. Adjusting Permitted Fees for Access to PHI and ePHI

Based on enforcement experience and comments received on the 2018 RFI, the Department is aware that individual access is at times expensive for individuals. At the same time, some large organizations have complained about the time and cost needed to respond to multiple, voluminous requests to provide PHI to third parties under the individual access right and reported struggling to meet the time limitations for such requests while also fulfilling requests for access received directly from individuals and provider-to-provider requests for PHI for continuity of care purposes. Additionally, commenters explained that requests to send medical records to a third party often ask for production of non-electronic copies, even when the PHI is in an EHR and could be provided electronically.

To address these multiple concerns and the *Ciox* v. *Azar* court ruling,[255] the Department proposes to modify the access fee provisions to create separate fee structures for individual requests for access and requests to direct electronic copies of PHI in an EHR to a third party. Each fee structure would contain two elements based on the type of access request: One element describing when access is to be provided without charge and another element describing the allowable costs for certain types of access, as follows.

For individual requests for access and copies of PHI:

(1) Under proposed 45 CFR 524(c)(4)(ii), always free of charge (*i.e.,* no fee permitted) when:

(a) An individual inspects PHI about the individual in person, including capturing images or video recordings of PHI in a designated record set with the individual's own device.

(b) An individual uses an internet-based method to view or obtain a copy of electronic PHI maintained by or on behalf of the covered entity.

(2) Under proposed 45 CFR 164.524(c)(4)(i), fee permitted, subject to the existing access right fee limits, when an individual requests electronic or non-electronic copies of PHI through a means other than an internet-based method.

For requests to direct an electronic copy of PHI in an EHR to a third party:

Under proposed 45 CFR 164.524(d)(6), a reasonable, cost-based fee for an access request to direct a covered health care provider to transmit an electronic copy of PHI in an EHR to a third party through other than an internet-based method, provided that the fee includes only the cost of:

(a) Labor for copying the PHI requested by the individual in electronic form; and

(b) Preparing an explanation or summary of the electronic PHI, if agreed to by the individual as provided in paragraph (d)(4).

The Department proposes the two types of no-charge access (for inspecting PHI in person or internet-based access, including directing electronic copies of EHRs to third parties) because there are no additional allowable labor costs or expenses for this type of access. The Department does not anticipate additional costs from adding this regulatory requirement because the current rule has no provision for fees for inspecting PHI and the proposal is based on the 2016 Access Guidance, which the Department understands many entities had been voluntarily following.

The proposal to limit the allowable costs for requests to direct PHI to third parties to only electronic copies of PHI in EHRs to the labor for making the electronic copies would increase covered entities' and business associates' costs for electronic media, labor for mailing and shipping, and actual postage and shipping. However, the concurrent proposal to narrow the right of individuals to direct only electronic copies of PHI in an EHR to third parties would allow covered entities and business associates to recoup additional costs for handling many requests, while maintaining the Privacy Rule's prohibitions on the sale of PHI [256] and preserving individuals' privacy regarding the purpose of their requests. As discussed in more detail later in this regulatory impact analysis, the Department estimates that the increased costs that covered entities and business associates could include in fees for sending non-electronic copies of PHI or electronic copies of PHI not in an EHR to third parties will exceed the cost items for which they will no longer be allowed to include in fees for requests to direct electronic copies of PHI in an EHR to third parties. Under these proposed changes, a covered entity could charge for reviewing a request to send non-electronic copies of PHI and electronic copies of PHI in an EHR, searching and retrieving, and segregating or otherwise preparing the PHI that is responsive to the request at higher rates than the Privacy Rule currently allows for access requests, when requests for copies are made with a valid authorization. However, by narrowing the scope of access requests to direct PHI to third parties to only electronic copies in an EHR, the Department does not intend to allow covered entities to engage in what would otherwise be considered a sale of PHI.[257] Thus, the permitted fees under 45 CFR 164.502 and 164.508—a reasonable, cost-based fee for preparing and transmitting PHI or a fee otherwise expressly permitted by other law—would apply to many requests that previously would have been made

[253] See 45 CFR 164.524(c)(ii).

[254] 45 CFR 164.524(c)(3)(ii) requires the covered entity holding the PHI to disclose it to the person designated by the individual. Thus, a health care provider seeking an individual's PHI may find it expedient at times to rely on this provision and be designated as the third party recipient rather than use the treatment disclosure permission under 45 CFR 164.502 and 164.506, which do not require a covered entity to respond to a request.

[255] No. 18–cv–0040 (D.D.C. January 23, 2020).

[256] The Privacy Rule prohibits the sale of PHI, which is defined generally as a disclosure where the covered entity or business associate directly or indirectly receives remuneration from or on behalf of the recipient of the PHI in exchange for the PHI. However, a sale does not include a disclosure for a purpose permitted by and in accordance with the Privacy Rule, ''where the only remuneration received by the covered entity or business associate is a reasonable, cost-based fee to cover the cost to prepare and transmit the PHI for such purpose or a fee otherwise expressly permitted by other law. *See* 45 CFR 164.502(a)(5)(ii). Further, the sale of PHI does not include providing access to the individual under 164.524, but it may include providing copies to a third party based on an authorization at a rate that is above a reasonable, cost-based fee. In that circumstance, the authorization must include a statement that the disclosure will result in remuneration to the covered entity.

[257] *See* 45 CFR 164.502(a)(5)(ii)(B)(2)(viii).

under the right of access to direct copies to a third party. This combination of proposed changes would likely result in a transfer of some costs from covered entities to individuals and third-party recipients. This cost transfer would include requests to direct non-electronic copies of PHI in an EHR to third parties and would also include requests to direct electronic copies of PHI not in an EHR that previously would have been made as part of the right of access, and that could be provided based on a valid authorization under the proposed rule.

vii. Notice of Access and Authorization Fees

Individuals report some barriers to accessing PHI due to surprisingly high bills for requested copies. To increase an individual's awareness of the cost of access and of sending copies to third parties and to enhance the ability for an individual to plan for such expenses, the Department proposes to expressly require in regulation that covered entities provide advance notice of approximate fees for copies of requested PHI by: (i) Posting a fee schedule online for all readily producible electronic and non-electronic forms and formats for copies if the covered entity has a website; (ii) providing the notice of fees to individuals upon request; and (iii) providing an individualized estimate of access and authorization fees upon request. The Department expects that this advance notice of fees requirement would provide certainty and improve access to PHI and payment for copies of PHI, to the benefit of individuals and covered entities. The Department also believes that many entities already provide such notice of fees, and thus the requirement to post the fee schedule should create only minimal additional expense beyond revising the fee schedule itself.

viii. Technical Amendment to Required Disclosures by Business Associates

The Department proposes a technical amendment to clarify in 45 CFR 164.502(a)(4)(ii) that a business associate is required to disclose PHI to the covered entity so the covered entity can meet its access obligations, but if the business associate agreement provides that the business associate will provide access directly to the individual or the individual's designee, the Privacy Rule requires the business associate to do so. The proposed change would expressly insert a reference to the business associate agreement as the factor triggering required disclosures by the business associate to the individual or the individual's designee instead of to or through the covered entity.

b. Reduce Identity Verification Burden for Individuals Exercising the Right of Access

Some covered entities impose seemingly unreasonable verification requirements on individuals seeking to obtain their PHI pursuant to the individual right of access. Examples include requiring individuals to request their PHI in person, or even to go through the process (and potential added expense) of obtaining a notarization on a written request, to exercise their right of access.

To address these barriers to an individual's access to their health information, the Department proposes to modify 45 CFR 164.514(h)(1) to expressly prohibit a covered entity from imposing unreasonable identity verification measures on an individual requesting PHI pursuant to the individual right of access. In addition, the Department would clarify that unreasonable verification measures include requiring individuals to provide proof of identity in person when a more convenient remote verification measure is practicable for the covered entity, requiring individuals to obtain notarization of access requests, or any other measure that creates a barrier to, or unreasonably delays, an individual's exercise of their rights. The Department also proposes to clarify that a covered entity that implements a requirement for individuals to submit a request for access in writing, pursuant to 45 CFR 164.524(b)(1), would not be permitted to do so in a way that imposes unreasonable burdens on individuals. This proposed change would provide additional clarity regarding the interaction between the individual right of access provisions and the verification provisions of the HIPAA Rules, and ensure that individuals do not have to expend unnecessary effort or expense when other methods are practicable for the covered entity.

While some covered entities would review and update their policies and procedures as a result of these proposals, which would cause them to incur some additional costs, the Department believes that entities would benefit from the regulatory certainty, and most entities would not need to change their policies and procedures because they currently do not impose unreasonable requirements on individuals.

c. Amending the Definition of Health Care Operations To Clarify the Scope of Care Coordination and Case Management

Some covered entities reported that, due to uncertainty about which provisions of the Privacy Rule apply in certain circumstances, they do not request or disclose PHI even when doing so would support care coordination and case management activities that constitute health care operations, which would facilitate the transformation of the health care system to value based care. Some have interpreted the existing definition of health care operations to include only population-based case management and care coordination, which would appear to exclude individual-focused case management and care coordination by health plans. Because health plans do not perform treatment functions under HIPAA, such an interpretation could limit a health plan's ability to perform such individual-level care coordination and case management activities.

The Department proposes to modify the definition of health care operations [258] to provide clarity to covered health care providers and health plans that ''health care operations'' includes not only population-based care coordination and case management, but also individual-focused care coordination and case management activities—and thereby facilitate those beneficial activities.

d. Creating an Exception to the Minimum Necessary Standard for Certain Disclosures for Care Coordination and Case Management

Uncertainty about how to apply the minimum necessary standard creates fears of HIPAA enforcement action among covered entities that could inhibit information sharing, and may result in less efficient and effective care. Because entities that qualify only as health plans do not perform treatment functions, any care coordination or case management activity conducted by such a health plan is a health care operation, subject to the minimum necessary standard. Disclosures by health care providers for treatment, including care coordination and case management, are subject to the minimum necessary standard only when the disclosure is made to a third party that is not a health care provider. Thus, the rule imposes greater restrictions on health plans than on covered providers when conducting care coordination and case management activities related to an individual.

[258] 45 CFR 164.501.

The Department proposes to add an express exception to the minimum necessary standard for disclosures to or requests by a health plan or covered health care provider for individual-level care coordination and case management activities that constitute treatment or health care operations. This proposal would relieve covered entities from the requirement to make determinations about the minimum information necessary (or whether it is reasonable to rely on the requestor's representation that it is the minimum necessary PHI) when the request is from, or the disclosure is made to, a covered health care provider or health plan for individual-level care coordination and case management activities. This proposed exception would apply only to those activities that support individual-level care coordination and case management, and not population-based activities. As the Department described above, commenters on the 2018 RFI, including covered entities, expressed concern about permitting additional disclosures without minimum necessary restrictions. The Department believes drawing a distinction between disclosures for individual-level versus population-based activities is responsive to these concerns, as disclosures for population-based activities lack the same nexus that individual-level activities have to the treatment of specific individuals.

As such, the proposal would enable health plans and covered health care providers to more easily request and disclose PHI for care coordination and case management for individuals. This proposal, in conjunction with the proposed clarification to the definition of health care operations, would result in significant cost savings to covered entities on an ongoing basis as they are relieved of conducting minimum necessary evaluations for care coordination and case management requests and disclosures among covered health care providers and health plans. Health plans and covered health care providers would continue to be responsible for meeting the minimum necessary requirements that apply to the *uses* of PHI for treatment and health care operations purposes [259] and to uses, requests, and disclosures for other purposes, including population-based activities, when applicable.[260]

e. Disclosing PHI to Social Services Agencies and Community Based Organizations To Facilitate Care Coordination and Case Management

Many covered entities that are health care providers make disclosures to social services agencies and community based organizations only after obtaining a valid authorization from the individual, or never disclose PHI to these health-related services—even when it would facilitate the individual's treatment. Some covered entities may not be aware that the Privacy Rule generally permits disclosure to social services agencies and community-based organizations for care coordination and case management.[261] Others may be uncertain about the scope of the permission to disclose or about when they need a business associate agreement with the recipient, and may fear that they will inadvertently violate the HIPAA Rules if they make such disclosures.

The Department therefore proposes to expressly permit covered entities to disclose PHI to social services agencies, community-based organizations, HCBS providers, or similar third parties that provide or coordinate health-related services that are needed for care coordination and case management with respect to an individual. Although such disclosures generally may be permitted as treatment or certain health care operations activities under the Privacy Rule, creating an express permission would provide clarity and assurance to covered entities about their ability to disclose PHI to such third parties for individual-level care coordination and case management. In addition, the premable explains when these third parties are business associates of the disclosing entities, and thus when a business associate agreement is required. This proposed change would facilitate greater wraparound care and targeted services for individuals, leading to better health outcomes. The Department expects that the costs for implementing this proposed change would be limited to changing policies and procedures, to the extent that some covered entities have limited their disclosures to agencies and organizations due to uncertainty about current policies.

f. Disclosing PHI When Needed To Help Individuals Experiencing Substance Use Disorder, Serious Mental Illness, and in Emergency Circumstances

Some covered entities are reluctant to disclose PHI to family members and other caretakers of individuals facing health crises, including individuals experiencing SMI and SUD (including opioid use disorder), for fear of violating the Privacy Rule. To help address this reluctance, the Department proposes to amend the five following provisions of the Privacy Rule to replace ''the exercise of professional judgment'' with a ''good faith belief'' as the standard to permit uses and disclosures in the best interests of the individual: (1) Parent or guardian not the individual's personal representative, (2) Facility directories, (3) Emergency contacts, (4) Emergencies and incapacity, and (5) Verifying requestor's identity. The Department also proposes to apply a presumption of compliance when covered entities make a disclosure based upon a good faith belief that the disclosure is in the best interests of the individual with regard to those five provisions (by adding a new subsection (k) to 45 CFR 164.502), and to replace ''serious and imminent threat'' with ''serious and reasonably foreseeable threat'' in 45 CFR 164.512(j)(1)(i)(A) as the standard under which uses and disclosures needed to prevent or lessen a threat are permitted.

The Department believes modifying the Privacy Rule to further encourage such disclosures would help health care providers, individuals, families, and caregivers assist in treatment and recovery. The Department also believes these proposed modifications would address the specific circumstances where more information disclosure is needed to better coordinate care for individuals experiencing SUD, SMI, and health related emergencies.

The Department anticipates that covered entities would incur costs to implement the changes due to revising policies and procedures and updating workforce member training, covered entities likely would experience (unquantified) cost savings due to improved patient care and harm reduction (*e.g.,* potentially decreasing the need for costly emergency care), and less perceived need to obtain legal review of each disclosure made under the changed provisions.

g. Changing the NPP Requirements

Comments on the 2018 RFI described the requirement for covered entities to make a good faith effort to obtain an individual's signed acknowledgment of receipt of the NPP as unduly

[259] *See* 45 CFR 164.502(b)(1); 164.514(d)(2).

[260] *See* 45 CFR 164.502(b); 164.514(d).

[261] *See* 45 CFR 164.506. *See* OCR FAQ, Does HIPAA permit health care providers to share PHI about an individual with mental illness with a third party that is not a health care provider for continuity of care purposes? Available at *https://www.hhs.gov/hipaa/for-professionals/faq/3008/does-hipaa-permit-health-care-providers-share-phi-individual-mental-illness-third-party-not-health-care-provider-continuity-care-purposes/index.html.*

burdensome and confusing to patients and health care workers, to the extent that, at times, it causes a barrier to treatment.

The Department proposes to eliminate the requirements for a covered health care provider to obtain a written acknowledgment of receipt of the NPP (and to retain such documentation for six years) and to replace them with an individual right to discuss the NPP with a person designated by the covered entity. In addition, the Department proposes to modify the content requirements of the NPP to specify to individuals that the notice provides information about: (1) How to access their health information, (2) how to file a HIPAA Privacy Rule complaint, and (3) individuals' right to receive a copy of the notice and ability to discuss its contents with a designated person. The required header also would specify whether the designated contact person is available onsite and must include a phone number and email address by which to reach the designated person. Further, the Department proposes to modify the required element of NPPs to describe how an individual can exercise the right of access to obtain a copy of their records at limited cost or, in some cases, free of charge, and to direct a covered health care provider to transmit an electronic copy of PHI in an electronic health record to a third party. Finally, the Department proposes to add an optional element to the NPP to inform individuals of alternatives for obtaining or requesting to send copies of PHI to a third party when the individuals seek to send PHI to a third party in a manner that does not fall within the access right.

To implement these proposed changes, covered entities would incur one-time costs for revising policies and procedures and training, as well as for updating the NPP. However, by replacing the acknowledgment process for all new patient encounters with a right to discuss the NPP, upon request, covered health care providers would experience ongoing costs savings from reduced paperwork burdens and the (likely small) proportion of individuals who contact the designated person would benefit from having meaningful discussions about an entity's privacy practices.

h. Permitting Disclosures for Telecommunications Relay Service (TRS)

Stakeholders have requested that the Department ensure that covered entities and business associates are able to disclose PHI to TRS communication assistants for individuals and workforce members, and to specifically address the use of TRS by covered entity and business associate workforce members to share PHI with other workforce members or outside parties as needed to perform their duties. These stakeholders have shared anecdotal accounts in which a covered entity or business associate refuses to allow a workforce member to use this essential service because of concerns about violating the Privacy Rule if they do not have a business associate agreement with the TRS provider.

The Department proposes in 45 CFR 164.512(m) to expressly permit covered entities (and their business associates, acting on the covered entities' behalf) to disclose PHI to TRS communications assistants to conduct covered functions.[262] This permission would cover all disclosures to TRS communications assistants, including communications necessary for care coordination and case management, relating to any covered functions performed by or on behalf of covered entities. The Department also proposes to add a new subsection (v) to 45 CFR 160.103(4) to expressly exclude TRS providers from the definition of business associate. This proposal would ensure that covered entities and business associates do not bear the burdens of analyzing whether they need business associate agreements with TRS providers (which provide services to the public, not covered entities and business associates) and, potentially, establishing such agreements, resulting in a cost savings for entities with workforce members who need TRS.

i. Expanding the Permission To Use and Disclose the PHI of Armed Forces Personnel To Cover all Uniformed Services Personnel

The existing rule limits the ability of the USPHS and NOAA Commissioned Corps to facilitate care coordination and case management for Corps personnel, because the Armed Forces permission to use and disclose PHI—which is important for ensuring that personnel meet medical readiness standards, and thus for fulfilling the Commissioned Corps' missions—does not apply to the USPHS and NOAA Commissioned Corps. The permission is important because personnel and the broader population are put at risk when personnel do not disclose medical conditions to Commissioned Corps leaders and are deployed on a Commissioned Corps mission, which often involve emergency situations or austere circumstances.

To improve care coordination and case management for individuals serving in the Uniformed Services, the Department proposes to expand to all Uniformed Services the Armed Services express permission for covered entities to use and disclose PHI, thus permitting USPHS and NOAA Commissioned Corps to use and disclose the PHI of such personnel for mission requirements and veteran eligibility.[263] The Department anticipates that the costs for covered entities to revise their policies and procedures to include such personnel would be minimal, as the proposed changes would merely extend existing permissions and the expanded disclosure permission would relieve covered entities of the need to obtain an individual's valid authorization.

3. Cost-Benefit Analysis

a. Overview and Methodology

For purposes of this RIA, the proposed rule adopts the list of covered entities and costs assumptions identified in the Department's 2019 Information Collection Request (ICR).[264] The Department also relies on certain estimates and assumptions from the 1999 proposed Privacy Rule [265] that remain relevant, and the 2013 Omnibus Rule,[266] as referenced in the analysis that follows.

In addition, the Department quantitatively analyzes and monetizes the impact that this proposed rule may have on covered entities' actions to re-train their employees on, and adopt policies and procedures to implement, the legal requirements of this proposed rule. The Department analyzes the remaining benefits and burdens qualitatively because of the uncertainty inherent in predicting other concrete actions that such a diverse scope of covered entities might take in response to this proposed rule. The Department requests comment on the estimates, assumptions and analyses contained herein—and any relevant information or data that would inform a quantitative analysis of proposed reforms that the Department qualitatively addresses in this RIA.

For reasons explained more fully below, the proposed changes to the right of access, acknowledgment of the NPP, and several use and disclosure permissions would result in net

[262] The terms ''Telecommunications Relay Service'' and ''Telecommunications Relay Service Communications Assistant'' have the same meaning used in 47 CFR part 64.

[263] 45 CFR 512(k), Standard: Uses and disclosures for specialized government functions.

[264] 84 FR 34905 (July 19, 2019).

[265] 64 FR 59918 (November 3, 1999).

[266] 78 FR 5566 (January 25, 2013).

economic cost savings of approximately $3.2 billion over five years based on the proposed changes.

TABLE 2—ACCOUNTING TABLE OF ESTIMATED BENEFITS AND COSTS OF ALL PROPOSED CHANGES, IN MILLIONS

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Costs:						
Undiscounted	$996	$55	$55	$55	$55	$1,218
3% Discount	834	45	44	43	41	1,007
7% Discount	664	35	32	30	28	789
Cost Savings:						
Undiscounted	880	880	880	880	880	4,400
3% Discount	737	716	695	675	655	3,477
7% Discount	586	548	512	479	447	2,573
Net (undiscounted)						Savings $3,182

Non-quantified benefits and costs are described below.

b. Baseline Assumptions

The Department based its assumptions for calculating estimated costs and benefits on a number of publicly available datasets, including data from the U.S. Census, the U.S. Department of Labor, Bureau of Labor Statistics (BLM), CMS, and the Agency for Healthcare Research and Quality (AHRQ). All calculations using mean hourly wages include benefits and overhead by multiplying the mean hourly pay for an occupation by two.[267] The Department relies on the annual number of U.S. health care encounters as reported by the AHRQ, 2.46 billion, for some of its calculated estimates.[268]

TABLE 3—ANNUAL U.S. HEALTH CARE ENCOUNTERS

Type of encounters	Number of health care visits or days in residence
Physician office visits	923 million.
Hospital outpatient	803 million.
Nursing home days	500 million.
Hospice days in residence.	120 million.
Home health visits	117 million.
Total Annual	2,463 million or 2.46 billion.

Implementing the proposed regulatory changes likely would require covered entities to engage workforce members or consultants for certain activities. The Department assumes that a lawyer would draft or review needed changes to HIPAA policies, including revisions to the NPP and the access fee schedule, and that a medical and health services manager (*e.g.,* compliance manager) would develop related changes to procedures. The Department expects a training specialist would revise the needed HIPAA training and a web developer would post the online access fee schedule and updated Notice of Privacy Practices. The Department further anticipates that a medical records technician or another workforce member at that pay level would implement changes to the right of access, that a nurse or health professional at a similar pay level would disclose PHI to a patient's family, friends, or others in a position to prevent harm, that a medical assistant would submit requests for PHI to health care providers and health plans, and that a receptionist would implement changes to the disclosure of directory information. To the extent that these assumptions would impact the Department's estimate of costs, the Department welcomes comment on its assumptions, particularly those in which the Department identifies the level of workforce member (*i.e.,* clerical staff, professional) that would be engaged in activities, and the amount of time that particular types of workforce members spend conducting activities related to this NPRM as further described below.

TABLE 4—OCCUPATIONAL PAY RATES [a]

Occupation code and title	Benefit loaded hourly labor wage [b]
23–1011 Lawyer	$139.72
11–9111 Medical and Health Services Manager	110.74
29–2098 Medical Records Technician	44.80
31–9092 Medical Assistant	34.34
13–1151 Training and Development Specialist	63.12
29–1141 Registered Nurse	74.48
43–4171 Receptionist and Information Clerk	30.04
15–1134 Web Developer and Digital Interface Designer	79.20

[a] Bureau of Labor Statistics (BLS), U.S. Department of Labor, "Occupational Employment and Wages," May 2019, available at *https://www.bls.gov/oes/current/oes_stru.htm.*

[b] To incorporate employee benefits, these figures represent a doubling of the BLS median hourly wage.

[267] This represents an increase of 50 percent from the Department's prior HIPAA Rules analyses.

[268] 2017 "National Healthcare Quality and Disparities Report," Agency for Healthcare Research and Quality (September 2018). AHRQ Pub. No. 18–0033–EF, available at *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr17/index.html.*

The Department assumes that the vast majority of covered entities would be able to incorporate changes to their workforce training into existing HIPAA training programs because the total time frame for compliance from date of finalization would be 240 days, just short of a year. In addition, the Department has included additional time spent in training by medical records technicians to the calculation of burden hours, due to the number of proposed changes to the right of access for which they would be responsible.

For a number of proposals where the Department is incorporating existing interpretive guidance into regulation, the Department assumes that a portion of covered entities are already voluntarily engaging in the best practices highlighted in OCR guidance. For example, the Department is aware that 35 percent of hospitals in one study had posted an access fee schedule online,[269] and assumes that many entities are voluntarily providing individuals with an estimate of access fees, consistent with its widely publicized guidance,[270] although not necessarily doing so in writing. Even for entities that are not providing advance fee estimates, the Department assumes that they are providing some type of billing statement when charging fees for access requests, which would necessitate having a fee structure.

With respect to cost savings, the Department proposes to recognize a previously unquantified burden associated with covered entities making minimum necessary determinations. The Department assumes that this burden, associated with time spent by workforce member equivalent to a Medical and Health Services Manager, would necessarily be reduced by alleviating the need to make the determination for disclosures for care coordination or case management on behalf of an individual. For cost savings associated with the proposal to remove the requirement that covered entities obtain a signed acknowledgement of the covered entity's NPP or document a good faith effort to do so, the Department assumes that time spent by clerical staff for a direct treatment provider, such as a Receptionist or Information Clerk, will vary widely depending on the practice of that provider in managing its own NPP process and whether the process is paper-based or electronic. For all of the proposed regulatory changes that covered entities are currently allowed to implement, consistent with its interpretive guidance, the Department seeks comment on the extent to which covered entities are already voluntarily implementing the proposed requirements, and thus would not incur additional costs or realize savings as a result of the proposed changes.

c. Covered Entities

This proposed rule would apply to HIPAA covered entities (*i.e.,* health care providers that conduct covered electronic transactions, health plans, and in certain circumstances, health care clearinghouses [271]), which the Department estimates to be 774,331 business establishments (see Table 5). By calculating costs for establishments, rather than firms (which may be an umbrella organization over multiple establishments), there is some tendency toward overestimating some burdens, because certain costs would be borne by a parent organization rather than each separate facility. Similarly, benefits and transfers would be overestimated, as entity assumptions flow through to those quantifications as well. However, decisions about what level of an organization is responsible for implementing certain requirements likely vary across the health care industry. The Department requests data on the extent to which certain burdens are borne by each facility versus an umbrella organization.

The Department expects that covered health care providers and health plans would be most directly affected by the proposed rule. While certain proposed changes would affect some providers and plans differently than others, all affected covered entities would need to adopt or change some policies and procedures and re-train some employees. Affected health care providers would include many federal, state, local, tribal, and private sector providers. The Department has not separately calculated the effect on business associates because the primary effect is on the covered entities for which they provide services. To the extent that covered entities engage business associates to perform activities under the proposed rule, the Department assumes that any additional costs will be borne by the covered entities through their contractual agreements with business associates. The Department requests data on the number of business associates (which may include health care clearinghouses acting in their role as business associates of other covered entities) that would be affected by the proposed rule and the extent to which they may experience costs or other burdens not already accounted for in the estimates of covered entity burdens.

According to Census data, there are 880 Direct Health and Medical Insurance Carrier firms compared to 5,350 Insurance Carrier firms, such that health and medical insurance firms make up 16.4% of insurance firms. Also, according to Census data, there are 2,773 Third Party Administration of Insurance and Pension Funds firms. The Department assumes that 16.4% of these firms service health and medical insurance. As a result, the Department estimates that 456 of these firms are affected by this proposed rule. Similarly, the Department estimates that 783 associated establishments would be affected by this proposed rule. See Table 5 below.

There were 67,753 community pharmacies (including 19,500 pharmacy and drug store firms identified in US Census data) operating in the U.S. in 2015.[272] Small pharmacies largely use pharmacy services administration organizations (PSAOs) to provide administrative services, such as negotiations, on their behalf.[273] A 2013 study identified 22 PSAOs, and notes there may be more in operation.[274] Based on information received from industry, the Department adjusts this number upward and estimates that the proposed rule would affect 40 PSAOs. The Department assumes that costs affecting pharmacies are incurred at each pharmacy and drug store firm and each PSAO.

Unless otherwise indicated, the Department relies on data about the number of businesses from the U.S.

[269] See Lye CT, Forman HP, Gao R, et al. ''Assessment of US Hospital Compliance With Regulations for Patients' Requests for Medical Records.'' JAMA Netw Open. 2018;1(6):e183014, available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2705850.*

[270] *See* 2016 Access Guidance, available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.*

[271] Only certain provisions of the Privacy Rule apply to clearinghouses as covered entities. In addition, certain provisions apply to clearinghouses in their role as business associates of other covered entities. *See* 45 CFR 164.500(b) and (c). Because the provisions addressed in this proposed rule generally do not apply directly to clearinghouses, the Department does not anticipate that these entities would experience costs associated with this proposed rule.

[272] *See* Qato, Dima Mazen; Zenk, Shannon; Wilder, Jocelyn; Harrington, Rachel; Gaskin, Darrell; Alexander, G. Caleb (2017). ''The availability of pharmacies in the United States: 2007–2015.'' *PLOS ONE. 12 (8): e0183172,* available at *https://doi.org/10.1371/journal.pone.0183172.*

[273] Government Accountability Office, GAO–13–176, (January 29, 2013), discussing generally that small and independent pharmacies often lack internal resources to support these services, available at *https://www.gao.gov/products/GAO–13–176.*

[274] *Ibid.*

Census.[275] The Department requests public comment on these estimates, including those for third party administrators and pharmacies where the Department has provided additional explanation. The Department additionally requests detailed comment on any situations in which covered entities other than those identified here would be impacted by this rulemaking.

TABLE 5—COVERED ENTITIES

NAICS code	Type of entity	Firms	Establishments
524114	Health and Medical Insurance Carriers	880	5,379
524292	Third Party Administrators	456	783
622	Hospitals	3,293	7,012
44611	Pharmacies	19,540	67,753
6211–6213	Office of Drs. & Other Professionals	433,267	505,863
6215	Medical Diagnostic & Imaging	7,863	17,265
6214	Outpatient Care	16,896	39,387
6219	Other Ambulatory Care	6,623	10,059
623	Skilled Nursing & Residential Facilities	38,455	86,653
6216	Home Health Agencies	21,829	30,980
532291	Home Health Equipment Rental	611	3,197
Total		549,713	774,331

d. Individuals Affected

The Department believes that, by having some contact with a HIPAA covered entity, a large proportion of the 329 million individuals in the United States [276] would be affected by this proposed rule, including those who do not have health insurance coverage or do not have a health care visit in the current year. The widespread effect on individuals would be due primarily to the proposed changes to the right of access, affecting the speed of access, the ability to easily direct the transmission of ePHI in an EHR to health plans and health care providers, notice of access and authorization fees, and the access and authorization fees that could be charged, as well as changes to covered entities' ability to disclose PHI to an individual's family, friends, and others who are involved in care or payment for care, or who are in a position to prevent harm, and disclosures for care coordination and case management to third parties such as social services agencies, community-based support organizations, and HCBS providers. Eliminating the requirement for a covered health care provider to attempt to obtain a signed acknowledgment of the NPP, and replacing it with the individual right to discuss a covered entity's NPP, will affect nearly all individuals who receive services from a health care provider.

To calculate the potential monetary effect on individuals for the proposed changes to allowable fees for certain copies of PHI, the Department first estimated a baseline average cost for an access request under the current Privacy Rule requirements. The Department increased the estimated average time for providing a copy of PHI requested from 3 minutes in its prior analyses to 5 minutes, resulting in an average labor cost of $3.73 per request.[277] The Department requests data on costs from covered entities' data and comments on individuals' experiences when charged a fee for copies of PHI or when it is provided for free. The Department has heard that many individuals are able to obtain a copy of their PHI without charge, but in contrast, others receive unexpectedly large bills for obtaining copies, possibly in violation of the HIPAA right of access fee limitations.[278]

The Department believes the persons most affected by the proposed changes to the rule permitting certain disclosures based on ''good faith'' would include individuals who are unable to agree or object to the use or disclosure of PHI due to incapacity or who are at risk of harming themselves or others and loved ones and caregivers of such individuals. This would include those experiencing a health emergency, SUD, or SMI; and individuals to whom permissible disclosures would be made as a result of the rule, such as family members and other caregivers, and persons in a position to prevent or lessen (*e.g.,* make less likely or less severe) a threat to health or safety. The proposed changes also would include individuals experiencing temporary incapacity due to injuries or health conditions, and those with long-term incapacity, such as from Alzheimer's disease or, in some cases, traumatic brain injury or stroke.

The individuals most affected by the proposal to add a regulatory permission for workforce members to disclose PHI to a TRS communications assistant, would be the estimated 170,000 persons employed in the health care sector who are deaf, hard of hearing, deaf-blind, or who have a speech disability.[279]

e. Qualitative Analysis of Non-quantified Benefits

Clarity Regarding the Scope of EHRs and Personal Health Applications

The Department proposes to add a new definition within the Privacy Rule at 45 CFR 164.501 for the term ''Electronic health record'' or EHR to clarify the intended scope of the Privacy Rule provisions pertaining to ePHI in an EHR. Additionally, the Department proposes to add a new definition for the

[275] *See* ''2015 Statistics of U.S. Businesses (SUSB) Annual Data Tables by Establishment Industry,'' (January 2018), available at *https://www.census.gov/data/tables/2015/econ/susb/2015-susb-annual.html.*

[276] U.S. Census Population Clock, available at *https://www.census.gov/popclock/.*

[277] Based on 5 minutes of a medical records technician's hourly wage, as noted in Table 4.

[278] A recent study found access fees for a 200-page record to range from $0 to $281.54. Lye CT, Forman HP, Gao R, et al. ''Assessment of US Hospital Compliance With Regulations for Patients' Requests for Medical Records.'' *JAMA Netw Open.* 2018:1(6):e183014. *See also* GAO–18–386, ''MEDICAL RECORDS Fees and Challenges Associated with Patients' Access,'' GAO Report to Congress (May 2018), *available at https://www.gao.gov/assets/700/691737.pdf. See also* 2016 Access Guidance, available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.*

[279] *See* ''Task Force on Health Care Careers for the Deaf and Hard-of-Hearing Community, Final Report'' (March 2012), p. 14, 79 (Table 4), available at *https://www.rit.edu/ntid/healthcare/task-force-report; see also* Moreland CJ, *et al.,*'' Deafness among physicians and trainees: a national survey.'' Acad. Med. 2013 Feb; 88(2):224–32, available at *https://journals.lww.com/academicmedicine/Fulltext/2013/02000/Deafness_Among_Physicians_and_TraineesA.27.aspx.*

term ''Personal health application'' to clarify the intended scope of the proposed changes to the right of access, including the form and format requirements and adjustments to allowable access fees. These definitions would benefit covered entities and individuals by increasing the understanding of how to apply the proposed changes to the right of access for PHI in an EHR, including allowable fees (if any).

Improved Access to Inspect PHI

The Department proposes to add a new subsection to amend the right of access provision at 45 CFR 164.524(a)(1) to establish that the right to inspect PHI generally includes the right to take notes, take photographs, and use other personal resources to capture their PHI in a designated record set, but that a covered entity is not required to allow an individual to connect a personal device to the covered entity's information systems when it would create a risk to the security of the covered entity's electronic systems. Expressly enabling individuals to take notes and photographs when inspecting their own PHI in person would help individuals exercise their right of access in a convenient way. Most individuals who inspect, rather than request a copy, of their PHI otherwise would be unable to retain the amount or details of PHI that would assist them with decision-making.

Reducing the Timeframe for Access to PHI (From 30 Days to 15 Calendar Days)

The Department proposes to amend 45 CFR 164.524(b) to shorten the allowable time limit for covered entities to provide copies of PHI by half, from 30 days (with the possibility of one 30-day extension) to 15 calendar days (with the possibility of one 15 calendar-day extension). In addition, where other federal or state law time limit requires covered entities to provide individuals with access to the PHI requested in less than 15 calendar days, the Department proposes to deem such time limits ''practicable'' under the Privacy Rule. The Department also proposes to add a requirement for covered entities to develop and implement a policy to explicitly prioritize urgent or otherwise high priority requests (especially with respect to health and safety) so as to limit the need to use a 15 calendar day extension for such requests. The Department does not propose to define what constitutes an urgent or high priority request, and does not intend with this proposal to encourage covered entities to require individuals to reveal the purposes for their requests for access. However, examples of urgent or high priority requests could include when an individual voluntarily reveals that the PHI is needed in preparation for urgent medical treatment, or that the individual needs documentation of a diagnosis of severe asthma to be allowed to bring medication to school the next day.

The proposal to shorten the time for covered entities to provide individuals with access to their PHI would improve patient-centered care by empowering individuals to review their health information in a timely manner and enhance patient decision making. It also would improve care coordination by enabling individuals to share their records more rapidly with other providers, informal caregivers, community based support services, and family members, as just a few examples. The Department believes that the overall effect would lead to improved health care communications and improved health outcomes. It also may reduce health expenditures due to a reduction in unnecessary, duplicative medical testing, reductions in medical errors, and more timely care delivery. For example, a research study found that the use of health information is ''important for improving patient attitudes regarding their health status and confidence in caring for themselves. Perceived health-status and patient confidence, in turn, are associated with preventative health behaviors.'' [280]

Although nine states require some health care entities to provide access within 15 days or a lesser period,[281] these requirements do not apply to all entities within such states. Therefore, the proposed shortened time requirement within HIPAA would expand the benefits of the short time limits to individuals interacting with all covered entities, even in states that already require it for certain health care providers.

Improving Production of Required Formats of PHI

The Department proposes to modify 45 CFR 164.524(c)(2) to clarify that where a covered entity is subject to other federal law that requires the provision of access to individuals in a particular form and format, such form and format is deemed readily producible under the Privacy Rule's individual access right. To the extent that other applicable federal laws require production of copies of PHI in a certain form and format, the proposed inclusion of these finalized requirements within the Privacy Rule would not significantly increase covered entities' compliance burdens. However, by providing that a form and format required to be produced under other federal law are readily producible under the Privacy Rule, the change would allow the Department to enforce the individual's right to receive their PHI in that form and format. Although quantifying the impacts of this provision is challenging, the Department believes the proposed clarification would benefit individuals by enhancing their ability to receive PHI in the form and format requested. It also would benefit covered entities by providing greater certainty about the Department's expectations regarding when a requested form and format is ''readily producible.''

The Department also proposes in 45 CFR 164.524(c)(2(iv) and (d)(4) to add a new set of parallel requirements so that when covered entities offer to provide or direct a summary of PHI in lieu of requested copies, they must inform individuals that they retain the right to obtain or direct the requested copies if they do not agree with the offered summary. These requirements would not apply when the covered entity denies access on unreviewable or reviewable grounds, in which case the covered entity must implement the required procedures for such denial under 45 CFR 164.524(e). These requirements would benefit individuals by ensuring that they are aware of their access rights and empowered to make choices about the form of access with full knowledge about the available options under the right of access. The proposals would benefit covered entities by engaging individuals in more robust discussions about requested forms of access early in the process, thus reducing potential complaints and fee disputes.

[280] Hearld, K. R., Hearld, L. R., Budhwani, H., McCaughey, D., Celaya, L. Y., & Hall, A. G. (2019). The future state of patient engagement? Personal health information use, attitudes towards health, and health behavior. *Health services management research, 32*(4), 199–208.

[281] California, Cal. Health & Safety Code 123110 (5 days to inspect; 15 days to receive a copy); Colorado, 6 Colo. Regs. 1011:1:II–5.2 (24 hours to inspect; 10 days to receive a copy); Hawaii, HRS 622.57 (10 days to receive a copy); Louisiana, LSA–R.S. 40:1165.1 (15 days to receive a copy); Montana, MCA 50–16–541(10 days, copy and inspect); Tennessee, TCA 63–2–101 (10 days to receive a copy); Texas, Tex. Health & Safety Code 241.154 (hosp.) (15 days, copy and inspect); Tex. Occupations Code 159.006 (physicians) (15 days to receive a copy), Tex. Health & Safety Code 181.102 (15 days to receive electronic copies), Tex. Admin. Code 165.2 (physicians) (15 days to receive a copy); and Washington, Wash. Rev. Code 70.02.080 (15 days, copy and inspect).

Clarifying the Right to Direct the Transmission of Certain PHI to Health Care Providers and Health Plans

The Department proposes to modify 45 CFR 164.524(c)(3)(ii) (and redesignate it as 45 CFR 164.524(d)) to clarify the access right to direct the transmission of an electronic copy of PHI in an EHR to another person designated by the individual and add a new provision for access requests to be submitted by covered health care providers and health plans at the request of the individual in 45 CFR 164.524(d)(7). The Department proposes to require covered health care providers and health plans to submit individuals' requests directing electronic copies of PHI in an EHR to be transmitted back to the entity that submitted the request. The new provision would specify that a covered health care provider or health plan must submit an individual's request to transmit an electronic copy of PHI in an EHR from another health care provider or health plan when the request is clear, conspicuous, and specific (which may be orally or in writing, including electronically) and that the covered health care provider or health plan must submit the access request as soon as practicable, but no later than 15 calendar days after receiving the individual's direction and information needed to make the request. The Department also proposes to add language clarifying that covered entities that receive access requests under this new provision are required to respond based on an individual's clear, conspicuous, and specific request.

The proposal to expressly include individual access requests submitted by health care providers and health plans as part of the right to direct the transmission of ePHI in an EHR to a third party would improve care coordination and patient-centered care by enhancing the individual's ability to direct the sharing of ePHI among health care entities. The change would improve health care communications and assist individuals' decision-making as they consult with various health care providers and health plans, and evaluate treatment alternatives, recommendations, and health plan coverage. All health care providers and health plans would benefit from receiving electronic records from other covered entities more quickly under the shortened timeframe, and the proposal to explicitly require covered health care providers and health plans to submit requests for copies of ePHI as directed by the individual within the right of access would enhance covered entities' compliance with responding to such requests received from other covered entities because such disclosures would be mandatory. This means of obtaining access also would ease the burden on individuals to separately contact their other providers and request that they transmit electronic records to their treating physician. Instead, the individual may initiate such requests through the provider (or health plan) with whom they are currently communicating or receiving services, and who will receive the ePHI. Taken together, these changes would empower individuals by clarifying the scope of a patient's HIPAA rights and providing a convenient means to effectuate certain mandatory transfers of electronic medical records between covered entities.

Improving Access to PHI by Specifying When Access Must be Free of Charge

The Department proposes to modify 45 CFR 164.524(c)(4) to prohibit covered entities from charging fees for access when an individual inspects PHI about the individual in person or accesses an electronic copy using an internet-based application method. The Department proposes to expressly provide that covered entities may not charge a fee when an individual, in the course of inspecting PHI, takes notes or photographs, or uses other personal resources to capture the information.

All individuals would benefit from improved access to their PHI and regulatory requirements stating the circumstances in which access is always to be provided free of charge. In addition to any quantifiable increases in the number of access requests fulfilled without charge, the Department believes that individuals' abilities to manage their own health care and payment for care would be improved by improving access to their own PHI.

Additionally, although the Department is not expressly prohibiting fees when an individual uses an internet-based method to direct the transmission of an electronic copy of PHI in an EHR to a third party, the Department expects that, in most cases, there will be no allowable labor costs for such access.

Improving Access to Pricing Information for Copies of PHI

The Department proposes to add a new subsection 525 to 45 CFR 164 to require a covered entity to provide advance notice to individuals of the fees the entity charges for providing access to and copies of PHI. Specifically, the Department proposes to require a covered entity to post a fee schedule online (if they have a website) and make the fee schedule available to individuals at the point of service upon request. The notice must include: (i) All types of access to PHI available free of charge; (ii) approximate fees for copies of PHI provided to individuals under 45 CFR 164.524(a), to third parties designated by the individual under 45 CFR 164.524(d), and to third parties with the individual's valid authorization under 45 CFR 164.508; (iii) provide, upon request, an individualized estimate of the approximate fee that may be charged for the requested copy of PHI; and (iv) upon request, provide an individual with an itemized list of charges for labor, supplies, and postage, if applicable, that constitute the total fee charged.

The Department anticipates that all individuals interested in access to PHI would benefit from having advance notice of a covered entity's approximate fee schedule for standard or common data access requests for PHI, by learning about how they may access their PHI for free, and obtaining pricing information for copies prior to or at the time of making an access request or a request for copies with a valid authorization. Readily available public information about access fees would also serve to promote compliance with the Privacy Rule because covered entities will want to avoid posting fee schedules that show noncompliance with fee limitations,[282] or that publicly misrepresent their business practices, and individuals will be empowered to insist on covered entities' compliance as well.

Providing an access and authorization fee schedule, and an individualized estimate of fees for an individual's request for copies of PHI upon request, would also benefit covered entities because this information is likely to prevent or resolve potential fee disputes that occur when individuals are surprised by unexpectedly high fees.

Improved Coordination of Care by Covered Entities, Including for Population-Based Activities

The Department proposes to add an exception to the minimum necessary standard in 45 CFR 164.502(b)(2) for

[282] In addition to the access fees limits contained in 45 CFR 164.524, the Privacy Rule limits the fees that may be charged for uses and disclosures of PHI based on an authorization. Under the Privacy Rule's provisions on the sale of PHI, covered entities generally must limit fees for disclosures pursuant to an authorization to a ''reasonable, cost-based fee to cover the cost to prepare and transmit the protected health information for such purpose or a fee otherwise expressly permitted by other law'' or must state in the authorization that the disclosure will result in remuneration to the covered entity. *See* 45 CFR 164.502(a)(5)(ii)(B)(*2*)(*viii*); 45 CFR 164.502(a)(5)(ii)(A); 45 CFR 164.508(a)(4).

disclosures to, or requests by, a health plan or covered health care provider for individual-level (*i.e.,* not population-based) care coordination and case management that constitute health care operations. The Department first recognized the ongoing annual burden of compliance with the minimum necessary standard in the 2000 Privacy Rule [283] and now quantifies the burden of this existing requirement. The Department believes the proposed exception to the minimum necessary standard, in addition to decreasing quantifiable burdens as described elsewhere, would contribute to non-quantifiable but qualitative improvements in the scale and design of care coordination and case management, and therefore improve health of individuals. Facilitating health plans' involvement in care coordination and case management may prove instrumental in improving individual health outcomes. The proposed change would eliminate some of the differential treatment between health plans' care coordination and case management disclosures under the health care operations provisions and covered health care providers' care coordination and case management under the provisions regarding treatment disclosures (which are not subject to the minimum necessary standard). The proposed change also would address the concerns of both covered health care providers and health plans about having to determine what PHI is or is not the minimum necessary for requests by, and disclosures to, health plans and health care providers, a requirement that may be an ongoing impediment to value-based care delivery and a disincentive to information sharing.

Increased Coordination of Care Between Covered Entities and Third Parties Such as Social Services Agencies, Community-Based Organizations, and HCBS Providers

The Department proposes to add an express permission for a covered entity to disclose PHI for individual-level care coordination and case management to a social services agency, community based organization, HCBS provider, or other similar third party that provides health-related services to those specific individuals, as a new paragraph (6) in 45 CFR 164.506(c). The Department believes the proposed changes and clarifications about the disclosures permitted for care coordination and case management would help covered entities and others achieve their health-related missions, particularly those that are not health care providers or HIPAA covered entities. The Department has continued to hear that health care providers and health plans want to refer individuals to such organizations for health-related supportive services, but are reluctant to do so because of uncertainty regarding the applicable permissions and obligations. The Department interprets the Privacy Rule to allow health care providers to disclose PHI for their own treatment activities to both covered entities and entities that are not subject to HIPAA, which may include supportive services in the community related to health. By expressly identifying social services agencies, community based organizations, and HCBS providers and similar third parties as entities to which PHI may be disclosed for individual-level care coordination and case management that constitute treatment or health care operations, the Department will remove regulatory uncertainty and ease the ability of covered health care providers to facilitate comprehensive transitions of care. The Department believes these proposed clarifications would affect at least 137,052 organizations providing social assistance to individuals.[284] The proposed clarifications to these use and disclosure permissions would enhance the ability of such organizations to receive PHI to improve service coordination and delivery for the individuals served within the scope of their respective missions. These organizations serve many individuals for whom supportive services are essential to regain health and maintain recovery and individuals who lack stable housing or communications capabilities, making the need for immediate referrals (*i.e.,* without needing to obtain an individual's valid authorization) imperative.

Improved Treatment and Recovery Outcomes Resulting From a Good Faith Standard With a Presumption of Compliance

The Department proposes to amend five provisions of the Privacy Rule to replace the exercise of ''professional judgment'' with a ''good faith belief'' as the standard to permit uses and disclosures in the best interests of the individual, and include a presumption of compliance with the good faith requirements. These proposed modifications would apply to uses and disclosures involving a parent or guardian who is not the individual's personal representative (45 CFR 502(g)(3)(ii)(c)), facility directories (45 CFR 164.510(a)(3)(i)(B)), emergency contacts (45 CFR 164.510(b)(2)(iii)), limited uses and disclosures when the individual is not present or incapacitated (45 CFR 164.510(b)(3)), and verifying a Requester-Recipient's identity (45 CFR 164.514(h)(2)(iv)). The proposed presumption of compliance could be overcome with evidence that a covered entity acted in bad faith.

The Department believes that replacing the professional judgment standard with one based on good faith, as proposed, would result in improved treatment and recovery outcomes for individuals who are most affected, for example, by the current opioid crisis, as well as those experiencing SMI or other SUD, by facilitating the increased disclosure of PHI by covered entities to persons who care about the individual and who need to be involved in the individual's care. The Department expects that health care providers who have confidence in their ability to disclose information to individuals' family members, friends, and others involved in care or payment for care when it is in an individual's best interests, without fear of violating HIPAA, would be more likely to disclose PHI that could be used by those persons to provide needed care and support.

The Department does not have data to quantify such benefits, but research supports the conclusion that family involvement improves the engagement in treatment and recovery of these individuals.[285] For example, a study by Dobkin, Civita, Paraherakis, and Gill examined the effect of social support on substance use and treatment retention. They found that ''higher functional social support at intake is a positive predictor of retention in treatment, and a modest predictor of reductions in

[283] *See* 65 FR 82462, 82767, 82773 (December 28, 2000).

[284] *See* ''2015 SUSB Annual Data Tables by Establishment Industry,'' (January 2018), available at *https://www.census.gov/data/tables/2015/econ/susb/2015-susb-annual.html.*

[285] *See* ''Alcohol and Drug Addiction Happens in the Best of Families . . . and it Hurts,'' U.S. Dept. of Health and Human Services, Substance Abuse and Mental Health Services Administration, available at *https://store.samhsa.gov/shin/content//PHD1112/PHD1112.pdf;* ''Incorporating the family in a culturally appropriate fashion within routine clinical settings improves access to treatment, client participation in care, integration of care, and ultimately, clinical outcomes for populations with SMI and SED.'' Interdepartmental Serious Mental Illness Coordinating Committee, ''The Way Forward: Federal Action for a System That Works for All People Living With SMI and SED and Their Families and Caregivers,'' U.S. Dept. of Health and Human Services, Substance Abuse and Mental Health Services Administration, (December 2017), Publication ID PEP17–ISMICC–RTC, available at *https://store.samhsa.gov/system/files/pep17-ismicc-rtc.pdf.*

alcohol intake, but not in drug use.'' [286] Another study examined the effect of social support on women's substance abuse relapse within 6 months following residential treatment and found that ''positive activities such as families getting along and helping each other during the post-discharge period significantly decreased the likelihood of relapse.'' [287] According to the National Institute on Drug Abuse of the National Institutes of Health, the degree of support from family and friends influences the degree of engagement by individuals with treatment and retention in treatment programs.[288] Therefore, the changes to the Privacy Rule proposed in this NPRM may result in improved outcomes in treatment and recovery.

Avoidance of Harm From Serious and Reasonably Foreseeable Threats

The Department proposes to amend the Privacy Rule at 45 CFR 164.512(j)(1)(i)(A) to replace the ''serious and imminent threat'' standard with the ''serious and reasonably foreseeable threat'' standard. This proposed change would permit covered entities to use or disclose PHI without determining whether the threat is imminent (which may be impossible to determine with any certainty), but rather whether it is likely to happen. The Department expects this proposed modification to improve the timeliness of uses and disclosures of PHI that would have otherwise occurred, but for the covered entity's uncertainty about whether a threat is ''imminent.'' The Department believes that individuals, covered entities, and communities would benefit from threat reduction and improved health and safety as a result. The Department also proposes to add a new paragraph (5) to this provision to define ''reasonably foreseeable.'' The Department's proposed definition of ''reasonably foreseeable'' would apply a reasonable person standard to permit uses and disclosures by covered health entities in instances where similarly situated covered entities would use or disclose PHI to avert a threat based on facts and circumstances known at the time of the disclosure. The proposed definition also would include an express presumption that threats to health or safety identified by a covered health care provider with specialized training, expertise, or experience in assessing an individual's risk to health or safety (such as a licensed mental or behavioral health professional)—and whose assessment relates to their specialized training, expertise, or experience—meet the definition of ''reasonably foreseeable.'' A covered entity, however, need not have such specialized training, expertise, or experience in order to meet the reasonably foreseeable standard. The Department expects that these proposed changes to the standard at 45 CFR 164.512(j) would improve communication and coordination between health care providers, caregivers and others in a position to lessen harm and avert threats, including opioid overdose and incidents of mass violence.

Improved Understanding of Covered Entities' Privacy Practices

The Department proposes to add subsection (G) to 45 CFR 164.520(b)(1)(iv), to give individuals the right to discuss the NPP with a person designated by the covered entity as the contact person pursuant to section 164.520(b)(1)(vii). The Department proposes to include information about this right in the header of the NPP to ensure that individuals are aware of their ability to discuss the NPP with a designated person. Requiring that an entity's NPP include the name or title and contact information for a designated person who is available to provide further information about the covered entity's privacy practices, and adding an individual right to discuss the notice with the designated person, would help improve an individual's understanding of the covered entity's privacy practices and the individual's rights with respect to his or her PHI. Even for individuals who do not request a discussion under this proposal, knowledge of the right may promote trust and confidence in how their PHI is handled.

Improved Access to Communications Assistance and Enhanced Service Delivery for Workforce Members Who are Deaf, Hard of Hearing, or Deaf-Blind, or Who Have a Speech Disability

The Department proposes to amend the Privacy Rule at 45 CFR 164.512, by adding a new standard in paragraph (m) to expressly permit covered entities (and their business associates, when acting on the covered entities' behalf) to disclose PHI to Telecommunication Relay Service (TRS) communications assistants when such disclosures are necessary for a covered entity, or a business associate to conduct covered functions. This permission would cover all disclosures to TRS communications assistants, including communications necessary for care coordination and case management, relating to any covered functions performed by or on behalf of covered entities. The Department also proposes to expressly exclude TRS providers from the definition of business associate. The Department intends for these new provisions to ensure that regulated entities do not bear the burdens of analyzing whether they need a business associate agreement with a TRS and, potentially, establishing one before a workforce member discloses PHI to a TRS communications assistant, to assist the workforce member, in the course of performing their duties. Adding an express permission for covered entities' workforce members to share PHI via a TRS communications assistant would improve communications for health care delivery and benefit covered entities by supporting their compliance with employment nondiscrimination laws, such as the ADA. Further, by enhancing the ability of an estimated 170,000 workforce members [289] to perform the necessary communication tasks of their jobs, the proposed change would also have a positive effect on health service delivery generally and improve health care services and payment for such services.

The Department requests comment or examples that could assist the Department in quantifying costs or cost savings in relation to the following:

- Any relationship between individuals' access to medical records and improved health outcomes, including data about any health effects related to the amount of time between a request for access and the provision of access;
- Any relationship between fees individuals pay to obtain medical records and the frequency with which the individual seeks treatment;
- Any relationship between the ease or difficulty faced by covered health care providers and health plans to make minimum necessary determinations and

[286] Dobkin, P. L., Civita, M. D., Paraherakis, A., & Gill, K. (2002). The role of functional social support in treatment retention and outcomes among outpatient adult substance abusers. *Addiction, 97*(3), 347–356.

[287] Ellis, B., Bernichon, T., Yu, P., Roberts, T., & Herrell, J. M. (2004). Effect of social support on substance abuse relapse in a residential treatment setting for women. *Evaluation and Program Planning, 27*(2), 213–221.

[288] *See* Principles of Drug Addiction Treatment: A Research-Based Guide (3rd Edition), ''What helps people stay in treatment?'', U.S. Dept. of Health and Human Services, National Institutes of Health, National Institute on Drug Abuse, (January 2018), available at *https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/frequently-asked-questions/what-helps-people-stay-in-treatment.*

[289] *See* ''Task Force on Health Care Careers for the Deaf and Hard-of-Hearing Community, Final Report,'' available at *https://www.rit.edu/ntid/healthcare/task-force-report.*

health outcomes of individuals or populations;

- Any relationship between the ease or difficulty faced by covered health care providers' and health plans' to disclose PHI based on a professional judgment standard or a good faith belief standard, and the frequency with which an individual will seek care from that provider or enroll with that plan, especially for treatment or coverage related to substance use disorders or serious mental illness.
- The frequency with which different types of covered entities currently disclose PHI based on:
  - Professional judgement about an individual's best interests; and
  - A good faith belief that a threat or harm is serious and imminent, and the type of harm; and
- Any relationship between improved compliance with non-discrimination laws, such as the ADA, and health outcomes of populations protected by those laws.

f. Estimated Cost Savings and Costs Arising From Proposed Changes

The Department provides below the basis for its estimated costs and savings due to the proposed changes to specific provisions of the Privacy Rule and invites comments on the Department's assumptions, data, and calculations, as well as any additional considerations that the Department has not identified here. Many of the estimates are based on assumptions formed through OCR's experience in its compliance and enforcement program and accounts from stakeholders received at outreach events. The Department welcomes information or data points from commenters to further refine its estimates and assumptions.

To evaluate the potential benefit and burden of changes to the right of access, the Department calculated a range of estimated total annual numbers of access requests for covered entities, from 1.5 million to 3.3 million. The Department's initial projections were drawn from prior rulemaking and burden estimates; however, based on its experience and comments received on the 2018 RFI, the Department believes an upward adjustment to the estimated number of access requests is needed. The Department developed the estimates herein based on three datasets: The total number of covered entities; the total number of U.S. health care encounters with a health care provider in a year; and the total population of the U.S. The calculated results are as follows: (1) 1.5 Million, by estimating that 774,331 covered entities receive an average of two access requests per year; (2) 2.46 million, by estimating that in one year one-tenth of a percent of health care encounters [290] with health care providers results in an access request (.001 × 2.46 billion); and (3) 3.3 million, by estimating that one percent of the U.S. population in 2019 makes an access request (.01 × 329,001,648).[291] For purposes of this analysis, the Department selected the mid-point estimate of the number of total annual access requests, 2.46 million.

The Department received widely varying reports from covered entities that commented on the RFI regarding the number of access requests they receive annually and it was unclear whether the numbers included requests that are not part of the right of access, such as disclosures accompanied by a valid authorization, disclosures for purposes of treatment, payment, or health care operations, or other disclosures permitted by the Privacy Rule.[292] In addition, while large covered entities may receive many more than two requests per year, the Department assumes that small doctor's offices, which make up the majority of covered entities, receive very few requests. The Department requests comment on these assumptions.

i. Estimated Cost Savings and Costs From Adding a Definition of EHR

The Department believes that covered entities would benefit from the certainty offered by its interpretation of the proposed definition of EHR; however, the Department lacks sufficient data to develop a quantifiable estimate. The Department does not anticipate additional costs for covered entities from the proposal to codify in regulation a definition of EHR because the definition itself imposes no requirements, the proposed definition is based on the statutory definition in the HITECH Act which has been in effect for more than a decade, and the proposed definition incorporates existing Privacy Rule definitions, such as direct treatment relationship, that are familiar to regulated entities. Costs savings and costs related to limiting the scope of the access right to direct a copy of PHI to a third party to PHI in an EHR are addressed elsewhere.

ii. Estimated Cost Savings From Changes to the Right to Inspect PHI

The Department proposes to add a requirement to the right of access at 45 CFR 164.524 (a)(1) to establish that the right to inspect PHI in a designated record set includes the right to take notes, take photographs, and use other personal resources to capture the information, but that a covered entity is not required to allow an individual to connect a personal device to the covered entity's information systems. The Department assumes that requests to inspect PHI may result in a reduction in requests for covered entities to make copies because individuals may choose to capture the information they need through notetaking, photographing, or other means, and that reviewing the PHI may enable individuals to narrow the scope of any request for copies. This could reduce costs for covered entities; however, the Department lacks sufficient data about the number of inspection requests received by covered entities to make a reasonable estimate of the projected savings. For individuals who prefer to view PHI in person and use their own resources, the proposed changes may offer out-of-pocket cost savings. Individuals who would not want to view their PHI in person would simply not exercise this new right, but would continue to access their PHI as before, thus not incurring any new costs or achieving any new savings. The Department requests data on the number of requests to inspect PHI received by covered entities and the experiences of entities and individuals with how the inspection of PHI affects the number, frequency, or scope of requests for copies.

iii. Costs Arising From Changes to the Right to Inspect PHI

Upon consideration of the instances where PHI is readily available at the point of service, such as when viewing x-rays or lab results, the Department anticipates that there may be a much greater demand by individuals for the ability to use one's own device to capture the images or other PHI as a result of this proposal. The Department anticipates this would result in

[290] *See* 2017 ''National Healthcare Quality and Disparities Report,'' Agency for Healthcare Research and Quality (September 2018). AHRQ Pub. No. 18–0033–EF, available at *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr17/index.html,* reporting 923 million total annual physician office visits, including visits to physicians in health centers, 803 million annual hospital outpatient visits, 117 million annual home health visits, 500 million annual patient days in nursing homes, 213 million annual days in hospitals, and 120 million annual days in hospice.

[291] ''U.S. Census Population Clock,'' available at *https://www.census.gov/popclock/* (visited June 5, 2019). Projections are based on a monthly series of population estimates starting with the April 1, 2010 resident population from the 2010 Census.

[292] For example, the Veterans Health Administration, reported that it receives 1.7 million access requests annually; however, rather than individuals' exercising the right of access, many of these requests likely are for benefit determinations, and may be based on an authorization. A Cincinnati health system reported that two of its hospitals receive 31,102 and 22,000 requests from individuals per year, respectively.

individuals having better access to their medical information, leading them to potentially make better decisions about their health. The Department does not anticipate that covered entities would incur additional costs for allowing this type of access to ''readily available'' PHI, but requests comment on this assumption and data on potential costs.

To the extent that covered entities are currently prohibiting individuals from notetaking, photographing, or other ways of capturing PHI using their own devices, they would incur costs involved in changing the existing policy for in-person access. The Department anticipates that a covered entity would need 25 minutes of lawyer time [293] to change its policy and procedure for individuals to inspect their own PHI to include taking notes and photographs or using other resources to capture the PHI (without connecting to the covered entity's system), and may experience costs for adding this policy to its HIPAA training content. This would amount to approximately 322,638 total burden hours for changing related policies and procedures and total costs of approximately $45 million. Revising the related training content would incur average costs for 20 minutes of a training specialist's time [294] for each covered entity, resulting in total increased burden hours of 258,110 and a total cost of approximately $16 million. The Department seeks comments on the extent to which covered entities already have policies permitting individuals to photograph or otherwise capture the PHI, and how changing policies to allow such activities would increase or decrease costs to the entity or individuals. For example, taking a photograph may decrease the time spent by individuals reviewing medical records in the covered entity's office, decrease the number of subsequent calls to the physician for information, or increase adherence to treatment regimens. In particular, the Department seeks comments providing any quantifiable projected cost increases or decreases due to the proposed changes, including allowing individuals to photograph PHI that is readily viewable at the point of service in conjunction with a health care appointment.

iv. Estimated Cost Savings From Shortening the Access Time Limits

The Department proposes to shorten the time for covered entities to provide copies of PHI from 30 days (with the possibility of one 30-day extension) to 15 calendar days, or shorter where practicable (with the possibility of one 15 calendar-day extension). The Department lacks sufficient data to quantify any potential cost savings to covered entities resulting from this proposal; however, the receipt of PHI more rapidly from other covered entities may create efficiencies throughout the entire health system and contribute to improved health outcomes and decreased treatment costs. While the Department believes that many covered entities already are providing copies of PHI in far less than 30 days, the increased certainty provided by the proposed regulatory time limit would create additional benefits. For individuals, shortened access times may result in cost savings due to an improved ability to make timely and cost-effective decisions about treatment options and a reduction in duplicative procedures, such as repeat lab tests. For example, an individual who is able to receive a timely copy of a lab result would be able to share it with a consulting provider who otherwise may need to re-order the test, thus saving time and money and enabling timely treatment; or a patient considering surgery who is able to receive a timely copy of PHI would be able to evaluate treatment alternatives with different providers to select which best fits the patient's circumstances. In short, the Department projects that the ability to obtain health information faster may result in cost savings overall. The Department invites comments providing data on projected cost savings from shortening the access time limits from 30 days to 15 calendar days.

v. Costs Arising From Shortening the Access Time Limits

The Department estimates that at least 50 percent of access requests are already being fulfilled in 15 calendar days or less, taking into account those covered entities (primarily health care providers) subject to state laws with 15-day (or shorter) requirements [295] and other covered entities that fulfill requests in 15 calendar days or less voluntarily.[296] The Department estimates that the burden to covered entities to provide copies of PHI to individuals in half the time than currently permitted would result in increased costs for responding to access requests by 1 minute of a medical records technician's labor which can be attributed to search and retrieval activities that are not included in the allowable labor costs that may be charged to individuals. Based on an estimated 1.46 million annual total access requests for copies of PHI provided to individual at an average increased labor cost of $.75 per request, the Department calculates the total additional annual burden would be approximately $918,400. The Department requests comment on these assumptions.

vi. Estimated Costs and Cost Savings From Addressing the Form and Format of Access

The Department proposes to clarify that a readily producible form and format includes access through an application programming interface (API) using a personal health application. It also proposes that a covered entity must inform any individual to whom it offers to provide a summary in lieu of a copy of PHI that the individual retains the right to obtain a copy of the requested PHI if the individual does not agree to receive such summary. The Department lacks sufficient information to quantify the potential costs or cost savings from these proposals and requests information about how these proposals would affect covered entities, business associates, and individuals.

[293] *See* Table 4.

[294] *Ibid.*

[295] At least eight states require some health care entities to provide copies within 15 days (or a shorter time) by law. Three additional states require access to view records within 10 days or a shorter period. New York State has published guidance that copies should be provided within 14 days, even though it is not a mandatory time limit. Thus, providers in three high-population states are currently subject to expectations of providing access within 15 days or less: New York, California, and Texas. As a percentage of the U.S. population, the 8 states with shorter requirements plus New York, represent over one-third of individuals (using 2018 projections based on the 2016 Census Bureau estimates drawn from 2010 data). There is variability as to how the days are counted within the state laws (*e.g.,* working days vs. calendar days); however, allowing for the proposed 15-day extension, these state requirements are still shorter than the total to be allowed under the proposed HIPAA changes.

[296] Half of the entities commenting on the RFI access question indicated that they are providing access within 15 days or less, including some in states where it is not required. In addition, an ONC report found that, ''In 2018, about half of individuals were offered online access to their medical record by a health care provider or insurer. Among these individuals, 58 percent viewed their online medical record at least once within the past year. Nationally, this represents about three in 10 individuals.'' Patel V & Johnson C. (May 2019). Trends in Individuals' Access and Use of Online Medical Records and Technology for Health Needs: 2017–2018. ONC Data Brief, no.48 Office of the National Coordinator for Health Information Technology: Washington DC, (May 2019), available at *https://www.healthit.gov/sites/default/files/page/2019-05/Trends-in-Individuals-Access-Viewing-and-Use-of-Online-Medical-Records-and-Other-Technology-for-Health-Needs-2017-2018.pdf* (last accessed June 14, 2019).

vii. Cost Savings From Addressing the Individual Access Right to Direct Copies of PHI to Third Parties

The Department proposes to limit the access right to direct a copy of PHI to a third party to only electronic copies of PHI in an EHR. The Department proposes to implement this proposal by adding an optional element to the Notice of Privacy Practices and changing the allowable fees for transmitting such copies—thus, most of the estimated costs and cost savings for those changes are discussed as cost transfers in separate sections on those topics. However, the Department recognizes that covered entities may incur some labor costs for requests by individuals under the right of access to direct electronic copies of ePHI to a third party and estimates that costs may increase for 25 percent of the estimated annual 615,000 such requests (153,750) in the amount of 2 minutes of labor at the hourly wage of a medical records technician ($44.80) or $1.49 per request that cannot be charged to the individual as an allowable fee for copies.

The Department also assumes that many covered entities correctly interpret the current HIPAA right to direct the transmission of electronic copies of PHI in an EHR to a third party to apply to individuals' requests to direct the transmission of such ePHI to another provider or to their health plan. With respect to such requests, the Department assumes that many covered health care providers and health plans are already disclosing PHI to other providers and plans in a timely manner, which in most instances would be far less than 30 days. The Department further expects that providers using HIEs and certified EHR technology (CEHRT) are disclosing ePHI to other providers in much less than 15 calendar days, as indicated by comments the Department received in response to the RFI. Thus, the Department projects that the costs for complying with the proposed changes for sending electronic copies of PHI in an EHR to health care providers and health plans in no more than 15 calendar days would be limited to a small percentage of covered entities and that those costs would mostly be attributable to changes in 45 CFR 164.524(c)(3), as described in the section above. However, in recognition that covered entities are unlikely to recoup costs for requests by individuals under the right of access to direct electronic copies of ePHI to health plans and health care providers, the Department estimates that costs may increase for 25 percent of the estimated annual 615,000 of such requests (153,750) in the amount of 4 minutes of labor at the hourly wage of a medical records technician ($44.80) or $2.99 per request. This is greater than the uncompensated burden estimate for copies sent to other third parties because the Department understands that health care providers and health plans may not routinely charge any fees for disclosures to other covered entities.

Additionally, the Department proposes, at 45 CFR 164.524(d)(7), to require that a covered health care provider or health plan must submit a request for an electronic copy of PHI in an EHR from another health care provider, to be directed to the requesting covered entity (*i.e.,* the third party recipient), when the request is clear, conspicuous, and specific, which may be orally or in writing (including an electronically executed request). The Department proposes to require that the covered health care provider or health plan must submit the access request as soon as practicable, but no later than 15 calendar days after receiving the individual's direction and information needed to make the request. A health care provider that receives the access request would be required to provide the electronic copy requested under this section as soon as practicable but no later than 15 calendar days upon receipt of an individual's request that is clear, conspicuous, and specific. The Department considers that a signed, written request and use of a personal health application are both examples of means that an individuals may use that meet the condition that the request be clear, conspicuous, and specific, and that a signature may be provided in electronic form.

Based on comments on the 2018 RFI, in many instances covered entities are already requesting copies of PHI from other health care providers within 30 days or less of communicating with an individual who requests such information to be added to his or her health record. The disclosure of PHI to the covered entity that submitted the request is permitted without an individual's authorization for purposes of treatment, payment, and certain health care operations, as applicable, and required under the current right of access when an individual submits a written request.[297] The Department anticipates that with the clear and certain path provided by this proposal to obtain ePHI from other covered health care providers (who are required to respond), covered entities may experience savings from spending less time attempting to obtain electronic copies of PHI in an EHR from other covered health care providers based on an individual's request. The Department has not quantified these cost savings, but invites comments on any projected savings to covered entities and/or individuals from this regulatory clarification.

viii. Costs Arising From Changes to the Individual Access Right to Direct Copies of PHI to Third Parties

The Department anticipates that once individuals and third party recipients learn about the changes (*i.e.,* limiting the right to only directing electronic copies of PHI in an EHR) they likely would shift to submitting access requests *and* authorizations when requesting that a complete medical record be sent to a third party. Although covered entities may bear some initial costs while the public is adjusting to the new requirements, they would benefit financially from the increased number of copies for which they can charge a less restricted fee (an effect categorized as a ''transfer'' from the society-wide perspective reflected in this regulatory impact analysis). The Department estimates that covered entities may incur some one-time costs for changing their policies and procedures and revising their training program for employees who handle access requests, as well as initial implementation costs for adjusting to the revised policies and procedures. Specifically, the Department estimates that covered entities will incur an increase in burden hours for 30 minutes of a lawyer's time to revise policies and procedures related to the changes to this part of the right of access. Additionally, the Department estimates that covered entities will incur an increase in labor expenses for 20 minutes of a training specialist's time to incorporate the newly revised policies and procedures into the covered entity's existing HIPAA training program.

As stated in the discussion of changes to the proposed access fees, the Department estimates a total of 2.46 million access requests per year and that half of these are for the individual to obtain his or her own records, one-fourth (615,000) are to direct the transmission of records to a health care provider or health plan, and the remaining one-fourth (615,000) are to direct the transmission of records to a third party. Of the 615,000 estimated requests to direct the transmission of PHI to a third party other than a health care provider or health plan, the

[297] Following the court's ruling in *Ciox* v. *Azar,* the Department is limiting the right to direct the transmission of PHI to third parties to requests for electronic copies of PHI in an EHR.

Department estimates that covered entities would not fulfill half (307,500) on the basis that the request is for non-EHR copies of PHI (*i.e.,* are requests that do not fall within the right of access).

The cost savings associated with these changes are discussed separately as cost transfers in the sections on the proposed changes to access fees.

The Department estimates that covered entities, primarily providers, would incur some costs from the proposed new requirement to submit requests for access on behalf of individuals who are seeking to direct the transmission of electronic copies of PHI in an EHR from another health care provider (''Discloser'') to the requesting entity (''Requester-Recipient''). The Department estimates that the proposed requirement would increase costs for 15 percent of the 615,000 annual requests to direct copies of ePHI to health plans and providers (92,250) by 3.5 minutes per request at the adjusted labor rate of a medical assistant ($34.34, see Table 4), for a total of 5,381 burden hours at a total annual cost of $184,792. These costs are presented in Table 12 as ongoing costs of the proposed rule.

The Department does not anticipate that covered entities would incur a significant additional burden from an express inclusion of health care providers and health plans as recipients to whom disclosures are mandated when the individual exercises the right to direct the transmission of electronic copies of PHI in an EHR to a third party. Based on a notable lack of comments or concerns expressed by stakeholders about directing PHI to covered entities as part of the right of access, the Department expects that most covered entities have correctly interpreted the Privacy Rule and included individuals' requests to direct the transmission of ePHI to health care providers and health plans into their access request fulfillment process. The small proportion of covered entities or business associates who are not already fulfilling individuals' access requests to transmit ePHI to health care providers or health plans may experience a small increase in costs resulting from their current noncompliance. The Department estimates that 25 percent of these requests (153,750 total) would result in transmitting an electronic copy of ePHI via a non-internet based means (*e.g.,* mailing a copy of ePHI stored on electronic media to a health plan or health care provider), at a labor cost of 4 minutes of a medical records technician's adjusted hourly rate of $44.80, for a total annual cost of $459,200.

Overall, the Department believes that, for covered health care providers and health plans, any costs to fulfill requests made under this proposal would be counterbalanced by the increased responsiveness from other covered entities that would transmit records to them, when requested, on a timelier basis, which would improve care and contribute to cost reductions.

ix. Estimated Cost Savings and Cost Transfers From Changes to Access Fees

The Department proposes to expressly prohibit covered entities from charging fees for access when an individual inspects PHI about the individual in person and for copies of PHI that an individual accesses using an internet-based method.

Expressly permitting individuals to copy and photograph their PHI for free during an in-person inspection may reduce the number and scope of subsequent access requests made by such individuals. In addition, to the extent that covered entities increase the free availability of PHI via an internet-based method, they may experience a decrease in other types of access requests for which costs are incurred. The Department expects that individuals may increasingly choose to initiate and obtain access via an internet-based method, which will result in cost savings to individuals.

Prohibiting covered entities from recouping certain costs for providing electronic copies of PHI, or transmitting an electronic copy of PHI in an EHR to third parties, would increase expenses for these items: electronic media onto which copies of PHI from an EHR are transferred, and actual mailing and shipping costs for electronic copies.[298] At the same time, covered entities' ability to charge fees for directing non-electronic copies of PHI and electronic copies of PHI not in an EHR to third parties based on a valid authorization would reduce unreimbursed costs for covered entities. Of an estimated 2.46 million annual access requests, the Department assumes that 50 percent (1.23 million) are for individuals to directly access PHI, 25 percent (615,000) direct copies to health care providers or health plans, and the remaining 25 percent (or 615,000) direct copies to other third parties, as indicated in Table 6. Of the 615,000 requests directed to other third parties, assuming an average record size of 200 pages, [299] the Department assumes 100 pages are electronic copies and 100 pages are non-electronic copies (a ''hybrid'' records request) because it lacks sufficient data to estimate the average length of a record that is requested by an individual. The Department expects that there is considerable variation, ranging from individuals who seek only billing records, those who want only records of a single hospitalization, those who request only lab results or a copy of a single doctor's order, to those who need a complete longitudinal record of all of their medical visits. The Department requests data that would refine its assumptions and estimates about the average size of a request for access.

TABLE 6—ESTIMATED NUMBER OF ANNUAL ACCESS REQUESTS, BY RECIPIENT

Recipient of PHI copies	Number of access requests
Individuals	1,230,000
Health Care Providers and/or Health Plans	615,000
Third Parties other than Providers and/or Plans	615,000
Total	2,460,000

Under the Department's proposed changes, covered entities would be disallowed from charging for certain expenses that the Privacy Rule currently allows when providing copies to an individual and when directing an electronic copy of PHI in an EHR to a third party under the right of access. The non-chargeable expenses would be the portion of costs attributable to emailing, mailing, or shipping the electronic copies and the costs of electronic media requested by individuals. Labor costs for copying or transferring EHR records to another electronic format (such as a PDF) or onto electronic media (*e.g.,* CDs, USB drives) would continue to be allowed as part of a reasonable, cost-based access fee. Table 7 indicates the allowable and non-allowable expense items for directing copies of PHI to third parties under the current right of access and as proposed.

[298] OCR's Breach Portal reflects numerous breaches involving the loss or destruction during transit of mailed electronic media, such as USB drives and CDs, affecting thousands (more) of individuals. *See https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf.*

[299] *See* Lye CT, Forman HP, Gao R, et al. ''Assessment of US Hospital Compliance With Regulations for Patients' Requests for Medical Records.'' JAMA Netw Open. 2018;1(6):e183014, available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2705850,* citing a study evaluating the state of medical records request processes in US hospitals in which a hypothetical assumption of 200 pages per request was used. The Department requests comment and evidence regarding the actual lengths of medical records.

TABLE 7—ALLOWABLE AND NON-ALLOWABLE ELEMENTS OF EXPENSES INCURRED FOR TRANSMITTING COPIES OF ELECTRONIC PHI IN AN EHR TO A THIRD PARTY

Cost elements	Expense item currently allowed	Expense allowed under proposed rule
Labor for making requested copies.	Yes	Yes
Postage and shipping.	Yes	No
Electronic media	Yes	No
Copying supplies	Yes	No
Costs of searching, retrieving, collating or preparing the PHI for copying.	No	No
Costs of EHR and other electronic information systems.	No	No

The Department has not estimated postage or shipping costs in earlier Privacy Rule rulemaking because the rule permitted actual costs for those expenses to be passed on to the individual making the request for copies of PHI. To estimate how the proposed changes would affect covered entities, the Department has estimated that a 100-page paper record (one pound of material) can be shipped via U.S. Mail for $7.50 and a CD or USB drive can be shipped for $3.00.

To readily compare the potential burden or burden reduction from various types of requests to direct copies of PHI to third parties, the Department presents its estimates in the charts below and provides detailed explanations of the included cost items for each calculation under the current rule, state law, and the proposed rule in the paragraphs that follow. State law remains a relevant consideration in two ways. First, to the extent that state law limits on fees for copies of medical records for individuals are lower than the limits in the Privacy Rule, the state law applies. For instance, some states require a free copy for individuals who are indigent or who are applying for public benefits. Second, for copies of PHI provided in response to a valid authorization, the Privacy Rule limits the allowable fee to ''a reasonable, cost-based fee to cover the cost to prepare and transmit the protected health information for such purpose or a fee otherwise expressly permitted by other law'' [300] (absent an authorization including a statement that the disclosure will result in remuneration to the covered entity). ''Other law'' includes, among other sources of law, state medical records laws addressing allowable fees for copies.

TABLE 8—ESTIMATED FEES FOR COPYING AND SENDING A 200-PAGE HYBRID RECORD (100 ELECTRONIC PAGES AND 100 NON-ELECTRONIC PAGES) TO A THIRD PARTY

Estimated allowable fees for a 200-page hybrid record under the current rule	Estimated allowable fees for a 200-page hybrid record under state law
$25.23	$133.50

TABLE 9—ESTIMATED FEES FOR COPYING AND SENDING A 100-PAGE RECORD TO A THIRD PARTY

Estimated allowable fees for 100 non-electronic pages under state law	Estimated allowable fees for 100 electronic pages under state law	Estimated allowable fees for 100 non-electronic pages under the current rule	Estimated allowable fees for 100 electronic pages under the current rule	Estimated allowable fees for 100 electronic pages under the proposed rule
$88.16	$76.70	$16.74	$8.49	$1.41

Allowable Access Fees Under Current Rule To Send a Copy to a Third Party

The Department's estimate of allowable costs that may be charged for a 200-page hybrid record directed to a third party under the current right of access is approximately $14.73 (estimating $3.73 for 5 minutes of labor [301] and $11 for supplies [302]) per request, plus estimated postage and shipping of $10.50 or $25.23 total. See Table 8. This represents an overall increase in labor of 2 minutes above the Department's prior burden estimates of 3 minutes for all access requests. The updated estimate allows 3 minutes of labor for the non-electronic copies and 2 minutes of labor for electronic copies, resulting in total allowable labor costs of 5 minutes for a hybrid record. The updated estimated allowable fee under the current rule for only the electronic portion of the request (100 pages in electronic format) is $5.49 ($1.49 for 2 minutes of labor and $4 for electronic media) plus postage of $3.00 or $8.49 total per request. See column 4 of Table 9. The estimated allowable fee under the current rule for only non-electronic copies (100 pages) is $9.24 (estimating $2.24 for 3 minutes of labor and $7 for supplies), plus postage of $7.50 or $16.74 total. See column 3 of Table 9.

In addition to the costs that may be charged as fees for providing copies, the Department estimates a previously unacknowledged burden of 2 minutes of labor per request that is not allowed to be charged to the individual or the third party recipient of the ePHI for copies that are sent via a non-internet method (*e.g.* on electronic media that is mailed). The Department assumes that none of the costs for electronic copies of ePHI sent to third parties that are health plans and health care providers through a non-internet method would be recouped as fees charged to individuals or the covered entity recipients. In recognition of this burden, the Department also estimates that all of the labor for sending electronic copies of ePHI to third parties that are health plans and health care providers is uncompensated, resulting in a previously unacknowledged uncompensated burden of 4 minutes of labor per request for electronic copies of ePHI sent to third parties that are health plans and health care providers through a non-internet method at the direction of the individual. The Department acknowledges the lack of data on actual labor associated with sending electronic copies of ePHI because some copies will be sent on electronic media and some by internet. The Department estimates no labor for sending copies via an internet-based method. These adjusted estimates

[300] 45 CFR 164.502(a)(5)(ii)(B)(*2*)(*viii*).

[301] *See* Table 4, median adjusted wage rate for medical records technician of $44.80.

[302] The costs of supplies includes $7 for paper, toner, etc., and $4 for electronic media such as a USB drive.

are included in the uncertainty analysis in subsection m. and the burden estimates in section G., Paperwork Reduction Act.

Allowable Fees Under State Law for Sending Copies of Medical Records to a Third Party

The Department estimates that the average charge allowed by state law for a 200-page hybrid record directed to a third party is $123 per request (including a handling or administrative fee [303] not allowed by the Privacy Rule), plus postage and shipping of approximately $10.50. This would result in an estimated total of $133.50 in state-allowed fees for a 200-page hybrid request. See Table 8. The estimated state-allowed fee for 100 electronic pages that are not contained in an EHR is $73.70 plus $3 postage for sending a USB drive or $76.70 total. See column 2 of Table 9. The estimated state-allowed charge for 100 non-electronic pages is $80.66 plus $7.50 for postage or $88.16 total. See column 1 of Table 9.

Allowable Fees Under Proposed Rule for Sending an Electronic Copy of PHI in an EHR to a Third Party

The estimated average allowable fee under the proposed rule (100 pages in electronic format) is $1.49 per request (estimating 2 minutes for labor).

In developing its estimated costs and cost benefits the Department employed several methods to arrive at a range of costs and cost benefits and average estimated costs and cost benefits for the proposed adjustments to the allowable access fees.

Methodology 1

The Department applied its estimated fees to a 200-page hybrid record and compared the costs under the proposed changes to a baseline of $25.23 in estimated allowable costs under the current right of access. See Table 8. The resulting estimated cost savings for three different types of requests are as follows.

When a Request is Entirely for Copying and Sending Copies That are not Contained in an EHR (100 Non-Electronic Pages and 100 Electronic Pages) to a Third Party

Under the proposed rule, a covered entity could charge the state law rate ($133.50) or $108.27 more for the request than allowed under the current rule.[304] For an estimated annual total of 615,000 requests directed to a third party, this type of request would generate an estimated cost savings for covered entities of $66,586,050.

When a Request is for 100 Electronic Pages That are not in an EHR and 100 Electronic Pages That are in an EHR

Under the proposed rule, a covered entity could charge the state law rate for copying and sending 100 electronic pages not in an EHR ($76.70) plus the allowable labor for copying the 100 EHR pages ($1.49) for a total of $78.19 or $52.96 more per request than allowed under the current rule.[305] For an estimated annual total of 615,000 requests directed to a third party, this type of request would generate an estimated cost savings for covered entities of $32,570,400.

When a Request is for 100 Non-Electronic Pages and 100 Electronic Pages That are in an EHR

Under the proposed rule, a covered entity could charge the state law rate for copying and sending 100 non-electronic pages ($88.16) based on a valid authorization, plus the allowable labor for copying the 100 EHR pages ($1.49) under the right of access, for a total of $89.65 or $64.42 more per request than allowed under the current rule.[306] For an estimated annual total of 615,000 requests directed to a third party, this type of request would generate an estimated cost savings for covered entities of $39,618,300.

To summarize, under the options presented above, the Department estimates that the cost savings of the proposed changes to the access right to direct an electronic copy of PHI in an EHR to a third party and allowable fees for directing copies of PHI to third parties, would range from $53 to $108 per request.

Methodology 2

The Department also applied a second method for estimating the potential costs and cost savings of the proposed fee changes. Under the second approach, the Department assumed that half of the 615,000 annual requests to direct copies of PHI to a third party would be for electronic copies of PHI in an EHR (307,500) and that half would no longer fall within the right of access (307,500), but then would be disclosed with a valid authorization. Costs for covered entities would increase for the estimated 307,500 requests that are accepted (for electronic copies of PHI in an EHR) by an estimated $7 per request in supplies and postage they would no longer be able to recoup in fees, for a total estimate of $2,152,500 annually.[307] Cost savings for covered entities would accrue for the estimated 307,500 requests that are no longer within the right of access (for non-electronic copies or electronic copies not in an EHR) by an estimated $108.27 for a total estimate of $33,293,025 [308] annually. This estimation method would result in an estimated net cost savings for covered entities of $31,140,525 annually ($33,293,025 minus $2,152,500).[309]

Summary Results of the Department's Estimated Costs and Cost Savings for Proposed Fee Adjustments

Under the proposed changes, a covered entity would be allowed to charge less per request to transmit an electronic copy of PHI to a third party under the right of access and significantly more per request to send non-electronic copies or electronic copies not maintained in an EHR to a third party with a valid authorization, as compared to what is allowed under the current right of access. Under the several methods for calculating estimated fees for copies of PHI the Department estimates total annual cost savings for covered entities ranging from $31 million to $67 million, or an average of $43 million. However, the Department estimates that all of these cost savings on the part of covered entities would be transferred to individuals and/or their third party designees as costs. The Department estimates that 50 percent of these costs savings would be transferred as an additional cost imposed on individuals and the other 50 percent would be transferred to the third parties to whom the PHI is directed. For each of the estimated 615,000 requests that would have been made under the current rule to direct the transmission of copies of PHI to a third party under the right of access the allowable fee for copies would increase by an estimated average of $70 ($43 million in estimated annual cost savings divided by 615,000 requests).

The Department seeks comments on these estimates, averages, and assumptions underlying its analysis and invites comments on the number and type of access requests received by covered entities, costs incurred, and fees charged.

[303] In states that have one search fee for electronic copies and another search fee for paper copies, the Department assumes that a covered entity would only charge the individual one administrative fee for a hybrid request.

[304] $133.50 minus $25.23.

[305] $78.19 minus $25.23.

[306] $89.65 minus $25.23.

[307] $7 multiplied by 307,500 requests.

[308] $108.27 multiplied by 307,500 requests.

[309] Estimated net costs subtracted from estimated net savings.

x. Costs Arising From Changes to Access Fees

The Department anticipates that the burden on covered entities for drafting or updating their access fee schedules would include the one-time costs for lawyer to review the new HIPAA provisions and evaluate the entity's fee structure based on changes to allowable access fees. This would include lawyer time at an adjusted mean hourly rate of $139.72. For each covered entity, the Department estimates an average of three hours for a lawyer to make policy and procedure revisions related to all the proposed changes to the right of access, including allowable fees. In total, the Department estimates 2,322,993 burden hours, for approximately $325 million in lawyers' costs related to the proposed changes to the right of access.

Covered entities also would need to add new access fee policies and procedures to their HIPAA training content. In its estimates, the Department includes two hours and thirty minutes of a training specialist's time for each covered entity to revise the training content for all of the proposed changes to the right of access, including fees and responding to requests for fee estimates, at an adjusted mean hourly rate of $63.12. The Department believes this estimate is reasonable, but welcomes comment and data to further inform its assumption. In total, the Department estimates 1,935,828 burden hours for all of the revisions to training content related to the right of access and costs of approximately $122 million. The Department assumes, for all of the proposed changes, that entities would incorporate the updated training content into their ongoing HIPAA training program, and that for most workforce members there would be no additional training costs for the time spent in HIPAA training. However, for medical records technicians, the Department has estimated an average seven minute increase in the time for spent in training on the proposed right of access changes in the first year of implementation, for a total estimate of 90,339 burden hours at a total estimated cost of $4 million.

Free Access for Inspecting PHI In-Person: To the extent that covered entities are charging individuals for the copies individuals make with their own devices or resources, the covered entities would incur some loss of revenue; however, the Department anticipates that any loss would be minimal and that covered entities do not view this as a significant source of revenue, if any do charge a fee to inspect PHI in person. The Department seeks comments on the number of requests covered entities receive to inspect PHI in person and on the number of covered entities that charge fees for or prohibit individuals from making copies with their own devices or taking notes of their own PHI, and if so, the amount of fees charged for such activities.

Free Internet-Based Access: Because covered entities do not incur additional costs for labor, supplies, or postage for this method of providing access and because it only applies to covered entities that choose to use this method, the Department does not anticipate an increased burden for expressly requiring entities to provide such access for free. The Privacy Rule requires a covered entity to provide an individual with access to existing PHI maintained electronically in the electronic form and format requested, if it is readily producible, but neither the current access standard nor this proposed change would require covered entities to create a patient portal or other internet-based access method. In practice, such internet-based access is ''readily producible'' for most covered entities that use EHRs because the Office of the National Coordinator of Health IT requires an EHR to implement API technology in order to be certified.[310]

Reducing the Expenses that can be Included in Calculated Access Fees for Providing Individuals with Copies of PHI in an EHR on Electronic Media: The Department proposes to disallow covered entities from charging individuals for the costs of electronic media and postage when providing access by mailing copies of PHI in an EHR on electronic media. The Department estimates that the costs of electronic media may range from $1 for a CD to $4 for a USB drive and the postage may range from $1 to $3, resulting in a range of estimated increased costs of $2 to $7 per request of this type or an average estimated increase of $4.50. The Department estimates that half of the 2.46 million total estimated annual access requests (or 1.23 million) would be made by individuals to obtain copies of PHI for themselves, and that half of those requests would be for non-electronic copies of PHI (or 615,000), one-fourth would be for internet-based access (or 307,500), and one-fourth would be subject to the proposed fee limitations for sending copies on electronic media (or 307,500). Thus, the Departments estimates a total cost incurred by covered entities of $1,383,750 due to this proposal. At the same time, these are costs that would have been borne by individuals, and thus may be considered a cost transfer from individuals to covered entities as reflected in Table 17.

Narrowing the Scope of Requests to Direct PHI to Third Parties that are Subject to the Access Fee Limits: Allowing covered entities to charge higher access fees than currently permitted when directing non-electronic copies of PHI or electronic copies of PHI not in an EHR to third parties, based on a valid authorization rather than an access request, would reduce their burden for directing copies of PHI to a third party, and shift the costs to the individuals or to the third parties to whom the responses to such requests are directed. Because individuals still may request copies of records to be sent to the individuals themselves at the lower rate currently allowed under the Privacy Rule, this proposed change would not impede individuals from receiving their own PHI; however, it may cause some individuals to bear the burden of transmitting non-EHR ePHI to some third parties to avoid the higher fees, expend higher amounts for using a valid authorization to request that the PHI be disclosed to a third party, or avoid making some requests to direct copies of non-electronic PHI to a third party. The Department has insufficient information to quantify the potential increased burden on individuals for these options and welcomes information and comment on these potential changes to individuals' expenditures of time and money.

xi. Estimated Cost Savings From Requiring Covered Entities To Provide Access and Authorization Fee Information

The Department proposes, in a new subsection 525 to 45 CFR 164, to require a covered entity to provide advance notice to individuals of the fees the entity charges for providing copies of PHI. Specifically, the Department proposes to require a covered entity to (i) post a fee schedule for standard or common types of access requests, including all types of access which are free, on the entity's website (if it has one), and make the fee schedule available to individuals; (ii) provide, upon request, an individualized estimate of the approximate fee that may be charged for the requested copy of

[310] In the Cures Act Final Rule, ONC has adopted a new secure, standards-based API certification criterion in § 170.315(g)(10) to implement the 21st Century Cures Act's requirement that developers of certified health IT publish APIs that can be used ''without special effort.'' See *https://www.healthit.gov/cures/sites/default/files/cures/2020-03/APICertificationCriterion.pdf.*

PHI, including any associated fees that may impact the form, format, and manner in which the individual requests or agrees to receive a copy of PHI; and (iii) upon request, provide an individual with an itemized list of charges for labor, supplies, and postage, if applicable, that constitute the total access fee charged. Finally, the Department proposes that such requests not automatically extend the deadline by which a covered entity is required to respond to an access request.

The Department thinks it is likely that covered entities that provide fee estimates for access and disclosures pursuant to a valid authorization would find that such action results in a narrower scope for some requests than would exist without the changes, improved collection rates for access fees, and reduced time needed for workforce members to resolve access payment disputes and complaints. Thus, the Department believes that the benefits of changing covered entities' access procedures in a way that incentivizes individuals to make more targeted access requests and informs them of fees in advance would counterbalance the burdens on covered entities. However the Department has no data with which to estimate the reduction in burden and welcomes comments on this change, including covered entities' experiences with the collection of access and authorization fees, the factors affecting the scope of individuals' requests for copies, and the costs to covered entities for handling fee disputes.

xii. Costs Arising From Requiring Covered Entities to Provide Access and Authorization Fee Information

Posting the fee schedule online or otherwise making the access and authorization fee schedule available: In calculating covered entities' burdens for posting a notice of access and authorization fees, the Department presumes that a number of entities charge no fees for copies provided under the access right [311] or for copies sent to other covered entities. These entities would have no burden for complying with the new notice provision.

The Department seeks comments on the number of covered entities that charge fees only for copies provided based on a valid authorization, no fees for fulfilling requests pursuant to the right of access.

The Department assumes that all entities that charge for providing copies of PHI already have some type of standard fee structure. The Department also presumes that some covered entities have already posted an online access and authorization fee schedule consistent with existing guidance recommending this practice, although this is not required by the Privacy Rule, and have been making it available to individuals. For those covered entities that have not yet posted the fee schedule online, the costs of doing so should be minimal because this requirement only applies to entities that have a website. The Department anticipates that posting an online notice of access and authorization fees would require the costs of reviewing, formatting, and posting one document. Making the notice available may include, for example, having copies available in the office where individuals make access and authorization requests or emailing it to individuals upon request.

Because the proposed change requires covered entities to make the access and authorization fee schedule available at the point of service and upon request (in addition to posting online when a website is utilized), it may be least burdensome for entities to add the fee schedule to their access and authorization request forms (although the Department does not propose to require this, or to require the use of a standard form for access requests), resulting in no additional labor costs for distribution. Further, for covered entities that already have a fee schedule, the proposed change would only require revisions to an existing document, resulting in no additional costs for paper. The Department estimates the potential burden on all covered entities (774,331) as the cost of 10 minutes of a web developer's time at a rate reported in Table 4, for a total labor cost of approximately $10 million. Although the Department assumes that 35 percent of covered entities have already posted an access and authorization fee schedule available, as discussed in the baseline assumptions following Table 4, it recognizes that all covered entities may need to post an updated fee schedule and accounts for this in its estimates. In addition, the Department estimates that all covered entities will incur first-year and ongoing capital costs for making the fee schedule available at a cost of $0.10 for paper and printing or a total of $232,299. This assumes each covered entity prints an average of three copies of the fee schedule as a separate document. We anticipate that covered entities will provide the fee estimate in a variety of ways, not all of which will incur additional costs, such as including the fee schedule on the access and/or authorization form and providing it electronically. The Department seeks comments and data on its assumptions, and on the number of covered entities that require individuals to use an access request form and how many currently make an access and/or authorization fee schedule available to individuals, either online or through other means, such as email or telephonically.

Providing the individual, upon request, with an individualized estimated access and/or authorization fee: The proposed changes would require billing information to be provided to individuals in advance as an estimate, upon request. Providing advance notice of the fees for providing the requested PHI would require a statement of charges pertinent to the individual's request (*e.g.,* giving some estimate of the number of pages if a per page fee is involved, identifying whether records are in paper or electronic form, and giving an estimate of the individual's access and/or authorization fees). The Department assumes that three percent of 2.46 million total access requests, or 73,800, would result in a request for a fee estimate at a cost per request of three minutes of a medical records technician's time, at the rate reported in Table 4, for a total new labor cost of approximately $165,312. The Department assumes that most of the requested fee estimates will be provided electronically or orally, and that only a small proportion will result in mailing a paper copy of the estimate to the individual. Thus, the Department estimates that 15 percent of 73,800 requests for an access fee estimate (or 11,070) would need to be printed and mailed, at a total estimated capital expense of $7,638 at a cost of $0.69 per estimate. The Department anticipates that many covered entities are already providing access fee estimates, as recommended in OCR's 2016 Access Guidance; however, the Department

[311] OCR's 2016 Access Guidance encourages covered entities to provide individuals with a free copy. At least one state, Kentucky, requires certain health care entities to provide an initial free copy, KRS section 422.317(1). Several states require a free copy for persons who are indigent and/or applying for public benefits. *See, e.g.,* California, CA Health and Safety Code § 123110(d), (e), Connecticut, Conn. General Statutes § 20–7c(d), Massachusetts, MGLA Ch. 111 § 70 and MGLA Ch. 112 § 12CC, Michigan, Mich. Comp. Laws 333.26269, sec. 9(4), Nebraska, Neb. Rev. Stat § 71–8405, Nevada, Nev. Rev. Stat. § 629.061(5), Ohio, Ohio Revised Code, section 3701.741(C), Rhode Island, RI § 23–17–19.1(16), Tennessee, TCA § 68–11–304(a)(2)(B), Texas, Texas Code, Health & Safety § 161.202, Vermont, 18 V.S.A. § 9419, and West Virginia, WV Code § 16–29–2(g).

seeks comments on the number of covered entities that provide estimates of access and authorization fees.

Providing an itemized list of allowable access and authorization charges for labor, copying, and postage: The Department assumes that: (a) Many entities are already providing this information when requested by an individual as recommended in OCR's existing guidance, although it is not required by the Privacy Rule; and (b) a small proportion of individuals who request copies of PHI will make such requests. Limiting this requirement to instances when the cost details are requested would further minimize the burden of this proposed change. The Department estimates the potential labor costs as one minute of a medical records technician's time at the hourly rate of $44.80 for an estimated 24,600 annual requests for an itemized list of access charges, or a total of 410 burden hours and $18,368 in total costs. The Department estimates that covered entities would incur capital costs for printing one sheet of paper at a cost of $0.10 per request for an itemized list of charges and no additional postage because the itemized list of charges would be included with the copies of PHI sent to the individual, for a total cost of $2,460 annually. The Department seeks comments on the number (and relative volume) of requests for the specific details of allowable charges for copies of PHI that covered entities receive from individuals or their personal representatives.

xiii. Estimated Cost Savings From Changes to the Verification Requirements

The Department proposes to add a new paragraph (v) to 45 CFR 164.514(h)(1), which would state that a covered entity may not impose identity verification requirements on an individual that would serve as a barrier to or unreasonably delay the individual from exercising an individual right under HIPAA when a less burdensome measure is practicable for the covered entity. Individuals would accrue cost savings by reductions in expenses for obtaining notarized documents, traveling in person to request access, paying verification fees, or meeting other unreasonable verification practices. Because the Department assumes that most entities do not impose such barriers to individual access, the Department anticipates that the total cost savings will be modest, but they may be significant for any particular affected individual. The Department invites comment and examples of the extent to which covered entities impose measures that some may view as unreasonable and create costs for individuals when seeking to request access to PHI.

xiv. Costs Arising From Changes to the Verifications Requirements

The Department, based on OCR's experience with HIPAA enforcement and recommendations in guidance, anticipates that most entities already are avoiding unreasonable verification measures. However, OCR has received some complaints and anecdotal reports that some entities are forcing individuals to engage in these burdensome practices, such as obtaining a notarized signature or appearing in-person to make an access request. The Department estimates that 5% of covered entities (38,717), and any business associates that fulfill requests for access on their behalf, would need to modify their verification policies and forms and update related HIPAA workforce training content. The Department estimates that these covered entities would incur costs for 30 minutes of a lawyer's time (or $69.86) to revise these policies and procedures, and costs for 10 minutes of a training specialist's time (or $10.52) to update the HIPAA training content on this provision for a total of approximately $80.38 per covered entity. As the Department does not have data upon which to refine its assumptions and estimates, the Department invites comments in this regard for future consideration, as well as on any costs associated with implementing the proposed changes.

xv. Estimated Cost Savings From Adding an Exception to the Minimum Necessary Standard for Care Coordination and Case Management for Individuals

The Department proposes to add, at 45 CFR 164.502(b)(2), an express exception to the minimum necessary standard for disclosures to or requests by a covered health care provider for individual-level care coordination and case management activities that constitute treatment or health care operations. The Department expects to achieve significant cost savings from this proposal. The Privacy Rule generally requires a covered entity to make reasonable efforts to limit use of, disclosure of, and requests for, PHI to the minimum necessary to accomplish the intended purpose and to make an assessment of what PHI is reasonably necessary for a particular purpose. These requirements apply to all requests for, and disclosures of PHI for payment and health care operations purposes, including care coordination and case management. In some circumstances, a covered entity may, but is not required to, rely on representations by a requesting covered entity that the amount of PHI requested is the minimum necessary. In such cases, the disclosing covered entity remains responsible for determining when such reliance is reasonable under the circumstances.[312]

The Department lacks quantifiable data on the number of such determinations that occur in every covered entity and requests comment on the number of determinations, the type and level of workforce members making the determinations, and how such determinations are made consistent with an entity's minimum necessary policies and procedures. The Department assumes that any covered entity makes numerous minimum necessary determinations daily as to whether a request or disclosure related to patient information can be made consistent with the covered entity's policies and procedures. The Department estimates that each covered health care provider and health plan would save 25 minutes per month in time currently spent considering requests for care coordination and case management disclosures, to determine whether the information requested could be provided consistent with its internal minimum necessary policies, and to follow the requisite procedure for doing so.

The Department assumes that this proposal would relieve covered entities from the requirement to make determinations about the minimum information necessary to accomplish the purpose of a disclosure (or whether it is reasonable to rely on the requestor's representation that it is requesting the minimum necessary) when the request is from, or the disclosure is made to, a covered health care provider or health plan for individual-level care coordination and case management activities. In the 2000 Privacy Rule, the Department estimated that the minimum necessary requirement was one of the two largest cost items of the Privacy Rule, imposing a likely burden of $926.2 million in the first year and $536.7 million annually in subsequent years.[313] Specifically, the Department estimated that on ''an annual ongoing basis (after the first year), hospitals will require 320 hours, health plans 100

[312] *See* 45 CFR 164.514(d)(3)(iii).

[313] 65 FR 82461, 82760, 82767 (December 28, 2000).

hours, and nonhospital providers 8 hours to comply with this provision.''

The Department has attempted to refine its estimates related to minimum necessary by reviewing publically available materials from the Agency for Healthcare Research and Quality Medical Expenditure Panel Survey,[314] and the Centers for Disease Control and Prevention National Health Interview Survey [315] for additional data but was unable to locate recent responsive information. Most recently, commenters on the 2018 RFI described how the minimum necessary standard had a negative impact on the ability of a covered entity to promote care coordination and case management. For example, one commenter noted that accountable care organizations rely on care coordination and case management to improve quality and costs, but believed that the current rule hampered the ability to receive complete data sets to conduct these activities.[316] Another commenter noted that minimum necessary requirements, when applied to population-based services and wellness activities, ''hindered'' the advancement of population-based analytics,[317] while yet another commenter described it having a ''detrimental impact'' on the ability of clinical registries to contribute expertise and research toward value-based care models.[318] None of the commenters estimated the amount of time it takes a covered entity to make a minimum necessary determination. The Department does not intend to more heavily weight the comments cited herein above other comments submitted in response to questions about minimum necessary determinations in the 2018 RFI. The Department does intend to illustrate that some covered entities continue to view minimum necessary determinations as burdensome and to the extent a new exception for care coordination and case management would relieve this burden, should be quantified as a cost savings. The Department requests comment on this approach.

The public comments on the 2018 RFI make clear that there is a burden associated with making minimum necessary determinations with respect to uses and disclosures of PHI for care coordination and case management, and therefore savings will be associated with relief from the burden. The Department's proposed estimates are informed first by the cost burdens the Department first identified in the 2000 Privacy Rule and for which the Department has not received public input to the contrary. The proposed estimates also are informed by the understanding that a covered entity is able to rely on the representations of certain requestors about the minimum necessary information to accomplish the purpose of a use or disclosure, and that minimum necessary determinations are a component of every covered entity's workflow. For purposes of calculating burden, the Department assumes that minimum necessary determinations generally are made outside of a patient encounter by workforce members at a registered nurse level, although the Department believes workforce members at a variety of levels in an organization may apply a covered entity's minimum necessary policies and procedures to routine disclosures of PHI. Recognizing the variability among the types and complexity of requests for PHI received by various types of covered health care providers and health plans, and that some record requests are not subject to the minimum necessary standard (*e.g.,* requests from treating providers or requests accompanied by authorizations from individuals), the Department has calculated a range of estimates for cost savings resulting from the combined effects of the proposed regulatory modifications to the definition of health care operations, and to the minimum necessary standard for disclosures for care coordination. At the low end, the Department estimates a cost savings of 1 hour of labor annually per covered entity at the adjusted mean hourly rate of a health services manager ($110.74, including benefits) for a total reduction of 774,331 burden hours and an annual cost savings of $85,749,415. At the high end, the Department estimates costs savings of 7 hours of labor for a total annual reduction of 5,420,317 burden hours and $600,245,905 in cost savings.

The Department proposes to adopt the mid-range estimate of burden reduction, which is 4 hours per covered entity per year for an annual reduced total of 3,097,324 burden hours and $342,997,660 in total annual projected cost savings. The estimate assumes that covered entities already are making minimum necessary determinations as part of normal workflow. These proposals do not introduce a new process into that workflow, but likely will tilt the scale in favor of disclosure rather than non-disclosure. The difference in the low and high end of the range is based on the Department's assumption that there is a wide range in the level of complexity of minimum necessary determinations that each covered entity makes for routine and non-routine requests for, or disclosures of, PHI. Using the mid-range estimate, the Department estimates that under the current rule covered entities spend, on average, one and a half hours of workforce member time per month evaluating uses and disclosures to comply with the minimum necessary requirement, or 18 hours annually. The Department estimates that the cost savings from its proposed changes with respect to uses and disclosures in connection with care coordination and case management would equal 25 minutes of burden reduction for each covered entity for a total annual burden reduction of 4 hours per covered entity, resulting in remaining annual burden for complying with the minimum necessary requirement of 14 hours on average. The Department welcomes comments and information about its estimates and the assumptions underlying its proposed burden calculations and cost savings, including:

- The level of workforce member (*e.g.,* clerical staff, professional) responsible for making minimum necessary determinations on behalf of covered health care providers and health plans and a description of how the determination is made based on a covered entity's minimum necessary policies and procedures;
- Time spent by a covered health care provider or health plan to make a minimum necessary determination;
- The frequency with which a covered health care provider or health plan makes minimum necessary determinations (*i.e.,* the number of determinations by day or month); and
- The frequency with which a covered health care provider or health plan currently obtains individuals' authorizations prior to making a disclosure of PHI for care coordination or case management for that individual.

xvi. Costs Arising From Adding an Exception to the Minimum Necessary Standard For Disclosures for Individual-Level Care Coordination and Case Management

The proposed changes to the minimum necessary standard are deregulatory in nature, so the Department anticipates that the costs arising from the proposal to add an exception to the minimum necessary standard would be due primarily to time spent revising policies and procedures for using and disclosing information and updating the content of workforce

[314] *Available* at *https://www.meps.ahrq.gov/mepsweb/.*

[315] *Available* at *https://www.cdc.gov/nchs/nhis/index.htm.*

[316] Comment No. HHS–OCR–2018–0028–0601.

[317] Comment No. HHS–OCR–2018–0028–0998.

[318] Comment No. HHS–OCR–2018–0028–0990.

training. While the expenses of actually conducting such training typically would be included in such estimates, the Department would expect covered entities to include the updates in their existing HIPAA training and, thus, to incur additional training costs only for updating the training content. The Department estimates that changes to policies and procedures for minimum necessary and disclosures for care coordination and case management would require 75 minutes of lawyer time at an adjusted mean hourly rate of $139.72, and revisions to training content would require one hour of training specialist time (including related training for care coordination and case management definitions and disclosures to third parties, such as social services agencies, community based support programs, and HCBS providers) at an adjusted mean hourly rate of $63.12.

xvii. Estimated Cost Savings From Changing ''Professional Judgment'' to ''Good Faith'' and ''Imminent'' to ''Reasonably Foreseeable''

The Department proposes to amend five provisions of the Privacy Rule to replace the exercise of ''professional judgment'' with a ''good faith belief'' as the standard to permit certain uses and disclosures in the best interests of the individual, to apply a presumption of compliance with the good faith requirement, and to replace ''serious and imminent threat'' with ''serious and reasonably foreseeable threat'' in 45 CFR 164.512(j)(1)(i)(A). As discussed in the analysis of non-quantifiable benefits, the Department does not have data sufficient to estimate the reduction in professional time spent analyzing the risk of harm; however the Department believes this change would result in cost savings to covered entities, in addition to the cost savings from improved patient safety and treatment outcomes, as well as, potentially, the decreased costs due to avoided public safety incidents The Department seeks comment on the potential cost savings from this proposed change.

xviii. Costs Arising From Changing ''Professional Judgment'' to ''Good Faith'' and ''Imminent'' to ''Reasonably Foreseeable''

The Department anticipates that some covered entities, such as covered entity facilities that maintain patient directories and covered entity facilities and providers that routinely treat patients with SMI or SUD, would need to update their policies and procedures and train their workforce about the modifications to the Privacy Rule. The Department estimates that these costs would be due to one hour of a lawyer's time to update policies and procedures (for a total of 768,169 burden hours at a cost of $107,328,573) and 40 minutes of a training specialist's time to update related HIPAA training content (for a total of 512,113 burden hours at a cost of $32,324,552). The Department believes there may be some initial increase in costs for health plans, including Medicare and state Medicaid agencies, who pay for treatment or recovery of individuals experiencing substance use disorder due to the increase in disclosures to family members and other caregivers. In this regard, the Department believes that family members and caregivers are likely to encourage and support these individuals in seeking treatment, and thus that these individuals will be more likely to seek or remain in treatment. However, the Department would expect lower long-term costs for potentially avoiding public safety incidents, emergency health care services to offset any initial higher utilization costs. The Department also acknowledges the concerns that the proposed changes could have the unintended adverse effect of deterring some individuals from seeking care, due to concerns about providers disclosing PHI to family members and others. The Department seeks comment on the extent to which the proposed changes would support or frustrate access to effective treatment, or impose costs and burdens on individuals or covered entities.

xix. Estimated Cost Savings From Eliminating the Acknowledgment of Receipt of the NPP

The Department proposes to eliminate the requirements in 45 CFR 164.520 for certain covered health care providers [319] to obtain a written acknowledgment of receipt of the providers' NPP and, if unable to obtain the written acknowledgment, to document their good faith efforts and the reason for not obtaining the acknowledgment. The proposal also would remove the current requirement to retain copies of such documentation for six years. The Department estimates that approximately 613 million individuals annually receiving care for the first time from a covered health care provider would receive the NPP from the health care provider.[320] In a prior Paperwork Reduction Act burden estimate, the Department projected that the requirements related to disseminating and obtaining an acknowledgment would impose, on average, three minutes for each covered health care provider with a direct treatment relationship with an individual to disseminate each notice and obtain a documented acknowledgment of receipt, or document the good faith effort to obtain the acknowledgment and reason it was not obtained.[321] This estimate was based on the assumption that the required notice and acknowledgment would be bundled with and disseminated with other patient materials. The total annual burden associated with this requirement was calculated to be 30,650,000 hours.[322]

In the 2018 RFI, the Department solicited public input to evaluate the accuracy of its burden estimates associated with obtaining an individual's acknowledgement of receipt of the NPP. Question 43 of the 2018 RFI asked ''[w]hat is the burden, in economic terms, for a covered health care provider that has a direct treatment relationship with an individual to make a good faith effort to obtain an individual's written acknowledgement of receipt of the provider's NPP? OCR requests estimates of labor hours and any other costs incurred, where available.'' [323] Question 49 asked ''[w]hat is the burden, in economic terms, for covered health care providers to maintain documentation of the good faith effort to obtain written acknowledgement and the reason why the acknowledgment was not obtained? What alternative methods might providers find useful to document that they provided the NPP?'' [324] Comments highlighted the burden but did not provide estimated numbers of labor hours associated with these activities. For example, one commenter representing community pharmacies noted that pharmacists spend ''many hours'' verifying and making good faith attempts to obtain an individual's written acknowledgment of receipt of the providers' NPPs in face-to-face or mail interactions. Removing this requirement would lead to ''additional

[319] The requirements related to the acknowledgment of receipt of an NPP apply only to covered health care providers that have direct treatment relationships with individuals. *See* 45 CFR 164.520(c)(2)(ii) and (3)(iii); 45 CFR 164.520(e).

[320] *See* 81 FR 31646 (May 19, 2016). The ICR estimated 613 million individuals would receive the notice of privacy practices from a health care provider and 100 million would receive the notice from their health plan via direct mail and another 100 million individuals would receive the notice from their health plan electronically.

[321] *Ibid.*

[322] *Ibid.*

[323] *See* 83 FR 64302, 64308 (December 14, 2008).

[324] *Id.* at 64309.

labor hours'' to spend with patients.[325] Another commenter discussed the burden associated with its field-based programs to obtain a signed acknowledgment of receipt, but did not describe the economic burden. This same commenter also noted that its NPP was always bundled with patient intake forms described as ''numerous'' and a part of a lengthy process but did not provide more specific data other than to state that the full NPP was eight pages.[326] Yet another commenter, a large medical group, responded that NPPs are part of a package of documents provided to patients at intake or registration, but the number of pages ''varies widely'' depending on the setting and nature of the particular provider. This same commenter explained that NPP acknowledgement forms were stored in the patient record but rarely, ''if ever,'' referenced.[327]

The Department acknowledges the uncertainty and wide variability in how different covered health care providers disseminate the NPP acknowledgement and make a good faith attempt to obtain the signed acknowledgement and store and maintain it. The comments to the 2018 RFI, described above, demonstrate that quantifying the burden would necessarily include examining the manner or process by which a covered entity obtains the acknowledgement, as well as the format. With the increasing use of technology by covered entities (*e.g.,* electronic check-in), it is reasonable to assume that the time associated with this burden is low in some instances but higher for those covered entities that have not integrated technology into the process, or who have fully integrated the acknowledgment into other NPP processes that may need to be revised if the proposal is finalized. Therefore, the Department is estimating a range, from 30 seconds to 2 minutes and 55 seconds, taken to disseminate the NPP acknowledgement, request the patient's signature, explain what the acknowledgement consists of, wait for the patient to sign, complete the check-off or other procedure applied when the patient is unable or unwilling to sign, file the acknowledgement documentation, and store the documentation for six years. The Department estimates that covered health care providers would experience total annual savings of: 5,108,331 burden hours and $153,454,272 in cost savings at the low end, up to 29,798,610 burden hours and $895,150,257 in cost savings at the high end. The Department utilizes the mid-range estimate of 17,879,169 reduction in burden hours for an annual cost savings of $537,090,228 associated with the proposal to eliminate the requirements associated with the good faith attempt to obtain acknowledgment of receipt of the NPP.

While the wide variation in procedures that covered health care providers use to fulfill the current requirements does not allow for precise quantification of burdens, the Department's assumptions and estimates reflect reasonable analysis of the available data and consideration of public input. With respect to the low end of the range, the Department assumes that in some instances, such as when a covered health care provider uses electronic means to disseminate and obtain the acknowledgement, the burden hours associated with these activities may be near negligible. For estimates at the high end of the range, the Department assumes that these covered entities expend more labor hours to disseminate and collect paper forms with individuals' signed acknowledgments of receipt of the NPP and file the forms. The Department accounts elsewhere in this regulatory impact analysis (RIA) for the increased time associated with the new individual right to discuss a covered entity's privacy practices. The remaining burden of one minute and 15 seconds encompasses time for direct treatment providers to copy and distribute each NPP. The Department calculates, based on the mid-range estimate of hours of a clerical employee's time (based on an adjusted mean hourly rate of $30.04) that this proposal would result in an estimated annual savings of $537,090,228. The Department seeks comment and other examples of how these reductions in compliance burdens translate into quantifiable cost savings, including the time spent by a covered health care provider to conduct the following health care activities, including by electronic means if applicable:

- Disseminate the NPP, including an acknowledgement form;
- Collect the NPP acknowledgment form;
- Determine whether an individual's acknowledgement form is current, including for processes that are paper-based or electronic.

The Department also assumes that eliminating the related requirement to maintain documentation of the acknowledgment of the NPP for six years would result in significant cost savings to direct treatment health care providers in the form of a reduction of one page (electronic or paper) of each patient's record, and reduced space needed for one page of medical records (if that is where such documentation is stored) per patient or reduced electronic storage space for systems that store these notices electronically; however, the Department has not quantified the potential savings. The Department anticipates that most of the savings would result from eliminating the collection and maintenance of these records in the future. The Department seeks comments on the cost savings covered health care providers would be likely to accrue as a result of these proposed changes.

xx. Costs Arising From Eliminating the Acknowledgment of Receipt of the NPP

The Department anticipates no costs for eliminating the requirement for direct treatment providers to make a good faith effort to obtain an individual's signed acknowledgment of receipt of the NPP and to maintain related documentation. The Department welcomes comments on this assumption.

xxi. Estimated Cost Savings Arising From Changes to the NPP Content

The Department proposes to modify the header of the NPP to specify to individuals that the notice provides information about: (1) How to access their health information, (2) how to file a HIPAA complaint, and (3) individuals' right to a copy of the notice and ability to discuss its contents with a designated person. The required header also would have to specify whether the designated contact person is available onsite and must include a phone number and email address an individual could use to reach the designated person.

The Department does not anticipate quantifiable cost savings to covered entities from making the required changes to the NPP; however, the improvements to individuals' right of access may contribute to improvements to health care delivery and the health of patients overall.

xxii. Costs Arising From Changes to the NPP Content

The Department believes the burden associated with revising the NPP consists of costs related to developing and drafting the revised NPP for covered entities. The Department estimates that the proposal to update and revise the language in the NPP (including drafting the language in the header) would require one hour of professional legal services at the wage reported in Table 4. There are no new costs for providers

[325] Comment No. HHS–OCR–2018–0028–0995.
[326] Comment No. HHS–OCR–2018–0028–0559.
[327] Comment No. HHS–OCR–2018–0028–0649.

associated with distribution of the revised notice other than posting it on the entity's website (if it has one), as providers have an ongoing obligation to provide the notice to first-time patients. The Department bases the estimate on its previous estimates from the 2013 Omnibus Rule, in which the Department estimated approximately 613 million first time visits with health care providers annually.[328] Health plans that post their NPP online would incur minimal costs by posting the updated notice, and then, including the updated NPP in the next annual mailing to subscribers.[329]

The Department further estimates the cost of posting the revised NPP on the covered entity's website would be ten minutes of a web developer's time at the wage reported in Table 4.

The Department assumes that about 1% of an estimated 613 million new patients [330] will ask for further discussion with the designated contact person. The Department believes this estimate is reasonable, given public comments indicating that individuals rarely ask questions about the NPP, and the assumption that most requests for discussion will be made in the context of a visit with a health care provider. The Department therefore estimates that 6,130,000 individuals may ask for a discussion on the NPP as a result of OCR's media campaigns as well as through general awareness of individual privacy rights under HIPAA. The Department does not have data to support a different assumption or estimate at this time, and the Department requests such data for future consideration. In particular, the Department seeks comments addressing the likelihood and any associated burden that individuals will contact their health plans to request a discussion of the plans' privacy practices, and if so, the frequency with which health plans would be contacted for these conversations. The Department estimates that its proposal to require covered entities to make available a person who may be contacted for further information on the covered entity's privacy practices would add $8.69 in burden per request for information or $53 million (or 715,167 burden hours) total per year. The Department assumes each discussion between the contact person and individual will last an average of 7 minutes as individuals ask questions and receive answers, at the adjusted mean hourly rate for a registered nurse, as reported in Table 4.

The Department invites comments on all aspects of its estimates and assumptions, including the time spent on the identified activities and the occupations or professions of persons designated to perform those tasks.

xxiii. Estimated Cost Savings From Adding a Permission to Disclose PHI to a TRS Communications Assistant

The Department proposes to expressly permit covered entities (and their business associates, acting on the covered entities' behalf) to disclose PHI to TRS communications assistants to conduct covered functions, at proposed 45 CFR 164.512(m), and to expressly exclude TRS providers from the definition of business associate at 45 CFR 160.103.

Based on information from stakeholders, the Department believes that some covered entities with workforce members who are deaf, hard of hearing, or deaf-blind, or who have a speech disability may have entered into, or tried to enter into, a business associate agreement with a TRS provider before permitting a workforce member to disclose PHI to a TRS communications assistant, while others limited the use of TRS communications assistants by workforce members. Thus, some covered entities incurred legal costs for entering into a BAA or for analyzing the legal risk of not permitting workforce members to use needed accommodations, which they would not have to incur under the proposed changes. The Department lacks sufficient data to quantify the cost savings of this proposed change, and requests comment on the extent to which covered entities and business associates currently have business associate agreements with TRS providers, and on any costs such entities incur when analyzing whether a business associate agreement is needed.

xxiv. Costs Arising From Adding a Permission to Disclose PHI Through TRS

The Department has not identified any additional costs to covered entities arising from the proposed change other than changes to policies and procedures and training, as TRS is provided without charge to the user.[331]

g. Quantifiable Cost Savings Estimates

Table 10 summarizes the estimated annual cost savings of the proposed rule for covered entities, as described in the preceding section.

TABLE 10 [a]

Cost item	Burden count	Multiplier	Savings (millions)
Clarifying Minimum Necessary	4 hours of health manager time × $110.74 = $442.96.	Total CEs (774,331)	$343
Eliminating NPP Acknowledgment	1 minute 45 seconds (.0292) of clerk/receptionist time × $30.04 = $.877.	613,000,000 1st time encounters	537
Total Annual Cost Savings			880
Total Cumulative Cost Savings (5 years) (undiscounted).			4,400

[a] Totals may not add up due to rounding.

[328] 78 FR 5566, 5675 (January 25, 2013).

[329] 45 CFR 164.520(c)(1)(v)(A).

[330] *See* 81 FR 31646 (May 19, 2019) and related explanation that there are an estimated 613 million individuals who would receive the NPP.

[331] *See* FCC's 2017 ''Consumer Guide, Telecommunications Relay Service'', available at *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

h. Estimated Quantifiable Costs to Covered Entities

The Department summarizes in Table 11 the additional estimated administrative costs that entities would incur on a one-time basis in the first year of implementing the proposed regulatory changes. The Department anticipates that these costs would be for posting an access fee schedule online for entities that have not already done so and posting a revised NPP online.

TABLE 11

One-time costs	Burden count	Multiplier	Total administrative cost (millions)
Post access fee schedule online	10 min. × web developer ($79.20) = $13.20.	Total covered entities (774,331)	$10
Post revised NPP online	10 min. × web developer ($79.20) = $13.20.	Total covered entities (774,331)	10
Total One-Time Administrative Burden.			[a] 20

[a] Totals may not add up due to rounding.

Table 12 summarizes the ongoing labor costs that the Department anticipates covered entities would incur as a result of the proposed regulatory changes. These new requirements would be based on an individual's request and include providing copies of PHI and ePHI under the right of access within a shorter time, providing an estimate of access and authorization fees, providing an itemized list of allowable access charges, discussing privacy practices with individuals, and submitting requests for copies of PHI to health care providers or health plans.

TABLE 12a [a]

Ongoing costs	Burden hours & pay	Multiplier	Total annual administrative cost (millions)
Access for Individuals —Search and retrieval within shorter times.	1 min. × records technician time ($44.80) = $.75.	50% of 2,460,000 access requests = 1,230,000.	$.9
Sending copies of ePHI to third parties other than covered entities—Non-internet based method.	2 min. × records technician time ($44.80) = $1.49.	25% of 615,000 access requests = 153,750.	[b] 0.230
Sending copies of ePHI to health plans and providers under the right of access—Non-internet methods.	4 min. × records technician time ($44.80) = $2.99.	25% of 615,000 access requests = 153,750.	[c] 0.459
Providing good faith fee estimates upon request.	3 min. × records technician time ($44.80) = $2.24.	3% (.03) of 2,460,000 access requests = 73,800.	0.165
Providing itemized list of access and authorization fees upon request.	1 min. × records technician time ($44.80) = $0.75.	1% (.01) of 2,460,000 access requests = 24,600.	[d] .018
Discussing privacy practices with individuals upon request.	7 min. × registered nurse time ($74.48) = $8.69.	1% (.01) of 613 million 1st time encounters = 6,130,000 requests.	53
Submitting access requests to providers & plans for individuals.	3.5 min. × medical assistant time ($34.34) = $2.00.	15% (.15) of 615,000 access requests = 92,250.	0.185
Total Ongoing Annual Administrative Burden.			55

[a] Totals may not add up due to rounding.
[b] The estimate is $229,600.
[c] The estimate is $459,200.
[d] The estimate is $18,368.

The total estimated additional first year administrative labor costs (including costs that will be ongoing) would be approximately $76 million (Table 11 total and Table 12a total).

Table 12b summarizes the increased capital costs that covered entities are estimated to incur as a result of the proposed new section 45 CFR 164.525 with respect to fee estimates for copies of PHI provided under the right of access and with a valid authorization.

TABLE 12b

Fees estimates section	Proposed regulatory requirement	Number of pages to be printed	Average cost	Total
164.525	Making fee schedule available at the point of service and upon request	2,322,993	$0.10	$232,299
164.525	Provide an individualized estimate of fees by mail [a]	11,070	[b] 0.69	7,638
164.525	Printing itemized list of copy charges [c]	[d] 24,600	0.10	2,460
Total Capital Costs		.....	.....	242,398

[a] This represents only the requests for which the individual asks for a written estimate to be mailed to them, which the Department estimates to be 10% of the annual 2.46 million total access requests.
[b] This includes costs for printing ($0.08), postage ($0.55), paper ($.02), and an envelope ($.04).
[c] This estimate assumes that the itemized list of charges would be included in the mailing of requested copies of protected health information, so postage costs are not added here.
[d] 1% of 2.46 million annual total access requests.

i. Additional Costs for Revising Policies and Procedures

Table 13 summarizes the total projected costs for covered entities to revise their policies and procedures to comply with the proposed regulatory changes to the Privacy Rule. The Department includes the costs for legal review and drafting of policies and for a compliance manager to revise procedures for relevant workforce members or departments.

TABLE 13

Revising policies & procedures	Time (mins.)	Covered entities affected	Burden hours
Minimum Necessary, Disclosures for Care Coordination & Disclosures to Social Services Agencies & CBOs.	75	774,331	967,914.
Right of access (multiple provisions, including fee schedule) ..	180	774,331	2,322,993.
Disclosures to family & friends of individual; Disclosures to prevent harm.	60	768,169 (providers)	768,169.
Revise NPP	60	774,331	774,331.
Disclosures for Uniformed Services & TRS	10	774,331	129,055.
Simplify verification & revise form	30	5% of 774,331 covered entities = 38,717.	19,358.
Total Burden Hours	.....	.....	4,981,820.
Total Costs	.....	.....	$696 million.

j. Estimated Additional Costs for Revising HIPAA Training Programs

TABLE 14

Training content to be revised	Time (mins)	Covered entities affected	Burden hours
Minimum Necessary, Disclosures for Care Coordination, & Disclosures to Social Services Agencies & CBOs.	60	774,331	774,331.
Changes to Access Times, Changes to Access Procedures, Submitting PHI to Providers & Plans, and Fees and Estimates.	150	774,331	1,935,828.
Disclosing PHI to Family & Friends; Uses and Disclosures to Prevent Harm.	40	768,169—Providers	512,113.
Disclosures for Uniformed Services; Telecommunications Relay Services.	15	774,331	193,583.
Right to Discuss NPP	5	774,331	64,528.
Verification of Identity	10	5% of covered entities = 38,717.	6,453.
Total Time to Update Training Content	.....	.....	3,486,834.
Total Costs for Updating Training Content	1 hour of Training Specialist time = $63.12		$220 million

The Department also estimates potential increased first-year costs for training medical records technicians to initially implement the changes to the right of access procedures, as shown in Table 14b.

TABLE 14b

Staff in training	Hourly wage [a]	Time (in minutes)	Covered entities affected	Burden hours	Costs (in millions)
Medical Records Technician	$44.80	7	774,331	90,339	$4,047

[a] *See* Table 4.

TABLE 14c—TOTAL ESTIMATED TRAINING COSTS

[Table 14a and 14b]

Cost item	Burden hours	Costs (in millions) [a]
Updated Training Content	3,486,834	$220
Increased Time in Training	90,339	4
Total New Training Costs	3,577,173	224

[a] Totals may not add up due to rounding.

k. Costs Borne by the Department

The Department expects that it would incur costs related to disseminating information about the proposed regulatory changes to covered entities, including health care providers and health plans. However, the Department expects that many of these costs could be made part of the ongoing dissemination of guidance and other explanatory materials that OCR already provides. The covered entities that are operated by the Department would be affected by the proposed changes in a similar manner to other covered entities, and those costs have been factored into the estimates above.

l. Comparison of Benefits and Costs

The Department expects the benefits of the proposed rule to outweigh any costs because covered entities will save costs each year after the first year, having experienced initial higher costs related to implementation of proposed changes. The proposed changes to, or clarifications of, the minimum necessary standard, access fees, and the acknowledgment of the NPP would be largely deregulatory. The Department expects covered entities and individuals to benefit from the increased flexibility and confidence covered entities would have to act in individuals' best interests without undue concerns about HHS enforcement actions. The Department also expects covered entities to realize savings from less frequent consultations with legal counsel about when they can disclose PHI regarding individuals who are incapacitated or experiencing another emergency and reductions in minimum necessary analyses when disclosing PHI for individual-level health care coordination and case management activities that constitute treatment or health care operations. The Department further expects that, by involving family members and others, this proposed action would result in improved care coordination and case management and better patient health outcomes. The Department also expects that changes to the right of access, such as a shortened time limit for responding to a patient's request, the right to photograph or otherwise capture PHI using the individual's own device, and the right to an estimate of access and authorization fees, would significantly strengthen the access right, to the benefit of individuals. Additionally, replacing the requirement to obtain an acknowledgment of an individual's receipt of the NPP with an individual right to discuss a covered entity's privacy practices upon request would improve access to care and strengthen individual's understanding of their rights. The Department expects these benefits would substantially outweigh estimated costs, such as covered entities providing access in a shorter time, providing the new discussion right, posting an access fee schedule, modifying internal policies, and providing new trainings to workforce members.

The Department requests comment on these assumptions and on all aspects of this regulatory impact analysis. The tables below present the Department's summary of estimated quantifiable costs and cost savings (Tables 15 and 16), cost transfers (Table 17), and non-quantifiable costs and benefits (Table 18).

TABLE 15—FIRST YEAR ESTIMATED QUANTIFIABLE COSTS/COST SAVINGS TO COVERED ENTITIES, IN MILLIONS [a]

Cost item	Costs	Savings
Revised Training	$224	
Revising P&P	696	
Administrative Costs	76	
Capital Costs	0.242	
Eliminating NPP Acknowledgment		($537)
Clarifying Minimum Necessary		(343)
Total	996	(880)
Net Savings/Cost—First Year		116

[a] Totals may not add up due to rounding.

TABLE 16—ONGOING ESTIMATED QUANTIFIABLE ANNUAL COSTS/COSTS SAVINGS ESTIMATES TO COVERED ENTITIES, IN MILLIONS

[Years 2–5] [a]

Cost item	Costs	Set-off amount (savings)
Access & Administrative Costs	$55	.....
Capital Costs	0.242	.....
Eliminating NPP Acknowledgment	.....	($537)
Clarifying Minimum Necessary	.....	(343)
Total	55	(880)
Net Costs/Savings	.....	(825)

[a] Totals may not add up due to rounding.

TABLE 17—ESTIMATED TRANSFERS, IN MILLIONS

Cost item	Amount of costs transferred (transferors)	Amount of new costs incurred (transferees)
Decreased fees for providing electronic copies in an EHR on electronic media to individuals.	$1.4 (individuals)	$1.4 (covered entities, primarily providers).
Additional fees for authorizing copies of non-EHR PHI to a third party.	43 (covered entities, primarily health care providers): 615,000 access requests × $70 average estimated increased fee.	21.5 (individuals). 21.5 (third party recipients).

Covered entities would benefit from a total estimated net increase of $41.6 million in transferred costs for allowable fees for providing copies of PHI, while individuals would incur the same amount.

TABLE 18—NON-QUANTIFIABLE COSTS/BENEFITS FOR COVERED ENTITIES AND INDIVIDUALS

Regulatory changes	Costs	Benefits
Changing to minimum necessary, health care operations definition, and the addition of permissible disclosures to social services agencies.	Potential increase in number of requests for disclosures for certain care coordination and case management purposes.	Improved care coordination and case management, resulting in better health outcomes.
Changing from ''professional judgment'' to ''good faith'' and from ''imminent'' to ''reasonably foreseeable''.	Potential increased complaints to OCR from individuals who did not want their PHI used or disclosed; potential to chill some individuals' willingness to access care.	Improved care coordination and case management; increased harm reduction; likely increase in adherence to treatment and increased service utilization.
Changing verifications	.....	Improved access to PHI.
Adding permission to disclose to TRS and excluding TRS providers from the definition of business associate.	.....	Improved employment conditions and opportunities for workforce members who are deaf, hard of hearing, or deaf-blind, or who have a speech disability; improved compliance with non-discrimination laws.
Adding right to discuss covered entity privacy practices, eliminating NPP acknowledgment requirement & changes to NPP.	.....	Improved understanding of individuals' rights & covered entities' privacy practices; improved access to care.
Better enabling individuals to direct the transmission of electronic PHI in an EHR among providers and plans as part of the right of access.	.....	Improved care coordination and case management; increased individual control over directing ePHI for health-related purposes.
Strengthening right of access (free online access; shorter access times; right to inspect; access fee information).	Increased burden on individuals to directly obtain lower cost copies of non-EHR PHI and send it to third parties to avoid paying higher fees under an authorization.	Improved access to PHI by individuals—receiving PHI twice as fast; improved access to ePHI by providers & plans; reduction in access fee disputes/improved collection of access fees; increased certainty about allowable fees; increased adoption and utilization of EHR technology.
Restricting the right to request that a covered entity direct the transmission of certain PHI to a third party.	Increased burden on individuals to submit two forms: An access request and an authorization, when seeking to send a complete medical record to a third party.	Improved clarity and certainty for covered entities.

TABLE 18—NON-QUANTIFIABLE COSTS/BENEFITS FOR COVERED ENTITIES AND INDIVIDUALS—Continued

Regulatory changes	Costs	Benefits
Adding an optional element of the NPP for covered entities to provide information about alternate ways to obtain PHI directly or have it sent to a third party, for certain requests to direct the transmission of certain PHI to a third party.	.....	Increased knowledge by individuals of their rights to access and their options for accomplishing their information sharing goals.

The Department's costs-benefits analysis asserts that the proposed regulatory changes would significantly advance care coordination and the transformation to value-based care and strengthen individual rights. Although there is a projected total net cost of $116 million in the first year, the total estimated annual net cost savings to covered entities in subsequent years would be approximately $825 million, with total projected net savings of $3.2 billion and an average increase in allowable fees for copies of $70 per request to direct copies of PHI to third parties.

m. Uncertainty Analysis for Estimated Costs and Cost Savings

The Department has analyzed a range of estimated costs and costs savings for key compliance burdens that are likely to be affected if the proposed regulatory changes are implemented as outlined. The Department performed an uncertainty analysis for each of the main drivers of costs and cost savings, reporting low, mid, and high values for each category, and for the proposed rule as a whole to better capture the range of potential outcomes. In summary, the Department estimates total costs of implementation over a five-year period ranging from a low of approximately $0.8 billion to a high of approximately $4 billion and a range of five-year cost savings of approximately $1.2 billion to $7.5 billion.

TABLE 19—RANGE OF TOTAL ESTIMATED COSTS OVER FIVE YEARS

[2021–2025]

Cost item	Low	Mid	High
Training	$195,651,092	$224,136,148	$250,512,185
Policies & Procedures	542,791,420	696,059,917	1,302,384,017
Access & Administrative Tasks	40,984,833	296,648,766	2,879,447,799
Capital Costs	1,175,457	1,211,988	1,979,493
Total Costs	780,602,802	1,218,056,819	4,434,323,494

TABLE 20—RANGE OF TOTAL ESTIMATED COST SAVINGS OVER FIVE YEARS

[2021–2025]

Cost savings item	Low	Mid	High
Eliminating NPP Acknowledgement	$767,271,360	$2,685,451,140	$4,475,751,287
Clarifying Minimum Necessary	428,747,075	1,714,988,299	3,001,229,523
Total Cost Savings	1,196,018,434	4,400,439,439	7,476,980,809

i. Cost Estimates

Updated Training Content

Because required HIPAA training is based on covered entities' policies and procedures, changes to the policies and procedures are accounted for separately, and a training specialist's time is allocated for time spent in updating existing training content. The burden hours are based on an adjusted hourly cost of $63.12 (see table 4). The content area for which the greatest training burden is estimated is due to the combination of proposed changes to the right of access and the new right to request fee estimates and itemized lists of charges for copies of PHI. At the low end, the Department estimates a burden of two hours for updating this section of the training content, and at the high end, three hours. This results in a low estimate of 1,548,662 total annual burden hours for all covered entities at a one-time cost of $97,751,545 and a high estimate of 2,322,993 burden hours at a cost of $146,627,318 for updating the access portions of the training program. The Department proposes to adopt a mid-range estimate of 2 hours and 30 minutes to update the access and fee estimate portions of the training content for a total of 1,935,828 burden hours at a cost of $122,189,432. The Department also estimates additional time spent in training for an average of one medical records technician per covered entity in the first year at an adjusted hourly labor cost of $44.80 (see Table 4), ranging from a low of 5 minutes to a high of 10 minutes. Overall one-time training costs for all proposed changes to the Privacy Rule are estimated to range from a low of $198,541,928 (and 3,164,196 burden hours) to a high of $250,512,185 (and 4,006,281 burden hours). The Department proposes adopting a mid-range estimate of 3,577,173 total burden hours at a one-time cost of $224,136,148. The 2013 Omnibus Final Rule contained no cost estimates for updates to HIPAA training programs and in the 2000 Privacy Rule the Department based its estimates on the time spent by covered entity workforce members to participate in training and not the time for a training specialist to update training content. In 2000, the Department anticipated that, in part,

professional associations and other organizations would develop training for different types of covered entities, thus reducing potential burden for implementing the new requirement. Because time spent in training by workforce members is already an acknowledged burden, the training estimates developed for this proposed rule reflect only the new burden: The time to update training program content. These estimates are slightly less than those for updating policies and procedures, to reflect that the foundation for the work is already laid by the updated policies and procedures established by legal counsel.

Updated Policies and Procedures

The Department estimates a range of average total burden hours per covered entity to update policies and procedures as a result of the proposed modifications to the Privacy Rule, based on only the adjusted hourly wage for a lawyer of $139.72 (see Table 4) for the low and mid-range estimates, and adds the adjusted hourly wage for a health care manager of $110.74 for the high-range estimate. At the low end, the Department estimates a total burden per covered entity of 5 hours and 30 minutes (for a total of 3,884,851 hours and a cost of $542,791,420) for updating policies and procedures and at the high end 13.51 hours (for a total of 10,014,867 hours and a cost of $1,302,384,017). The Department proposes adopting a mid-range estimate of 6 hours and 55 minutes for a total estimate of 4,981,820 burden hours at a one-time cost of $696,059,017.

Access and Administrative Tasks

Post an Access Fee Schedule Online

The Department estimates a low burden of 8 minutes of a web developer or designer's hourly wage of $79.20 (see Table 4) to post an access fee schedule online per covered entity and a high estimated burden of 15 minutes. These costs would range from 103,244 total annual burden hours to 193,583 burden hours, and costs of $8,176,935 at the low end to $15,331,754 at the high end. The Department proposed to adopt the mid-range estimate of 10 minutes for posting the new access fee schedule for a one-time total of 129,055 burden hours and a cost of $10,221,169.

Post an Updated Notice of Privacy Practices (NPP)

The Department estimates a range of costs for covered entities to post an updated NPP at the hourly wage of a web developer or designer from a low of 8 minutes (and total burden hours of 103,244) to a high of 15 minutes (and total burden hours of 193,583), and total costs from a low of $8,176,935 to a high of $15,331,754. The Department proposes to adopt the mid-range estimate of 10 minutes for posting the revised NPP for a one-time total of 129,055 burden hours and a cost of $10,221,169.

Unreimbursed Costs of Providing Access

The Department has separately estimated the charges that a covered entity may pass on to individuals who request copies of their PHI in the form of fees and allocated those as a transfer of costs. However, the Department estimates that due to the proposed changes to the access right covered entities may incur some costs above those that are allowed to be charged as fees. The Department has developed a range of cost estimates based on the hourly wage of a medical records technician ($44.80, see Table 4), ranging from .5 to 2.5 additional minutes of labor, and total burden hours ranging from a low of 10,250 total annual burden hours to a high of 51,250 hours. Annual cost estimates range from a low of $459,200 to a high of $2,296,000. The Department proposes to adopt the mid-range estimate of 1 minute per request of uncompensated labor for providing access within a shorter time period for a total of 20,500 annual burden hours and an annual cost of $918,400. All of these estimates are based on an estimate that 50 percent of the total estimated 2,460,000 annual access requests (or 1.23 million) will be from individuals seeking copies of their own PHI or ePHI.

Submit Access Requests for Individuals to Health Plans and Providers

The Department estimates on the low end that 10 percent of the total 615,000 requests by individuals to direct electronic copies of their PHI to their health care provider or health plan will be made by requesting that the receiving health care provider or health plan submit the request on the individual's behalf (or 61,500) and on the high end that 20 percent of such requests (or 123,000) will be made by requesting the assistance of the receiving health care provider or health plan. The Department believes that a medical assistant would submit these access requests to health plans and providers for individuals, at an hourly wage of $34.34 (see Table 4). The range of estimated costs is based on a low estimate that this task, on average, will take 2 minutes to complete, to a high estimate of 5 minutes. The total estimated annual burden hours ranges from 2,050 (and a cost of $70,397) to 10,250 (and a cost of $351,985). The Department proposes to adopt the mid-range estimate of 3.5 minutes for submitting 92,250 requests (15 percent of 615,000) for individuals for a total of 5,381 annual burden hours and an annual total cost of $184,792.

Transmit ePHI to Health Plans and Providers Through Non-Internet Means

The Department's proposal to prohibit covered entities from charges fees for the labor associated with sending electronic copies of PHI through non-internet means (*e.g.,* the mail) could result in some unreimburseable costs for covered entities. The Department estimates that the costs would be based on the hourly wage of a medical records technician ($44.80, see Table 4) and a low estimate of 3 minutes to a high estimate of 5 minutes for 153,750 requests (representing 25 percent of the estimated 615,000 total annual requests to direct copies of PHI to health plans and providers). This results in a low estimate of 7,688 total annual burden hours at a cost of $344,400 and a high estimate of 12,813 total annual burden hours at a cost of $574,000. The Department proposes to adopt the mid-range estimate of 4 minutes per request for transmitting ePHI to health plans and providers through non-internet means for a total of 10,250 annual burden hours and a cost of $459,200. These estimated costs have not been previously calculated as a potential burden on covered entities and the Department requests comment on these ranges and the assumptions underlying them.

Transmit ePHI to Third Parties Through Non-Internet Means

The Department estimates that the unreimburseable costs for transmitting electronic copies of ePHI to third parties other than health plans and providers would be half of that for transmitting the same information to health plans and providers because some of the costs are likely to be charged as fees to individuals for copies. The estimated costs are based on the hourly wage of a medical records technician ($44.80, see Table 4), ranging from a low estimate of 1.5 minutes to a high estimate of 2.5 minutes for 153,750 requests (representing 25 percent of the total estimated 615,000 annual requests to direct copies of PHI to third parties other than health plans and providers). This results in a low estimate of 3,844 total annual burden hours at a cost of $172,200 and a high estimate of 6,406 total annual burden hours at a cost of $287,000. The Department proposes to adopt the mid-range estimate of 2 minutes per request for transmitting

ePHI to health plans and providers through non-internet means for a total of 5,125 annual burden hours and a cost of $229,600.00.

Providing Fee Estimates

The Department estimates costs for providing good faith individualized fee estimates to individuals for a low of 24,600 requests (1% of total 2.46 million annual access requests) to a high of 123,000 requests (5% of 2.46 million annual access requests). The Department has also estimated the time it would take a medical records technician to develop a good faith individualized fee estimate from a low of 3 minutes to a high of 5 minutes per request, or an annual total of burden hours ranging from 1,230 (at a cost of $55,104) to 10,250 (at a cost of $459,200). The Department proposes to adopt the low-range estimate of 3 minutes of labor and the mid-range number of 73,800 requests (3 percent of 2.46 million total annual access requests) resulting in a total of 3,690 annual burden hours and a total annual cost of $165,312.

Providing Itemized Lists of Charges

The Department estimates costs for providing an itemized list of charges for requested copies of requested PHI, ranging from a low of 2,460 requests (0.1% of total 2.46 million annual access requests) to a high of 123,000 (5% of total annual access requests). The Department has also estimated a range of burden from a low of 41 total annual burden hours (at a cost of $1,837) to a high of 2,050 total annual burden hours (at a cost of $91,840). The Department proposes to adopt the mid-range estimate of 410 annual burden hours and a total annual cost of $18,368.

Discussing Privacy Practices

The Department estimates a range of costs for the requirement to discuss a covered entity's privacy practices with an individual upon request. The range is based on a low of 5 minutes of a registered nurse's time for 613,000 health care encounters (.1% of 613,000,000 total new health care encounters per year) to a high of 10 minutes of a health care manager's time for 30,650,000 health care encounters (5% of total new health care encounters per year). The total estimated annual burden hours for this proposed regulatory change ranges from 51,083 at the low end to 5,108,333 at the high end, and costs of $3,804,687 at the low end to $565,696,833 at the high end. The Department proposes to adopt the mid-range estimate of 7 minutes of a registered nurse's time for 6,130,000 requests (1 percent of 613,000,000) for a total estimate of 715,167 annual burden hours and a total annual cost of $53,265,613.

Capital Costs

The Department estimates annual capital costs for three elements of the proposed rule: making an access fee schedule available, providing fee estimates for copies of PHI, and providing itemized lists of charges for copies of PHI. The capital costs for fee estimates and itemized lists of charges are based on the estimated number of requests, while the range of access fee schedule costs varies due to the number of copies provided by each covered entity. The total annual capital cost estimates range from a low of $235,091, a mid-range of $242,398, to a high of $395,899.

ii. Cost Savings Estimates

Minimum Necessary

Because the Department is without data to estimate the actual average compliance burden, it has calculated a range of estimates for the costs savings resulting from the combined effects of the proposed regulatory modifications to the definition of health care operations and the minimum necessary standard. At the low end, the Department estimates a cost savings of 1 hour of labor annually per covered entity at the hourly rate of a health services manager ($110.74, see Table 4) for a total reduction of 774,331 burden hours and an annual cost savings of $85,749,415. At the high end, the Department estimates costs savings of 7 hours of labor for a total annual reduction of 5,420,317 burden hours and $600,245,905 in cost savings. The Department proposes to adopt an approximate mid-range estimate of burden reduction, which is 4 hours per covered entity for an annual total of 3,097,324 burden hours and $342,997,660 in total annual projected cost savings.

NPP Acknowledgement

The Department has previously estimated a burden of 3 minutes for providing the NPP and obtaining the signed acknowledgement of receipt or documenting a good faith effort to do so. The Department estimates that the requirement to obtain the signed acknowledgement or document a good faith effort accounts for a large portion of the 3-minute burden because it involves engaging with the individual or their personal representative, obtaining or creating documentation, and storing the documentation for each individual. Lacking data to precisely estimate the amount of burden reduction for the proposed removal of the acknowledge requirements, the Department estimates a range of labor cost savings from a high of two minutes and 55 seconds to a low of 30 seconds for each NPP that is provided by a direct treating health care provider to a new patient. On an annual basis for all covered entities, this would range from a total savings of 5,108,331 burden hours and $153,454,272 in cost savings at the low end to 29,798,610 burden hours and $895,150,257 in cost savings at the high end. The Department proposes adopting a mid-range estimate of burden reduction in the amount of one minute and 45 seconds of labor for each NPP due to the proposed regulatory modifications for a total annual reduction of 17,879 burden hours and $537,090,228 of cost savings.

4. Consideration of Regulatory Alternatives

The Department carefully considered several alternatives to issuing this NPRM, including the option of not pursuing any regulatory changes, but rejected that approach for several reasons. First, the proposed regulatory changes would further the Administration's goal of reducing regulatory burden on individuals and the regulated community and promoting care coordination. Second, many commenters on the 2018 RFI believed the Privacy Rule could be improved, and offered comments supportive of some of the ideas suggested in the RFI that now are proposed in this NPRM. Revising the Privacy Rule would clarify covered entities' obligations and flexibilities, improve individuals' access to their PHI, and improve care coordination and case management overall.

a. Increase Outreach and Issue Additional Clarifying Guidance Without Rulemaking

As an alternative to rulemaking, the Department considered expanding OCR outreach, guidance, and educational materials to address misconceptions about (1) when HIPAA permits uses and disclosures of PHI, including to social services agencies and to family, friends, caregivers, and others; (2) what fees may be charged for providing access to PHI; (3) when the minimum necessary standard applies to disclosures for case management and care coordination; (4) when covered entities are required to transmit PHI to third parties, including health care providers and health plans; and (5) when individuals have the right to take photos of their own PHI.

The Department has published extensive guidance on existing

standards in the form of videos, fact sheets, FAQs, decision trees, and infographics. Still, OCR has received comments and heard anecdotal evidence that, despite the existing guidance and ongoing outreach efforts, covered entities remain fearful of incurring HIPAA penalties for using and disclosing PHI in the circumstances addressed in this proposed rule. In addition, some of the beneficial disclosures that this NPRM proposes to expressly permit currently are not permitted, or are burdensome to complete, under the existing Privacy Rule, as described throughout the preamble. Therefore, in addition to continued outreach efforts, the Department believes it would effectively address the concerns outlined in the preamble discussion by modifying the existing standards.

b. Alternative Regulatory Proposals Considered

The Department welcomes public comment on any benefits or drawbacks of the following alternatives it considered while developing this proposed rule.

Right of Access

Changing the Right To Direct Electronic Copies of EHR to a Third Party and Form and Format for Such Requests

The Department considered how to modify the Rule consistent with the HITECH Act and the *Ciox* v. *Azar* decision. An approach considered and not adopted would have created two new unreviewable grounds to deny an access request to direct a copy of PHI to a third party: (1) If the requested copy was for PHI not contained in an EHR; and (2) if the request was for a copy of PHI not in electronic format. As part of the response to the written denial a covered entity would have been required to provide information about how the individual could access the requested PHI directly or how to request it with a valid authorization.

The Department also considered a simplified approach, which would have required a covered entity to inform the individual about other options to obtain PHI, but without creating new grounds for denying the request. Instead, the Department decided to propose an optional element that covered health care providers may add to their Notice of Privacy Practices (NPP) that would address individuals' requests to direct copies of PHI to a third party that are not in an EHR or that are not electronic copies of PHI by informing them of the ability to request the copies of PHI directly and how to use a valid authorization to request the disclosure of the requested copies to a third party.

The Department also considered requiring covered health care providers to provide the electronic copies to third parties in a readable form and format as agreed to by the individual and the covered entity. This approach would not have required health care providers to provide the copies in the format requested by the individual, but would have required some mutual agreement about the format. The Department, however, believes that the *Ciox* v. *Azar* decision does not permit it to propose requirements with respect to the form and format of copies of PHI directed to an individual's designated third party. Instead, the preamble to this NPRM encourages covered health care providers to produce copies in a readable electronic format that provides meaningful access to the requested PHI. The preamble also describes several examples of commonly accepted electronic formats for copies of PHI from an EHR.

As raised in the 2018 RFI, the Department considered whether to require covered entities to disclose PHI to other covered entities for purposes of treatment, payment, or health care operations and variations on that idea, such as limiting the requirement to health care providers or limiting such required disclosures to treatment purposes only. The Department also considered how much individual control should be permitted for disclosures between covered entities, such as an opt-in or opt-out mechanism or some type of express permission. Due to the privacy concerns raised in comments on the RFI, the Department adopted a different approach whereby an individual could direct their current health care provider or health plan to submit an access request to another health care provider (''Discloser'') on the individual's behalf to have the individual's PHI sent to the current provider or plan (''Requester-Recipient''). This new pathway promotes disclosures to individuals' current health care providers and health plans in a manner that retains individual control. The Department believes that this proposal would be less burdensome than imposing mandatory disclosures for all requests for PHI for treatment, payment, and health care operations purposes.

Access Time Limits

The Department considered the feasibility of changing the access time limits by requiring covered entities to provide copies of electronic PHI within a shorter time period than non-electronic PHI. The comments on this question in the 2018 RFI revealed that multiple factors affect how long it takes a covered entity to provide access to PHI, separate from whether the PHI was created, or is maintained, in electronic or non-electronic format. Given this input, the Department believes that imposing a shorter time limit in the Privacy Rule for individual's access to electronic PHI than for non-electronic PHI would create unnecessary complexity and add to covered entities' burdens. For example, a request for a complete medical record may require the production of copies of both electronic and non-electronic PHI, and complying with differing time limits for different parts of a request would be difficult to track. However, the Department's proposals would result in different timelines for electronic and non-electronic copies of PHI sent to third parties because certain requests could be made by means of the right of access (for electronic copies of PHI in an EHR) and other requests would not be within the right of access (for non-electronic copies or electronic copies not in an EHR), and there is no time limit for disclosures requested using an authorization which are not required disclosures.

The Department also considered whether to modify the Privacy Rule to require covered entities to disclose PHI for continuity of care or medical emergencies within a shorter time than required under the access right. Many commenters on the 2018 RFI supported this concept; however, commenters also stressed the importance of streamlined and simplified requirements for ensuring compliance with any changes to the Privacy Rule. In light of this feedback, rather than impose a different time requirement for providing access for continuity of care or emergencies, the Department proposes at 45 CFR 164.524(b)(2)(ii)(C) to require entities to adopt a policy addressing the prioritization of access requests, to reduce or avoid the need for an extension of the time limit for providing copies of PHI at the direction or with the agreement of the individual. The Department understands that many covered health care providers already prioritize requests for PHI for these purposes. This proposed change would require covered entities that do not yet have such a policy to incur the one-time cost of developing a new policy and procedures and incorporate them into existing HIPAA training content.

The Department also considered whether to change the access time limits overall to a period shorter than the 15 calendar-day proposed time and did not

pursue this approach because that is more stringent than many of the short time limits contained in state access laws and may overly burden covered entities and affected business associates. However, to the extent a shorter requirement in which to provide access to individuals already exists in state or other laws, the Department is proposing at 45 CFR 164.524(b)(2)(iii) that said requirement be deemed practicable under the Privacy Rule. The Department requests comment on whether a time limit shorter than 15 calendar days would be appropriate, and welcomes data on the burdens and benefits such a time limit would impose or concerns about using others laws as a measure of practicability.

Access Fees

The Department considered retaining the existing access fee structure without change. However, the Department believes it can address the concerns of some commenters on the 2018 RFI that multiple, voluminous access requests to direct copies of PHI to third parties may be taking entities' time and resources away from fulfilling access requests to provide copies to individuals themselves and requests from other covered entities for disclosures for care coordination and case management.

The Department also considered allowing covered entities to charge no more than the limited access fee amounts for directing non-electronic copies of PHI to a third party for any treatment, payment, and health care operations purposes, while permitting higher fees for directing non-electronic copies of PHI to a third party for any other purposes. The Department does not propose this approach because it would open the door for covered entities to inquire into individuals' purposes in directing their own PHI to third parties. Instead, the Department proposes to adopt an approach that decreases the fees for access requests to direct electronic copies of PHI in an EHR to third parties. However, covered entities could charge higher fees for disclosing non-electronic copies of PHI or electronic copies of PHI that is not in an EHR, provided the fee does not result in an impermissible ''sale'' of PHI under 45 CFR 164.502(a)(5)(ii).

Verification of Identity

The Department considered modifying the individual right of access provision to prohibit burdensome paperwork requirements for individuals without also changing the identity verification provisions. However, the Department determined that changing both would help covered entities and individuals understand how the access and verification provisions interact. The Department also considered applying the proposed prohibition against unreasonable measures only to identity verification related to access requests, which would be more narrowly tailored to situations the Department has seen in complaints filed with the Department. However, the Department does not see a meaningful distinction between the access right and the other individual rights under HIPAA that would justify treating them differently with respect to verification of identity.

Exceptions to the Minimum Necessary Standard

The Department considered limiting the new exception to the minimum necessary standard to disclosures to and requests by covered health care providers for all health care operations purposes. This would have relieved the burden on covered health care providers who conduct population-based care coordination and case management of needing to assess the minimum necessary PHI when exchanging information with other covered health care providers. Limiting the exception to health care providers also would have addressed the concerns of commenters who opposed an exception for disclosures to health plans due to concerns that the plans may use the information against patient interests. The Department rejected this option, however, because health plans collaborate with health care providers, other health plans and other entities, including public health agencies, to improve patient health through care coordination and case management activities. In response to concerns raised about privacy protections, the Department is limiting this proposal to disclosures for individual-level activities that constitute treatment or health care operations. In addition, covered health care providers and health plans would continue to be responsible for meeting the minimum necessary requirements that currently apply, including when using PHI for treatment and health care operations purposes, as applicable. The proposed exception should reduce overall compliance burdens for both health plans and health care providers.

Disclosures to Third Parties Such as Social Services Agencies, Community Based Organizations, and HCBS Providers

The Department considered proposing to clarify in the definition of treatment when a covered health care provider's disclosures to a social services agency, community based organization, or HCBS provider are considered part of that covered health care provider's treatment activities, without adding an express disclosure permission. The Department also considered limiting the proposed disclosure permission to only covered entity health care providers and excluding health plans from the proposed policy. Ultimately, the Department rejected that option and proposed a permission for covered health care providers and health plans to encourage beneficial information sharing that would support care coordination and case management for individuals. As described more fully in the preamble above, the Department seeks comments on the appropriate recipients of PHI under this proposal, activities and purposes for which the PHI should be used or disclosed, and the covered entities to which an expanded disclosure permission would apply.

''Professional Judgment'' and ''Good Faith''

Replace the Professional Judgment Standard With the Good Faith Standard Throughout the Privacy Rule

The Department considered applying a presumption of good faith to all fourteen provisions in the Privacy Rule that allow covered entities to use or disclose PHI based on the exercise of professional judgment. However, the Department intends this proposed modification to carefully expand the ability of covered entities to use or disclose PHI to facilitate the involvement of family and caregivers in the treatment and recovery of people experiencing the impacts of the opioid crisis, serious mental illness, and health emergencies. The Department believes the remaining nine provisions would be beyond the scope of this goal.

The Department further believes there likely could be unintended consequences if it replaced the exercise of professional judgment standard with a good faith standard across all fourteen provisions, including those provisions not rooted in emergency circumstances. For example, in the case of disclosures to government agencies pursuant to 45 CFR 164.512(c), *Standard: Disclosures about victims of abuse, neglect or domestic violence,* the Department believes these provisions are well suited to ensuring that the necessary reporting can occur, and it does not believe replacing the professional judgment standard would change or prevent a course of action related to an individual affected by the opioid crisis or other urgent health situations. Covered

entities still would be permitted to exercise professional judgment to use or disclose PHI under the nine remaining provisions.

The Department requests comment on whether the Department should apply the good faith standard to any or all of the other nine provisions in the Privacy Rule that call upon health care providers to exercise professional judgment, identified below.

- Disaster relief. 45 CFR 164.510(b)(4).
- Law enforcement—crime victims. 45 CFR 164.512(f)(3).
- Reviewable grounds for denying individual access to records. 45 CFR 164.524(a)(3).
  - Safety or endangerment. 45 CFR 164.524(a)(3)(i).
  - References another person. 45 CFR 164.524(a)(3)(ii).
  - Personal representative. 45 CFR 164.524(a)(3)(iii).
- Victims of abuse, neglect, domestic violence. 45 CFR 164.512(c)(1)(iii)(A).
  - Informing the individual. 45 CFR 164.512(c)(2)(i).
  - Informing the personal representative. 45 CFR 164.512(c)(2)(ii).
- Personal representative suspected of abuse or neglect. 45 CFR 164.502(g)(5)(ii).

Apply a Presumption of Compliance to All Privacy Rule Provisions Referencing Professional Judgment Without Changing the Professional Judgment Standard to a Good Faith Standard

The Department considered proposing to apply a presumption of compliance to all existing provisions that permit covered entities to make decisions about uses and disclosures of PHI based on the exercise of professional judgment, without replacing the standard with a good faith standard. However, as noted above, where the Department summarizes its proposed application of the good faith standard, the Department intends not only to presume compliance with existing permissions, but to broaden the circumstances in which covered entities will use or disclose PHI in order to help address the needs of individuals experiencing opioid use disorder and other similarly situated individuals. The exercise of professional judgment generally is limited to covered entities who can, for example, draw upon a professional license or training and therefore, by definition, limits the scope of persons who could use or disclose PHI to aid individuals experiencing substance use disorder, SMI, or a health emergency.

Replace the Professional Judgment Standard With a Good Faith Standard Only in Specified Provisions of 45 CFR 164.510

The Department considered replacing the professional judgment standard with a good faith standard only in those provisions in 45 CFR 164.510 that are included in this rulemaking: 45 CFR 164.510(a)(3)(B), 164.510(b)(2)(iii) and 164.510(b)(3). However, modifying only 45 CFR 164.510 would encourage the disclosure of information only to family members, friends, caregivers, and other involved persons and only in the circumstances addressed at 45 CFR 164.510. As previously stated, the Department intends through this proposal to carefully broaden the permissible uses and disclosures of PHI by covered entities in circumstances that relate to the opioid crisis, serious mental illness, and health emergencies, to ensure that covered entities are able to share information as needed to care for individuals and protect the public. Changing only the applicable provisions at 45 CFR 164.510 would limit the scope of individuals and circumstances that would benefit from this proposed rule.

Define ''Imminent'' in 45 CFR 164.512(j)(1)(A) Instead of Replacing the Term With ''Reasonably Foreseeable''

The Privacy Rule does not define the term ''imminent,'' although common understanding of the term conveys that an event will happen soon.[332] The Department considered defining the term to provide improved clarity, but believes that defining the term could have the unintended consequence of further restricting uses and disclosures under this provision. Instead, the Department proposes to create a standard based on reasonable foreseeability because the Department believes it would provide needed flexibility for covered entities to address serious threats to health and safety that are likely to occur. The new standard would address serious threats that might only be prevented if the covered entity is free of the constraint of having to predict the timeframe for a serious threat to occur.

NPP and Acknowledgment of Receipt

The Department considered requiring the online posting of the NPP by all covered entities, including those that do not currently have a website. However, the Department believes the burden of creating a website solely to post the NPP for those few covered entities without a website outweighed the benefits to individuals of such a requirement.

Telecommunications Relay Service

The Department considered an alternative proposal to categorize TRS providers as ''conduits'' because of their temporary access to PHI,[333] and thus deem them not to be business associates. However this alternative would not have addressed the lack of an applicable permission to disclose PHI for some necessary communications not contemplated under the current Privacy Rule. In addition, TRS communications assistants have ''access on a routine basis'' to PHI, which is clearly distinguishable from the narrow category of conduits with only transient access, which was intended to exclude only those entities providing mere courier services such as the U.S. Postal Service or United Parcel Service and their electronic equivalents such as internet service providers (ISPs) providing mere data transmission services.[334] In addition, the Department considered clarifying that the definition of health care operations includes activities for purposes of providing accommodations for persons with disabilities; however, the Department believes the permission to disclose PHI for health care operations would be too narrow to fully address circumstances in which a covered entity's workforce member needs to disclose PHI to a communications assistant helping another entity's workforce member to perform activities of the second entity. Thus, the Department believes it is necessary to propose an express permission to disclose PHI to TRS communications assistants without a business associate agreement.

5. Request for Comments on Costs and Benefits

The Department requests comments on all of the assumptions and analyses within the cost-benefits analysis. The Department also requests comments on whether there may be other indirect costs and benefits resulting from the proposed changes in the proposed rule, and welcomes additional information that may help quantify those costs and benefits.

[332] *See* Merriam-Webster definition of ''imminent'': Ready to take place: Happening soon; often used of something bad or dangerous seen as menacingly near, available at *https://www.merriam-webster.com/dictionary/imminent.*

[333] *See* OCR's guidance on conduits, available at *https://www.hhs.gov/hipaa/for-professionals/faq/245/are-entities-business-associates/index.html* and *https://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html#_ftn14.*

[334] *See* 78 FR 5566, 5571 (January 25, 2013), available at *https://www.govinfo.gov/content/pkg/FR-2013-01-25/pdf/2013-01073.pdf.*

B. Executive Order 13771

Executive Order 13771 (January 30, 2017) declares that ''it is important that for every one new regulation issued, at least two prior regulations be identified for elimination,'' and that ''whenever an executive department or agency (agency) publicly proposes for notice and comment or otherwise promulgates a new regulation, it shall identify at least two existing regulations to be repealed.'' The Department intends to comply as necessary with Executive Order 13771 at the time a final rule is issued.

The Department believes this proposed rule will be deemed an Executive Order 13771 deregulatory action when finalized. The Department estimates that this final rule would generate $0.6 billion in net annualized savings at a 7% discount rate (discounted relative to year 2016, over a perpetual time horizon, in 2016 dollars).

EO 13771 SUMMARY TABLE

[In millions of 2016 dollars, over an infinite time horizon]

Item	Primary estimate (7%)
Present Value of Costs	$1,122,453,212
Present Value of Cost Saving	9,209,556,752
Present Value of Net Costs	−8,087,103,541
Annualized Costs	78,571,725
Annualized Cost Savings	644,668,973
Annualized Net Costs	−566,097,248

C. Regulatory Flexibility Act

The Department has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The Act defines ''small entities'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, and (3) a small government jurisdiction of less than 50,000 population. Because 90 percent or more of all health care providers meet the SBA size standard for a small business or are nonprofit organization, the Department generally treats all health care providers as small entities for purposes of performing a regulatory flexibility analysis. The SBA size standard for health care providers ranges between a maximum of $8 million and $41.5 million in annual receipts, depending upon the type of entity.[335]

With respect to health insurers, the SBA size standard is a maximum of $41.5 million in annual receipts, and for third party administrators it is $35 million.[336] While some insurers are classified as nonprofit, it is possible they are dominant in their market. For example, a number of Blue Cross/Blue Shield insurers are organized as nonprofit entities; yet they dominate the health insurance market in the states where they are licensed.

For the reasons stated below, it is not expected that the cost of compliance would be significant for small entities. Nor is it expected that the cost of compliance would fall disproportionately on small entities. Although many of the covered entities affected by the proposed rule are small entities, they would not bear a disproportionate cost burden compared to the other entities subject to the proposed rule.

The projected costs and savings are discussed in detail in the regulatory impact analysis. The Department does not view this as a burden because the result of the changes would be a net average estimated cost per covered entity of $150 in year one, followed by an average of $1,065 of estimated annual savings thereafter, for an average estimated total savings over five years of approximately $4,110 per covered entity. Thus, this proposed rule would not impose net costs on small entities, and the Secretary certifies that this proposed rule would not result in a significant negative impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Section 202(a) of The Unfunded Mandates Reform Act of 1995 (URMA) (section 202(a)) requires the Department to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending that may result in expenditures in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This proposed rule is not anticipated to have an effect only on state, local, or tribal governments, in the aggregate, of $154 million or more, adjusted for inflation. The Department believes that the proposed rule would impose mandates on the private sector that would result in an expenditure of $154 million in at least one year. As the estimated costs to private entities alone may exceed the $154 million threshold, UMRA requires the Department to prepare an analysis of the costs and benefits of the rule. The Department has already done so, in accordance with Executive Orders 12866 and 13563, and presents this analysis in the preceding sections.

E. Executive Order 13132—Federalism

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. The Department does not believe that this rulemaking would have any federalism implications.

The federalism implications of the Privacy and Security Rules were assessed as required by Executive Order 13132 and published as part of the preambles to the final rules on December 28, 2000 (65 FR 82462, 82797), February 20, 2003 (68 FR 8334, 8373), and January 25, 2013 (78 FR 5566, 5686). Regarding preemption, the preamble to the final Privacy Rule explains that the HIPAA statute dictates the relationship between state law and Privacy Rule requirements, and the Rule's preemption provisions do not raise federalism issues. The HITECH Act, at section 13421(a), provides that the HIPAA preemption provisions shall apply to the HITECH Act provisions and requirements.

The Department anticipates that the most significant direct costs on state and local governments would be the cost for state and local government-operated covered entities to revise policies and procedures, including drafting, printing, and distributing NPPs for individuals with first-time health encounters, which would include the cost of mailing these notices for state health plans, such as Medicaid. The regulatory impact

[335] *See* U.S. Small Business Administration, *Table of Small Business Size Standards* (Version 2019), available at *https://www.sba.gov/document/support--table-size-standards.*

analysis above addresses these costs in detail.

In considering the principles in and requirements of Executive Order 13132, the Department has determined that these proposed modifications to the Privacy Rule would not significantly affect the rights, roles, and responsibilities of the states.

F. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. The Department believes that these regulations would positively impact the ability of individuals and families to coordinate treatment and payment for health care by increasing access to PHI, particularly for families to participate in the care and recovery of their family members experiencing SMI, SUD, or health emergencies. These changes must necessarily be carried out by the Department through the modification of the Privacy Rule. The Department does not anticipate negative impacts on family well-being as a result of this regulation.

G. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (Pub. L. 104–13), agencies are required to submit to the Office of Management and Budget (OMB) for review and approval any reporting or record-keeping requirements inherent in a proposed or final rule, and are required to publish such proposed requirements for public comment. The PRA requires agencies to provide a 60-day notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to OMB for review and approval. To fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that the Department solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The PRA requires consideration of the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section. The Department explicitly seeks, and will consider, public comment on its assumptions as they relate to the PRA requirements summarized in this section. To comment on the collection of information or to obtain copies of the supporting statements and any related forms for the proposed paperwork collections referenced in this section, email your comment or request, including your address and phone number to *Sherrette.Funn@hhs.gov,* or call the Reports Clearance Office at (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60 days.

In this NPRM, the Department is revising certain information collection requirements and, as such, is revising the information collection last prepared in 2019 and previously approved under OMB control # 0945–0003. The revised information collection describes all new and adjusted information collection requirements for covered entities pursuant to the implementing regulation for HIPAA at 45 CFR parts 160 and 164, the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules.

The estimated annual burden presented by the proposed regulatory modifications in the first year of implementation, including one-time and ongoing burdens, is 9,577,626 burden hours at a cost of $996,122,087 (including capital costs of $242,398), reduced by first year annual costs savings of $880,087,888, for an estimated first year net cost of $116,034,199 and $880,087,888 of estimated annual cost savings in years two through five, resulting in annual net cost savings of $824,604,205. The overall total burden for respondents to comply with the information collection requirements of all of the HIPAA Privacy, Security, and Breach Notification Rules, including one-time and ongoing burdens presented by proposed program changes, is 952,089,673 burden hours at a cost of $93,937,597,924, plus $118,269,943 in capital costs for a total estimated annual burden of $94,055,867,867 in the first year following the effective date of the final rule, assuming all changes are adopted as proposed. Details describing the burden analysis for the proposals associated with this NPRM are presented below.

1. Explanation of Estimated Annualized Burden Hours

Due to the number of proposed changes to the Privacy Rule that would affect the information collection, the Department presents in separate tables, in Section V.G.2 below, the collections that reflect estimates to existing burdens, new and previously unquantified ongoing burdens, and new one-time burdens. Below is a summary of the significant program changes and adjustments made since the 2019 information collection. These program changes and adjustments form the bases for the burden estimates presented in the tables that follow:

Adjusted Estimated Annual Burdens of Compliance

(1) Increasing the number of covered entities from 700,000 to 774,331 based on program change;

(2) Increasing the number of access requests under 45 CFR 164.524 from 200,000 to 2,460,000 annually based on program change;

(3) Increasing the estimated burden hours for responding to access requests under 45 CFR 164.524 from 3 to 5 minutes per request due to program change and allocating 1 minute as uncompensated;

(4) Increasing the burden hours by a factor of two for responding to individuals' requests for restrictions on disclosures of their protected health information under 45 CFR 164.522 due to program change;

(5) Newly estimating the burdens resulting from the pre-existing, ongoing requirement for covered entities to make minimum necessary evaluations under 45 CFR 164.514 before using or disclosing protected health information for payment and health care operations purposes (and for using protected health information for treatment) in the amount of 18 hours annually per covered entity, and decrease the annual minimum necessary burden to by 4 hours per covered entity due to program change, resulting in a total ongoing annual burden of 14 hours per covered entity;

(6) Recognizing for the first time burdens associated with providing electronic copies of PHI to third parties designated by individuals under 45 CFR 164.524 in the amount of 2 minutes per request for 25 percent of 615,000 such requests received annually;

(7) Recognizing for the first time burdens associated with providing electronic copies of PHI to health plans and health care providers as third

parties designated by individuals under 45 CFR 164.524 in the amount of 4 minutes per request for 25 percent of 615,000 such requests received annually; and

(8) Decreasing the estimated burden for disseminating the Notice of Privacy Practices and obtaining an acknowledgement of receipt under 45 CFR 164.520, from 3 minutes to 1 minute and 15 seconds due to program change.

New Burdens Resulting From Program Changes

In addition to these changes, the Department added new burdens as a result of program changes:

(1) An annualized burden of 10 minutes per covered entity for posting an updated Notice of Privacy Practices due to program changes;

(2) An annualized burden of 3.5 minutes per request for submitting an access request for an individual to another provider for an estimated 92,250 annual requests;

(3) An annualized 10-minute burden per covered entity for posting an access and authorization fee schedule online under 45 CFR 164.525;

(4) An annualized 7-minute burden for each of an estimated 6,130,000 annual requests from individuals to discuss their direct treating health care provider's Notice of Privacy Practices under 45 CFR 164.520;

(5) An annualized three-minute burden for each of an estimated 73,800 annual requests from individuals for an individualized estimate of the fees to provide copies of requested protected health information under 45 CFR 164.525;

(6) An annualized one-minute burden for each of an estimated 24,600 annual requests from individuals for an itemized list of charges for their requested copies of protected health information under 45 CFR 164.525;

(7) A one-time burden of 6 hours and 55 minutes for each covered entity to update its policies and procedures under 45 CFR 164.530 due to program changes; and;

(8) A one-time burden of 4 hours and 40 minutes for each covered entity to update the content of its HIPAA training program under 45 CFR 164.530 and a related one-time burden of 7 additional minutes of workforce member time spent in training on 45 CFR 164.524 per covered entity.

2. Tables Demonstrating Estimated Burden Hours Ongoing Annual Burdens of Compliance With the Rules

Section	Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
160.204	Process for Requesting Exception Determinations—states or persons.	1	1	1	[a] 16	16
164.308	Contingency Plan—Testing and Revision.	1,774,331	1	1,774,331	8	14,194,648
164.308	Contingency Plan—Criticality Analysis.	1,774,331	1	1,774,331	4	7,097,324
164.310	Maintenance Records	1,774,331	12	21,291,972	6	127,751,832
164.314	Security Incidents—Business Associate reporting of non-breach incidents to Covered Entities.	1,000,000	12	12,000,000	20	240,000,000
164.316	Risk Analysis—Documentation, 164.308.	[b] 1,774,331	1	1,774,331	[c] 10	17,743,310
164.316	Information System Activity Review—Documentation, 164.308.	1,774,331	12	21,291,972	.75	15,968,979
164.316	Security Reminders—Periodic Updates, 164.308.	1,774,331	12	21,291,972	1	21,291,972
164.316	Security Incidents—Other than breaches—Documentation, 164.308.	1,774,331	52	92,265,212	5	461,326,060
164.316	Documentation—Review and Update, 164.306.	1,774,331	1	1,774,331	6	10,645,986
164.404	Individual Notice—Written and E-mail Notice—Drafting.	[d] 58,482	1	58,482	.5	29,241
164.404	Individual Notice—Written and E-mail Notice—Preparing and documenting notification.	58,482	1	58,482	.5	29,241
164.404	Individual Notice—Written and E-mail Notice—Processing and sending.	58,482	[e] 1,941	113,513,562	.008	908,108
164.404	Individual Notice—Substitute Notice—Posting or publishing.	[f] 2,746	1	2,746	1	2,746
164.404	Individual Notice—Substitute Notice—Staffing toll-free number.	2,746	1	2,746	[g] 3.42	9,391

Section	Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
164.404 ...	Individual Notice—Substitute Notice—Individuals' voluntary burden to call toll-free number for information.	[h] 113,264	1	113,264	[i] .125	14,158
164.406 ...	Media Notice	[j] 267	1	267	1.25	334
164.408 ...	Notice to Secretary—Notice for breaches affecting 500 or more individuals.	267	1	267	1.25	334
164.408 ...	Notice to Secretary—Notice for breaches affecting fewer than 500 individuals.	[k] 58,215	1	58,215	1	58,215
164.410 ...	Business Associate notice to Covered Entity—500 or more individuals affected.	20	1	20	50	1,000
164.410 ...	Business Associate notice to Covered Entity—Less than 500 individuals affected.	1,165	1	1,165	8	9,320
164.414 ...	500 or More Affected Individuals—Investigating and documenting breach.	267	1	267	50	13,350
164.414 ...	Less than 500 Affected Individuals—Investigating and documenting breach.	2,479 (breaches affecting 10–499 individuals).	1	2,479	8	19,832
		55,736 (breaches affecting <10 individuals).	1	55,736	4	222,944
164.504 ...	Uses and Disclosures—Organizational Requirements.	774,331	1	774,331	0.083333333	64,528
164.508 ...	Uses and Disclosures for Which Individual Authorization is Required.	774,331	1	774,331	1	774,331
164.512 ...	Uses and Disclosures for Research Purposes.	[l] 113,524	1	113,524	0.08333333	9,460
164.520 ...	Notice of Privacy Practices for Protected Health Information—Health plans—Periodic distribution of NPPs by paper mail.	[m] 100,000,000	1	100,000,000	0.00416666 [1 hour per 240 notices].	416,667
164.520 ...	Notice of Privacy Practices for Protected Health Information—Health plans—Periodic distribution of NPPs by electronic mail.	100,000,000	1	100,000,000	0.00278333 [1 hour per 360 notices].	278,333
164.520 ...	Notice of Privacy Practices for Protected Health Information—Health care providers—Dissemination.	[n] 613,000,00	1	613,000,000	[o] 0.02083333°	12,770,833
164.522 ...	Rights to Request Privacy Protection for Protected Health Information.	[p] 40,000	1	40,000	0.05	2,000
164.524 ...	Access of Individuals to Protected Health Information—Copies of PHI.	[q] 1,230,000	1	1,230,000	[r] 0.016666 67	20,500
164.526 ...	Amendment of Protected Health Information—Requests.	150,000	1	150,000	0.08333333	12,500
164.526 ...	Amendment of Protected Health Information—Denials.	50,000	1	50,000	0.08333333	4,167

Section	Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
164.528 ...	Accounting for Disclosures of Protected Health Information.	[s] 5,000	1	5,000	0.05	250
Total						931,691,910

New or previously unquantified ongoing burdens of compliance, annualized section	Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
164.514	Minimum necessary evaluations for treatment, payment, and health care operations—Uses and disclosures.	774,331	1	774,331	[t] 14	[u] 10,840,634
164.520	Notice of Privacy Practices for Protected Health Information—Right to discuss privacy practices.	6,130,000	1	[v] 6,130,000	0.1166667	715,167
164.524	Access of Individuals to Protected Health Information—Provider submitting individual's access request to another provider or plan.	92,250	1	[w] 92,250	[x] .0583333	5,381
164.524	Access of Individuals to Protected Health Information—Directing copies of ePHI to health plans and providers.	[y] 153,750	1	153,750	0.0666666	10,250
164.524	Access of Individuals to Protected Health Information—Directing copies of ePHI to third parties other than health plans and providers.	[z] 153,750	1	153,750	0.0333333	5,125
164.525	Notice of Access and Authorization Fees—Individualized estimates.	73,800	1	[aa] 73,800	0.05	3,690
164.525	Notice of Access and Authorization Fees—Itemized list of charges for copies.	[bb] 24,600	1	24,600	0.0166667	410
Total						11,580,657

[a] The figures in this column are averages based on a range. Small entities may require fewer hours to conduct certain compliance activities, particularly with respect to Security Rule requirements, while large entities may spend more hours than those provided here due to their size and complexity.

[b] This estimate includes 774,331 estimated covered entities and 1 million estimated business associates. The Omnibus HIPAA Final Rule burden analysis estimated that there were 1–2 million business associates. However, because many business associates have business associate relationships with multiple covered entities, the Department believes the lower end of this range is more accurate.

[c] The figures in this column are averages based on a range. Small entities may require fewer hours to conduct certain compliance activities, particularly with respect to Security Rule requirements, while large entities may spend more hours than those provided here due to their size and complexity.

[d] Total number of breach reports submitted to OCR in 2015. Breaches reported to OCR in 2015 affected more individuals than have been affected by breaches reported in each subsequent year; therefore, the Department bases its burden estimates on 2015 data to ensure that it fully accounts for the annual burdens of the Breach Notification Rule.

[e] Average number of individuals affected per breach incident reported in 2015.

[f] This number includes all 267 large breaches and all 2,479 breaches affecting 10–499 individuals that were reported to OCR in 2015. As the Department stated in the preamble to the Omnibus HIPAA Final Rule, although some breaches involving fewer than 10 individuals may require substitute notice, it believes the costs of providing such notice through alternative written means or by telephone is negligible.

[g] This assumes that 10% of the sum of (a) all individuals affected by large breaches in 2015 (113,250,136) and (b) 5% of individuals affected by small breaches ($0.05 \times 285{,}413 = 14{,}271$) will require substitute notification. Thus, the Department calculates $0.10 \times (113{,}250{,}136 + 14{,}271) = 11{,}326{,}441$ affected individuals requiring substitute notification for an average of 4,125 affected individuals per such breach. The Department assumes that 1% of the affected individuals per breach requiring substitute notice annually will follow up with a telephone call, resulting in 41.25 individuals per breach calling the toll-free number. The Department assumes that call center staff will spend 5 minutes per call, with an average of 41 affected individuals per breach requiring substitute notice, resulting in 3.42 hours per breach spent answering calls from affected individuals.

[h] As noted in the previous footnote, this number equals 1% of the affected individuals who require substitute notification ($0.01 \times 11{,}326{,}441$).

[i] This number includes 7.5 minutes for each individual who calls with an average of 2.5 minutes to wait on the line/decide to call back and 5 minutes for the call itself.
[j] The total number of breaches affecting 500 or more individuals for which OCR received reports in 2015.
[k] The total number of breaches affecting fewer than 500 individuals for which OCR received reports in 2015.
[l] The number of entities who use and disclose PHI for research purposes.
[m] As in the Department's previous submission, it assumes that half of the approximately 200,000,000 individuals insured by covered health plans will receive the plan's NPP by paper mail, and half will receive the NPP by electronic mail.
[n] The Department estimates that each year covered health care providers will have first-time visits with 613 million individuals, to whom the providers must give an NPP.
[o] This represents 1 minute and fifteen seconds (75/3,600) to disseminate the NPP and eliminates the 1 minute and 45 seconds previously allocated for obtaining the signed patient acknowledgement.
[p] The Department doubled the estimated number of requests for confidential communications or restrictions on disclosures per year due to the combined effect of changes to the minimum necessary standard and the information blocking provisions of the ONC Cures Act Final Rule.
[q] The Department has increased our estimate of the number of requests from individuals for copies of their PHI that covered entities annually provide to them directly to 1,230,000.
[r] This represents an estimated average of 1 minute per request which is not chargeable as a fee to the individual.
[s] The Department estimates that covered entities annually fulfill 5,000 requests from individuals for an accounting of disclosures of their PHI.
[t] The figures in this column are averages based on a range. Small entities may require fewer hours to conduct certain compliance activities, particularly with respect to Security Rule requirements, while large entities may spend more hours than those provided here due to their size and complexity.
[u] This represents a previously unacknowledged annual burden of 18 hours per covered entity for making minimum necessary evaluations for purposes of treatment, payment, and health care operations uses and disclosures, reduced by an estimated 4 burden hours annually per covered entity (or 3,097,324 total) as a result of the proposed changes to the minimum necessary standard combined with proposed changes to the definition of health care operations.
[v] 1% of an estimated 613 million new patient encounters annually.
[w] 15% of 615,000 annual access requests to direct electronic copies of ePHI to health plans and providers as third parties under the right of access.
[x] This represents 3.5 minutes for a medical assistant to obtain the needed information and submit it for the individual.
[y] This represents one-fourth of the estimated 615,000 annual requests under the right of access for copies of ePHI directed to health plans and health care providers as third parties and reflects only the labor burden for such requests for ePHI to be sent via other than an internet-based method (*e.g.,* on electronic media and mailed to the recipient).
[z] This represents one-fourth of the estimated 615,000 annual requests for copies of ePHI directed to third parties and reflects only uncompensated the labor burden for requests for ePHI to be sent via other than an internet-based method (*e.g.,* on electronic media and mailed to the recipient).
[aa] 3% of an estimated 2.46 million annual access requests for copies of PHI.
[bb] 1% of an estimated 2.46 million annual access requests for copies of PHI.

NEW ONE-TIME BURDENS OF COMPLIANCE

Section	Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
164.520 ..	Notice of Privacy Practices for Protected Health Information—Post updated notice online.	774,331	1	774,331	[a] 0.16666667	129,055
164.525 ..	Notice of Fees for Copies of PHI—Post fee schedule online.	774,331	1	774,331	0.16666667	129,055
164.530 ..	Administrative Requirements—Training Minimum necessary, 164.514.	774,331	1	774,331	1	774,331
164.530 ..	Administrative Requirements—Training—Right of access, 164.525, and fee estimates, 164.525—Updated training content.	774,331	1	774,331	2.5	1,935,828
164.530 ..	Administrative Requirements—Training—Access—Workforce member time in training, 164.524.	774,331	1	774,331	0.116666667	90,339
164.530 ..	Administrative Requirements—Training—Disclosing PHI under164.510; uses and disclosures to prevent harm, 164.512.	768,169	1	768,169	0.6666667	512,113
164.530 ..	Administrative Requirements—Training—Disclosures for Uniformed Services, & disclosures to Telecommunications Relay Services for treatment, payment and health care operations, 164.512.	774,331	1	774,331	0.25	193,583
164.530 ..	Administrative Requirements—Training—Notice of privacy practices, changes in content & right to discuss privacy practices, 164.520.	774,331	1	774,331	0.0833333	64,528
164.530 ..	Administrative Requirements—Training—Verification of identity, 164.514.	[b] 38,717	1	38,717	0.1666667	6,453
164.530 ..	Administrative Requirements—Policies & Procedures—Individual care coordination and case management, 164.501 & 164.502, minimum necessary, 164.514, and social services agencies for care coordination, 164.506.	774,331	1	774,331	1.25	967,914
164.530 ..	Administrative Requirements—Policies & Procedures—Right of access, 164.524, & fee estimates, 164.525.	774,331	1	774,331	3	2,322,993

NEW ONE-TIME BURDENS OF COMPLIANCE—Continued

Section	Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
164.530 ..	Administrative Requirements—Policies & Procedures—Disclosing PHI under 164.510; uses and disclosures to prevent harm, 164.512(j).	[c] 768,169	1	768,169	1	768,169
164.530 ..	Administrative Requirements—Policies & Procedures—Revising the Notice of Privacy Practices, 164.520.	774,331	1	774,331	1	774,331
164.530 ..	Administrative Requirements—Policies & Procedures—Disclosures for Uniformed Services & Telecommuni-cations Relay Services, 164.512.	774,331	1	774,331	[d] 0.16666667	129,055
164.530 ..	Administrative Requirements—Polices & Procedures—Identity verification changes, 164.514.	[e] 38,717	1	38,717	0.5	19,358
Total	.....	.....	.....	10,131,413	.....	[f] 8,817,103

[a] The figures in this column are averages based on a range. Small entities may require fewer hours to conduct certain compliance activities, particularly with respect to Security Rule requirements, while large entities may spend more hours than those provided here due to their size and complexity.
[b] This represents 5% of all covered entities.
[c] This represents all health care providers.
[d] This equates to 10 minutes.
[e] This represents 5 percent of all covered entities.
[f] Total may not add up due to rounding.

List of Subjects

45 CFR Part 160

Administrative practice and procedure, Computer technology, Electronic information system, Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health professions, Health records, Hospitals, Investigations, Medicaid, Medical research, Medicare, Penalties, Privacy, Reporting and record keeping requirements, Security.

45 CFR Part 164

Administrative practice and procedure, Computer technology, Drug abuse, Electronic information system, Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health professions, Health records, Hospitals, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements, Security.

Proposed Rule

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR Subtitle A, Subchapter C, Parts 160 and 164 as set forth below:

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 160 is revised to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); 5 U.S.C. 552; secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279 (42 U.S.C. 17921, 17931–17954); and sec. 1104 of Pub. L. 111–148, 124 Stat. 146–154.

■ 2. Amend § 160.103, by adding new paragraph (4)(v) to the definition of ''Business associate'' to read as follows:

§ 160.103 Definitions

* * * * *

Business associate * * *

(4) * * *

(v) A provider of Telecommunications Relay Service, as defined in 47 U.S.C. 225(a)(3), with respect to enabling communications through services regulated under 47 CFR part 64.

* * * * *

PART 164—SECURITY AND PRIVACY

■ 3. The authority citation for part 164 is revised to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); and secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279 (42 U.S.C. 17921, 17931–17954).

■ 4. Amend § 164.501 by:

■ a. Adding in alphabetical order a definition for ''Electronic health record'';

■ b. Revising paragraph (1) of the definition of ''Health care operations''; and

■ c. Adding in alphabetical order a definition for ''Personal health application''.

The additions and revision read as follows:

§ 164.501 Definitions.

* * * * *

Electronic health record means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and their staff. Such clinicians shall include, but are not limited to, health care providers that have direct treatment relationships with individuals as defined at § 164.501, such as physicians, nurses, pharmacists, and other allied health professionals. For purposes of this paragraph, ''health-related information on an individual'' covers the same scope of information as the term *individually identifiable health information* as defined at § 160.103.

* * * * *

Health care operations * * *

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR 3.20); population-based activities relating to improving health or reducing health care costs; protocol development; case management and care coordination; contacting of health care providers and

patients with information about treatment alternatives; and related functions that do not include treatment.

* * * * *

Personal health application means an electronic application used by an individual to access health information about that individual, which can be drawn from multiple sources, provided that such information is managed, shared, and controlled by or primarily for the individual, and not by or primarily for a covered entity or another party such as the application developer.

* * * * *

■ 5. Amend § 164.502 by:
■ a. Revising paragraph (a)(4)(ii) and (a)(5)(ii)(B)(*2*)(*vi*)
■ b. Revising paragraph (b)(2)(i);
■ c. Adding paragraph (b)(2)(vii);
■ d. Revising paragraph (g)(3)(ii)(C); and
■ e. Adding new paragraph (k).

The revisions read as follows:

§ 164.502 Uses and disclosures of protected health information: General Rules.

(a) * * *

(4) * * *

(ii) To the covered entity or, when specified in the business associate agreement, to the individual or the individual's designee, as necessary to satisfy a covered entity's obligations with respect to §§ 164.524(c)(2)(ii) or 164.524(d)(1).

(5) * * *

(ii) * * *

(B) * * *

(*2*) * * *

(*vi*) To an individual, or a third party designated by the individual, when requested under §§ 164.524 or 164.528.

* * * * *

(b) * * *

(2) * * *

(i) Disclosures to or requests by a health care provider for treatment, including for care coordination and case management activities with respect to an individual;

* * * * *

(vii) Disclosures to or requests by a health plan for care coordination and case management activities with respect to an individual.

* * * * *

(g) * * *

(3) * * *

(ii) * * *

(C) Where the parent, guardian, or other person acting *in loco parentis,* is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under state or other law, including case law, a covered entity may provide access under § 164.524 to a parent, guardian, or other person acting *in loco parentis,* if such action is consistent with state or other applicable law, provided that such decision must be made by a licensed health care professional, based on a good faith belief that providing access is in the best interests of the individual.

* * * * *

(k) Standard: Good Faith—Presumption of Compliance. When using or disclosing protected health information as provided in §§ 164.502(g)(3)(ii)(C); 164.510(a)(3)(i)(B); 164.510(b)(2)(iii); 164.510(b)(3); and 164.514(h)(2)(iv), a covered entity is presumed to have complied with the good faith requirement, absent evidence that the covered entity acted in bad faith.

* * * * *

■ 6. Amend § 164.506, by adding new paragraph (c)(6) to read as follows:

§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.

* * * * *

(c) * * *

(6) A covered entity may disclose an individual's protected health information to a social services agency, community-based organization, home and community based services provider, or similar third party that provides health or human services to specific individuals for individual-level care coordination and case management activities (whether such activities constitute treatment or health care operations as those terms are defined in § 164.501) with respect to that individual.

* * * * *

■ 7. Amend § 164.510 by revising paragraphs (a)(3)(i)(B), (b)(2)(iii), and (b)(3) to read as follows.

§ 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.

* * * * *

(a) * * *

(3) * * *

(i) * * *

(B) In the individual's best interests based on a good faith belief of the covered health care provider.

* * * * *

(b) * * *

(2) * * *

(iii) Reasonably infers from the circumstances, based on a good faith belief, that the individual does not object to the disclosure.

(3) *Limited uses and disclosures when the individual is not present.* If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, based on a good faith belief that the disclosure is in the best interests of the individual, disclose only the protected health information that is directly relevant to the person's involvement with the individual's care or payment related to the individual's health care or that is needed for notification purposes. A covered entity may make reasonable inferences of the individual's best interests in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.

* * * * *

■ 8. Amend § 164.512 by:
■ a. Revising paragraph (j)(1)(i)(A);
■ b. Adding paragraphs (j)(5) through (6);
■ c. Revising the heading for paragraph (k)(1);
■ d. Revising paragraphs (k)(1)(i) introductory text, (k)(1)(i)(A), and (k)(1)(ii); and
■ e. Adding paragraph (m).

The revisions and additions read as follows:

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

* * * * *

(j) * * *

(1) * * *

(i) (A) Is necessary to prevent a serious and reasonably foreseeable harm, or lessen a serious and reasonably foreseeable threat, to the health or safety of a person or the public; and

* * * * *

(5) ''Reasonably foreseeable'' means that an ordinary person could conclude that a threat to health or safety exists and that harm to health or safety is reasonably likely to occur if a use or disclosure is not made, based on facts and circumstances known at the time of the disclosure.

(6) When a covered health care provider (or a member of the workforce of the covered health care provider) that has specialized training, expertise, or experience in assessing an individual's risk to health or safety—such as a licensed mental or behavioral health professional—determines that it is appropriate to use or disclose protected health information under paragraph (j)(1)(i)(A) of this section, such determination will be entitled to heightened deference if the determination is related to facts and circumstances about which the covered

entity (or a member of its workforce) has such training, expertise, or experience.

* * * * *

(k) * * *

(1) *Uniformed Services and veterans activities—*

(i) *Uniformed Services personnel.* A covered entity may use and disclose the protected health information of individuals who are Uniformed Services personnel for activities deemed necessary by appropriate Uniformed Services command authorities to assure the proper execution of the Uniformed Services mission, if the appropriate Uniformed Services authority has published by notice in the **Federal Register** the following information:

(A) Appropriate Uniformed Services command authorities; and

* * * * *

(ii) Separation or discharge from Uniformed Service. A covered entity that is a component of the Departments of Defense, Homeland Security, Commerce, or Health and Human Services may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Uniformed Services upon the separation or discharge of the individual from Uniformed Service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.

* * * * *

(m) *Standard: Disclosures to Telecommunications Relay Service.* A covered entity may disclose protected health information to a Telecommunications Relay Service Communications Assistant, as defined at 47 CFR 64.601(a)(10), as necessary to conduct covered functions.

* * * * *

■ 9. Amend § 164.514 by:

■ a. Revising paragraph (h)(2)(iv); and

■ b. Adding paragraph (h)(2)(v).

The revision and addition read as follows:

§ 164.514 Other requirements related to uses and disclosures of protected health information.

* * * * *

(h) * * *

(2) * * *

(iv) *Exercise of good faith.* The verification requirements of this paragraph are met if the covered entity acts on a good faith belief in making a use or disclosure in accordance with § 164.510 or making a disclosure in accordance with § 164.512(j).

(v) *Exercise of individual rights.* A covered entity may not impose unreasonable verification measures on an individual that would impede the individual from exercising a right under this part. An unreasonable measure is one that causes an individual to expend unnecessary effort or resources when a less burdensome verification measure is practicable for the covered entity. Practicability considerations include a covered entity's technical capabilities, its obligations to protect the privacy of protected health information under § 164.530(c), the security of electronic protected health information under § 164.306, and the costs of implementing measures that are more convenient for individuals. Examples of unreasonable measures include requiring an individual to provide proof of identity in person when a method for remote verification is practicable for the covered entity and more convenient for the individual, or requiring an individual to obtain notarization of the individual's signature on a written request to exercise the individual right.

■ 10. Amend § 164.520 by:

■ a. Revising paragraphs (b)(1)(i) and (b)(1)(iv)(C);

■ b. Adding new paragraph (b)(1)(iv)(G);

■ c. Revising paragraph (b)(1)(vii);

■ d. Adding new paragraph (b)(2)(iii);

■ e. Removing paragraph (c)(2)(ii);

■ f. Redesignating paragraph (c)(2)(iii) and (iv) paragraphs (c)(2)(ii) and (iii);

■ g. Revising paragraph (c)(3)(iii); and

■ h. Revising paragraph (e).

The revisions and additions read as follows:

§ 164.520 Notice of privacy practices for protected health information.

* * * * *

(b) * * *

(1) * * *

(i) Header. The notice must contain the following statement as a header or otherwise prominently displayed:

NOTICE OF PRIVACY PRACTICES OF [NAME OF COVERED ENTITY, AFFILIATED COVERED ENTITIES, OR ORGANIZED HEALTH CARE ARRANGEMENT, AS APPLICABLE]

THIS NOTICE DESCRIBES:

• HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED

• YOUR RIGHTS WITH RESPECT TO YOUR MEDICAL INFORMATION

• HOW TO EXERCISE YOUR RIGHT TO GET COPIES OF YOUR RECORDS AT LIMITED COST OR, IN SOME CASES, FREE OF CHARGE

• HOW TO FILE A COMPLAINT CONCERNING A VIOLATION OF THE PRIVACY, OR SECURITY OF YOUR MEDICAL INFORMATION, OR OF YOUR RIGHTS CONCERNING YOUR INFORMATION, INCLUDING YOUR RIGHT TO INSPECT OR GET COPIES OF YOUR RECORDS UNDER HIPAA.

YOU HAVE A RIGHT TO A COPY OF THIS NOTICE (IN PAPER OR ELECTRONIC FORM) AND TO DISCUSS IT WITH [ENTER NAME OR TITLE AT [PHONE AND EMAIL] IF YOU HAVE ANY QUESTIONS.

* * * * *

(iv) * * *

(C) The right of access to inspect and obtain a copy of protected health information at limited cost or, in some cases, free of charge; and the right to direct a covered health care provider to transmit an electronic copy of protected health information in an electronic health record to a third party, as provided by § 164.524;

* * * * *

(G) The right to discuss the notice with a designated contact person identified by the covered entity pursuant to § 164.520(b)(vii);

* * * * *

(vii) *Contact.* The notice must contain the name or title and telephone number and email for a designated person who is available to provide further information and answer questions about the covered entity's privacy practices, as required by § 164.530(a)(1)(ii).

* * * * *

(2) * * *

(iii) A covered entity may provide in its notice information about how an individual who seeks to direct protected health information to a third party, when the protected health information is not in an electronic health record and/or is in a non-electronic format, can instead obtain a copy of protected health information directly under § 164.524 and send the copy to the third party themselves, or request the covered entity to send a copy of protected health information to a third party using a valid authorization under § 164.508.

* * * * *

(c) * * *

(2) * * *

(ii) If the covered entity health care provider maintains a physical service delivery site:

* * * * *

(3) * * *

(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service.

* * * * *

(e) *Implementation specifications: Documentation.* A covered entity must

document compliance with the notice requirements, as required by § 164.530(j), by retaining copies of the notices issued by the covered entity.

* * * * *

■ 11. Amend § 164.524 by:
■ a. Redesignating paragraphs (a)(1) introductory text and (a)(1)(i) and (ii) as paragraphs (a)(1)(i) and (a)(1)(i)(A) and (B), respectively;
■ b. Adding new paragraph (a)(1)(ii);
■ c. Revising paragraph (a)(2) introductory text;
■ d. Revising paragraph (a)(3) introductory text;
■ e. Removing paragraph (a)(4);
■ f. Redesignating paragraph (b)(1) as paragraph (b)(1)(i);
■ g. Designating the second sentence of newly redesignated paragraph (b)(1)(i) as paragraph (b)(1)(ii) and revising newly designated paragraph (b)(1)(ii);
■ h. Revising paragraph (b)(2)(i) introductory text;
■ i. In paragraph (b)(2)(i)(B), removing ''paragraph (d)'' and adding in its place ''paragraph (e)'';
■ j. In paragraph (b)(2)(ii), removing ''30 days'' and adding in its place ''15 calendar days'';
■ k. In paragraph (b)(2)(ii)(A), removing the word ''and'' at the end;
■ l. In paragraph (b)(2)(ii)(B), removing the period at the end and adding in its place ''; and'';
■ m. Adding paragraph (b)(2)(ii)(C) and (b)(2)(iii)
■ n. Redesignating paragraphs (c)(2)(iii) introductory text and (c)(2)(iii)(A) and (B) as paragraphs (c)(2)(iv)(A) introductory text and (c)(2)(iv)(A)(*1*) and (*2*);
■ o. Adding paragraphs (c)(2)(iii) and (c)(2)(iv)(B);
■ p. Revising paragraphs (c)(3) and (4);
■ q. Redesignating paragraphs (d) and (e) paragraphs (e) and (f), respectively;
■ r. Revising newly redesignated paragraph (e);
■ s. Adding a new paragraph (d);
■ t. Further redesignating newly redesiganted paragraph (f)(2) as paragraph (f)(3); and
■ u. Adding a new paragraph (f)(2).

The revisions and additions read as follows:

§ 164.524 Access of individuals to protected health information.

(a) * * * *Standard: Access to protected health information*—

(1) *Right of access.* (i) Except as otherwise provided in paragraphs (a)(2) or (3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:

(A) Psychotherapy notes; and

(B) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

(ii) An individual's right to inspect protected health information about the individual in a designated record set includes the right to view, take notes, take photographs, and use other personal resources to capture the information, except that a covered entity is not required to allow an individual to connect a personal device to the covered entity's information systems and may impose requirements to ensure that an individual records only protected health information to which the individual has a right of access.

(2) *Unreviewable grounds for denial.* A covered entity may deny an individual access under paragraph (a)(1) of this section, without providing the individual an opportunity for review, in the following circumstances.

* * * * *

(3) *Reviewable grounds for denial.* A covered entity may deny an individual access under paragraph (a)(1) of this section, provided that the individual is given a right to have such denials reviewed, as required by paragraph (e)(4) of this section, in the following circumstances:

* * * * *

(b) * * *

(1) *Individual's request for access.*

(i) The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set.

(ii) The covered entity may require an individual to make a request for access in writing (in electronic or paper form), provided that it informs the individual of such a requirement and does not impose unreasonable measures that impede the individual from obtaining access when a measure that is less burdensome for the individual is practicable for the entity. For example, requiring individuals to complete a standard form containing only the information the covered entity needs to process the request is a reasonable measure because it does not cause an individual to expend unnecessary effort or expense. In contrast, examples of unreasonable measures include requiring an individual to do any of the following when a measure that is less burdensome for the individual is practicable for the entity: fill out a request form with extensive information that is not necessary to fulfill the request; obtain notarization of the individual's signature on a request form; or submit a written request only in paper form, only in person at the entity's facility, or only through the covered entity's online portal.

(2) * * *

(i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access as soon as practicable, but no later than 15 calendar days after receipt of the request as follows.

* * * * *

(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (e) of this section.

(ii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) of this section, as applicable, the covered entity may extend the time for such actions by no more than 15 calendar days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request;

(B) The covered entity may have only one such extension of time for action on a request for access; and

(C) The covered entity has implemented a policy to prioritize urgent or otherwise high priority requests (especially those relating to the health and safety of the individual or another person), so as to limit the use of a 15 calendar-day extension for such requests.

(iii) Where another federal or state law requires a covered entity to provide an individual with access to the protected health information requested in less than 15 calendar days, that shorter time period is deemed practicable under paragraph (b)(2)(i) of this section.

* * * * *

(c) * * *

(2) * * *

(iii) Where another federal or state law applicable to the covered entity requires the provision of access in a particular electronic form and format, the protected health information is deemed readily producible in such form and format under paragraphs (c)(2)(i) and (ii) of this section.

(iv)(A) The covered entity may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information, or may

provide an explanation of the protected health information to which access has been provided, if:

(*1*) The individual agrees in advance to such a summary or explanation; and

(*2*) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.

(B) The covered entity must inform any individual to whom it offers to provide a summary in lieu of a copy of protected health information that the individual retains the right to obtain a copy of the requested protected health information if the individual does not agree to receive such summary. This requirement does not apply if a covered entity is offering to provide a summary in lieu of a copy of protected health information because the covered entity is denying an individual's request for a copy; however, the covered entity still must follow the denial procedures under § 164.524(e).

(3) *Time and manner of access.* The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or, at the individual's request, mailing or electronically transmitting the copy of the protected health information to the individual, including by email, or to or through the individual's personal health application (if a copy is readily producible to or through such application). When protected health information is readily available at the point of care in conjunction with a health care appointment, a covered health care provider is not permitted to delay the right to inspect. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access; however, such discussion shall not extend the time allowed for the covered entity to provide access.

(4) *Fees.* (i) If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

(A) Labor for copying the protected health information requested by the individual, whether in non-electronic (*e.g.,* paper, film) or electronic form;

(B) Supplies for creating a non-electronic copy;

(C) Postage, when the individual has requested that a non-electronic copy, or the summary or explanation, be mailed; and

(D) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(iii) of this section.

(ii) A covered entity may not impose a fee when:

(A) an individual inspects the protected health information about the individual, as described at (a)(1)(ii) of this section, or

(B) an individual accesses electronic protected health information maintained by or on behalf of the covered entity using an internet-based method such as a personal health application.

* * * * *

(d) Standard: Right to direct the transmission of certain protected health information in an electronic format to a third party—(1) An individual has a right of access to direct a covered health care provider to transmit an electronic copy of protected health information in an electronic health record directly to another person designated by the individual (a ''third party''). The covered health care provider must provide access under this paragraph when the individual's request to exercise the right of access is clear, conspicuous, and specific, which may be orally or in writing (including electronically), except for:

(i) Psychotherapy notes; and

(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

(2) *Unreviewable grounds for denial.* A covered entity may deny an individual's request to exercise the right of access to direct a covered health care provider to transmit an electronic copy of protected health information in an electronic health record directly to a third party under paragraph (d)(1) of this section, without providing an opportunity for review, in the following circumstances:

(i) The protected health information is excepted from the right of access by paragraph (d)(1) of this section.

(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to exercise of the right of access, if transmitting such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.

(iii) An individual's ability to exercise of the right of access may be temporarily suspended by a covered health care provider in the course of research that includes treatment for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.

(iv) An individual's request to exercise the right of access may be denied if the protected health information is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, and if the denial of access under the Privacy Act would meet the requirements of that law.

(v) An individual's request to exercise the right of access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and providing the copy to the third party would be reasonably likely to reveal the source of the information.

(3) *Reviewable grounds for denial of a request to direct an electronic copy of protected health information in an electronic health record.* A covered entity may deny an individual's request under paragraph (d)(1) of this section, provided that the individual is given a right to have such denials reviewed, as required by paragraph (e)(4) of this section, in the following circumstances:

(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access is reasonably likely to endanger the life or physical safety of the individual or another person; or

(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access is reasonably likely to cause substantial harm to such other person.

(4) *Implementation specification: Summary or explanation prepared by covered health care provider.* (i) A covered health care provider may transmit, to a third party designated by an individual, a summary of requested protected health information in an electronic health record, in lieu of transmitting a copy of the protected health information, or may transmit an explanation of the requested protected health information in an electronic

health record in addition to such protected health information, if:

(A) The individual agrees in advance to such a summary or explanation; and

(B) The individual agrees in advance to the fees imposed, if any, by the covered health care provider for such summary or explanation.

(ii) A covered health care provider must inform any individual to whom it offers to transmit a summary in lieu of a copy of protected health information that the individual retains the right to direct an electronic copy of the requested protected health information in an EHR if the individual does not agree to receive such summary. This requirement does not apply if a covered entity is offering to provide a summary in lieu of a copy of protected health information because the covered entity is denying an individual's request for a copy; however, the covered entity still must follow the denial procedures under § 164.524(e).

(5) *Implementation specification: Timely action by the covered entity.* (i) Except as provided in paragraph (d)(5)(ii) of this section, a covered health care provider is required to provide the copy requested under paragraph (d)(1) of this section as soon as practicable but no later than 15 calendar days after receipt of the individual's request.

(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (d) of this section.

(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (e)(2) of this section.

(ii) If the covered entity is unable to take an action required by paragraph (d)(5)(i)(A) or (B) of this section within the time required by paragraph (d)(5)(i) of this section, as applicable, the covered entity may extend the time for such actions by no more than 15 calendar days, provided that:

(A) The covered entity, within the time limit set by paragraph (d)(5)(i) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request.

(C) The covered entity has implemented a policy to prioritize urgent or otherwise high priority requests (especially those relating to the health and safety of the individual or another person), so as to limit the use of a 15 calendar-day extension for such requests.

(iii) Where another federal or state law requires a covered entity to provide an individual with an electronic copy of the protected health information in an electronic health record in less than 15 calendar days, that shorter time period is deemed practicable under paragraph (d)(5)(i) of this section.

(6) *Fees.* A covered health care provider may impose a reasonable, cost-based fee for an access request to direct an electronic copy of protected health information in an electronic health record to a third party, provided that the fee includes only the cost of:

(i) Labor for copying the protected health information requested by the individual in electronic form; and

(ii) Preparing an explanation or summary of the protected health information, if agreed to by the individual as provided in paragraph (d)(4) of this section.

(7) *Right to direct covered health care providers or plans to submit an access request.*

(i) An individual has a right of access to direct a covered health care provider or health plan (''Requester-Recipient'') to submit to a covered health care provider (''Discloser'') a request for an electronic copy of the individual's protected health information in an electronic health record maintained by or on behalf of the Discloser.

(ii) A Requester-Recipient must submit to the Discloser a request made by the individual, orally or in writing (including electronically), and that is clear, conspicuous, and specific, if the individual is:

A. a current or prospective new patient of the Requester-Recipient health care provider, or

B. a current enrolled member (or dependent) of the Requester-Recipient health plan.

(iii) The Requester-Recipient must submit the access request to the identified Discloser as soon as practicable, but no later than 15 calendar days after receiving the individual's direction and any information needed to submit the request. An extension is not available for submitting the request. The Discloser must respond to the access request within the time limits in paragraph (d)(5) of this section.

(e) *Implementation specifications: Denial of access.* If a covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

* * * * *

(2) *Denial.* The covered entity must provide a timely, written denial to the individual. The denial must be in plain language and contain:

* * * * *

(ii) If applicable, a statement of the individual's review rights under paragraph (e)(4)(i) of this section, including a description of how the individual may exercise such review rights;

* * * * *

(3) *Other responsibility.* If the covered entity (or its business associate on the covered entity's behalf) does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested protected health information is maintained, the covered entity must inform the individual where to direct the request for access.

* * * * *

(4) *Review of a denial of access.* If access is denied on a ground permitted under paragraphs (a)(3) or (d)(3) of this section:

(i) The individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny access. The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (e)(4)(i) of this section.

(ii) If the individual has requested a review of a denial under paragraph (e)(4)(i) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) or (d)(3) of this section, whichever is applicable, of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.

(f) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by § 164.530(j):

(1) The designated record sets that are subject to access by individuals under paragraph (a) of this section;

(2) The electronic health records that are subject to the right of access to direct the transmission of an electronic copy of protected health information in an electronic health record under paragraph (d) of this section; and

(3) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

■ 12. Add § 164.525 to subpart E to read as follows:

§ 164.525 Notice of Access and Authorization Fees.

(a) If a covered entity imposes fees allowed under §§ 164.524(c)(4), 164.524(d)(6) or 164.502(a)(5)(ii)(A) and 164.508(a)(4), the covered entity must provide advance notice of such fees as follows.

(1) The covered entity must post a fee schedule on its website, if it has one, and make the fee schedule available to individuals at the point of service and upon request. The fee schedule must specify:

(i) All types of access to protected health information available free of charge; and

(ii) Standard fees for:

(A) Copies of protected health information provided to individuals under § 164.524(a), with respect to all readily producible electronic and non-electronic forms and formats for such copies;

(B) Copies of protected health information in an electronic health record and directed to third parties designated by the individual under § 164.524(d), with respect to any available electronic forms and formats for such copies; and

(C) Copies of protected health information sent to third parties with the individual's valid authorization under § 164.508, with respect to any available forms and formats for such copies.

(2) Upon request, the covered entity must provide an individualized estimate of the approximate fee that may be imposed for providing a copy of the requested protected health information for any type of request covered by the fee schedule required by paragraph (1) of this section.

(3) Upon request, the covered entity must provide an individual with an itemized list of the specific charges for labor, supplies, and postage, if applicable, that constitute the total fee charged for any type of request covered by the fee schedule required by paragraph (1) of this section.

(b) A request under paragraph (a)(2) or (3) of this section shall not automatically extend the time allowed for the covered entity to provide copies of protected health information under 164.524.

* * * * *

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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The President

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Thursday, January 21, 2021

Presidential Documents

Title 3—

The President

Proclamation 10133 of January 14, 2021

To Continue Facilitating Positive Adjustment to Competition From Imports of Large Residential Washers

By the President of the United States of America

A Proclamation

1. On January 23, 2018, pursuant to section 203 of the Trade Act of 1974, as amended (the ''Trade Act'') (19 U.S.C. 2253), I issued Proclamation 9694, which imposed a safeguard measure for a period of 3 years plus 1 day comprising both a tariff-rate quota (TRQ) on imports of large residential washers (washers) provided for in subheadings 8450.11.00 and 8450.20.00 of the Harmonized Tariff Schedule of the United States (HTS) and a TRQ on covered washer parts provided for in subheadings 8450.90.20 and 8450.90.60 of the HTS. I exempted covered imports from Canada and certain designated beneficiary countries under the Generalized System of Preferences (GSP) from the application of the measure.

2. On May 16, 2019, I issued Proclamation 9887, which removed Turkey from the list of GSP beneficiary countries, and modified the safeguard measure so that imports from Turkey were no longer excluded. On May 31, 2019, I issued Proclamation 9902, which removed India from the list of GSP beneficiary countries, and modified the safeguard measure so that imports from India were no longer excluded.

3. On August 7, 2019, the United States International Trade Commission (ITC) issued its report pursuant to section 204(a)(2) of the Trade Act (19 U.S.C. 2254(a)(2)), on the results of its monitoring of developments with respect to the domestic washers industry (ITC, Large Residential Washers: Monitoring Developments in the Domestic Industry, No. TA–204–013). After taking into account the information provided in the ITC's report and receiving a petition from the representative of the majority of the domestic industry, I determined that the domestic industry had begun to make positive adjustment to import competition but that, despite that adjustment, increased imports of washers at peak times of the year impaired the effectiveness of the action I proclaimed in Proclamation 9694. On January 23, 2020, pursuant to sections 204(b)(1)(B) and 204(b)(2) of the Trade Act (19 U.S.C. 2254(b)(1)(B) and (b)(2)), I issued Proclamation 9979 to modify the action I took in Proclamation 9694 by allocating on a quarterly basis, within-quota quantities of 1.2 million units during the third year of the action, beginning February 7, 2020.

4. On December 8, 2020, in response to a petition by the representatives of the domestic industry, the ITC issued its determination and report pursuant to section 204(c) of the Trade Act (19 U.S.C. 2254(c)), finding that the safeguard measure I imposed continues to be necessary to prevent or remedy the serious injury to the domestic industry, and that there is evidence that the domestic industry is making a positive adjustment to import competition (ITC, Large Residential Washers: Extension of Action, No. TA–201–076 (Extension)).

5. Section 203(e)(1)(B) of the Trade Act (19 U.S.C. 2253(e)(1)(B)) authorizes the President, after receiving an affirmative determination from the ITC pursuant to section 204(c) of the Trade Act (19 U.S.C. 2254(c)), to extend the effective period of any action taken under section 203 of the Trade Act if the President determines that the action continues to be necessary

to prevent or remedy the serious injury and there is evidence that the domestic industry is making a positive adjustment to import competition.

6. Pursuant to section 203(e)(1)(B) of the Trade Act (19 U.S.C. 2253(e)(1)(B)), I have determined that the action continues to be necessary to prevent or remedy the serious injury to the domestic washers industry and there is evidence that the domestic washers industry is making a positive adjustment to import competition, and I have further determined to extend the safeguard measure proclaimed in Proclamation 9694, as modified, as follows:

(a) continuation of the tariff-rate quota on imports of washers described in paragraph 1 of this proclamation for an additional period of 2 years, with unchanging within-quota quantities, annual reductions in the rates of duties entered within those quantities in the fourth and fifth years, and annual reductions in the rates of duty applicable to goods entered in excess of those quantities in the fourth and fifth years; and

(b) continuation of the tariff-rate quota on imports of covered washer parts described in paragraph 1 of this proclamation for an additional period of 2 years, with increasing within-quota quantities and annual reductions in the rates of duty applicable to goods entered in excess of those quantities in the fourth and fifth years.

7. As provided in Proclamation 9694, as modified by Proclamations 9887 and 9902, this safeguard measure shall apply to imports from all countries, except for products of Canada and except as provided in paragraph 8 of this proclamation.

8. As I further provided in Proclamation 9694, as modified by Proclamations 9887 and 9902, this safeguard measure shall not apply to imports of any product described in paragraph 1 of this proclamation of a developing country that is a Member of the World Trade Organization (WTO), as listed in subdivision (b)(2) of Note 17 in the Annex to this proclamation, as long as such country's share of total imports of the product, based on imports during a recent representative period, does not exceed 3 percent, provided that imports that are the product of all such countries with less than 3 percent import share collectively account for not more than 9 percent of total imports of the product. If I determine that a surge in imports of a product described in paragraph 1 of this proclamation of a developing country that is a WTO Member results in imports of that product from that developing country exceeding either of the thresholds described in this paragraph, the safeguard measure shall be modified to apply to such product from such country. In addition, if I determine within 60 days of the date of this proclamation, as a result of consultations between the United States and other WTO Members pursuant to Article 12.3 of the WTO Agreement on Safeguards, that it is necessary to modify the terms of extension of the safeguard measure, or to terminate the safeguard measure, I shall proclaim the corresponding modification or termination within 40 days of the date of my determination.

9. As I further provided in Proclamation 9694, the in-quota quantity in each year under the tariff-rate quota described in subparagraph (a) of paragraph 6 of this proclamation shall be allocated on a quarterly basis as provided for in Proclamation 9979.

10. Section 604 of the Trade Act (19 U.S.C. 2483) authorizes the President to embody in the HTS the substance of the relevant provisions of that Act, and of other acts affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, acting under the authority vested in me by the Constitution and the laws of the United States, including but not limited to sections 203, 204, and 604 of the Trade Act, do proclaim that:

(1) In order to extend the measure applicable to imports of washers and covered parts described in paragraph 1 of this proclamation, subchapter

III of chapter 99 of the HTS is modified as set forth in the Annex to this proclamation. Any merchandise subject to the safeguard measure that is admitted into United States foreign trade zones on or after 12:01 a.m., eastern standard time, on February 8, 2021, must be admitted as ''privileged foreign status'' as defined in 19 CFR 146.41, and will be subject upon entry for consumption to any tariffs or quantitative restrictions related to the classification under the applicable HTS subheading.

(2) Imports of washers and covered washer parts that are the product of Canada shall continue to be excluded from the safeguard measure extended by this proclamation, and such imports shall not be counted toward the tariff-rate quota limits that trigger the over-quota rates of duty.

(3) Except as provided in clause (4) below, imports of washers and covered washer parts that are the product of WTO Member developing countries, as listed in subdivision (b)(2) of Note 17 in the Annex to this proclamation, shall continue to be excluded from the safeguard measure extended by this proclamation, and such imports shall not be counted toward the tariff-rate quota limits that trigger the over-quota rates of duties.

(4) If, after the extension proclaimed herein is in effect, the United States Trade Representative (USTR) determines that:

(a) the share of total imports of the product of a country listed in subdivision (b)(2) of Note 17 in the Annex to this proclamation exceeds 3 percent;

(b) imports of the product from all listed countries with less than 3 percent import share collectively account for more than 9 percent of total imports of the product; or

(c) a country listed in subdivision (b)(2) of Note 17 in the Annex to this proclamation is no longer a developing country for purposes of this proclamation;

the USTR is authorized, upon publication of a notice in the *Federal Register,* to revise subdivision (b)(2) of Note 17 in the Annex to this proclamation to remove the relevant country from the list or suspend operation of that subdivision, as appropriate.

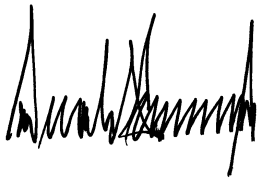
(5) If, after the extension proclaimed herein is in effect, the USTR determines that the out-of-quota quantity in units of covered washer parts entered under the tariff lines in chapter 99 enumerated in the Annex to this proclamation has increased by an unjustifiable amount and undermines the effectiveness of the safeguard measure, the USTR is authorized, upon publication of a notice in the *Federal Register* of such determination, to modify the HTS provisions created by the Annex to this proclamation so as to modify the tariff-rate quota on covered washer parts with a quantitative restriction on covered washer parts at a level that the USTR considers appropriate.

(6) In order to continue allocating, on a quarterly basis, the within-quota quantities of the TRQ limits applicable to imports of washers under HTS subheadings 8450.11.00 and 8450.20.00, subchapter III of chapter 99 of the HTS is modified as set forth in the Annex to this proclamation. These allocations shall continue in effect as provided in the Annex to this proclamation, unless such actions are earlier expressly reduced, modified, or terminated.

(7) One year from the termination of the safeguard measure established in this proclamation, the U.S. note and tariff provisions established in the Annex to this proclamation shall be deleted from the HTS.

(8) Any provision of previous proclamations and Executive Orders that is inconsistent with the actions taken in this proclamation is superseded to the extent of such inconsistency.

IN WITNESS WHEREOF, I have hereunto set my hand this fourteenth day of January, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.



Billing code 3295–F1–P

ANNEX

1. U.S. note 17(d) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is amended by inserting the following provisions at the end of subdivision (d):

   "If entered during the period from
   February 8, 2021 through February 7,
   2022……..15%
   If entered during the period from
   February 8, 2022 through February 7,
   2023……..14%".

2. U.S. note 17(e) to subchapter III of chapter 99 of the HTSUS is amended by inserting the following provisions at the end of subdivision (e):

   "If entered during the period from
   February 8, 2021 through February 7,
   2022……..35%
   If entered during the period from
   February 8, 2022 through February 7,
   2023……..30%".

3. U.S. note 17(g) to subchapter III of chapter 99 of the HTSUS is amended by inserting the following provisions at the end of subdivision (g):

   "If entered during the period from
   February 8, 2021 through February 7,
   2022……110,000 units
   If entered during the period from
   February 8, 2022 through February 7,
   2023……130,000 units".

4. U.S. note 17(h) to subchapter III of chapter 99 of the HTSUS is amended by inserting the following provisions at the end of subdivision (h):

   "If entered during the period from
   February 8, 2021 through February 7,
   2022……..35%
   If entered during the period from
   February 8, 2022 through February 7,
   2023……..30%".

5. U.S. note 17(i) to subchapter III of chapter 99 of the HTSUS is amended by inserting the following provisions at the end of subdivision (i):

   "If entered during the period from
   February 8, 2021 through May 7,
   2021……300,000 units
   If entered during the period from
   May 8, 2021 through August 7,
   2021……300,000 units
   If entered during the period from
   August 8, 2021 through November 7,
   2021……300,000 units
   If entered during the period from
   If entered during the period from
   November 8, 2021 through February 7,
   2022……300,000 units
   If entered during the period from

February 8, 2022 through May 7, 2022……300,000 units
If entered during the period from May 8, 2022 through August 7, 2022……300,000 units
If entered during the period from August 8, 2022 through November 7, 2022……300,000 units
If entered during the period from November 8, 2022 through February 7, 2023……300,000 units".

6. Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern standard time on February 8, 2021:

   a. the "Rates of Duty 1-General" column of subheading 9903.45.01 is modified by deleting "20%" and by inserting "15%" in lieu thereof;

   b. the "Rates of Duty 1-General" column of subheading 9903.45.02 is modified by deleting "50%" and by inserting "35%" in lieu thereof; and

   c. the "Rates of Duty 1-General" column of subheading 9903.45.06 is modified by deleting "50%" and by inserting "35%" in lieu thereof.

7. Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern standard time on February 8, 2022:

   a. the "Rates of Duty 1-General" column of subheading 9903.45.01 is modified by deleting "15%" and by inserting "14%" in lieu thereof;

   b. the "Rates of Duty 1-General" column of subheading 9903.45.02 is modified by deleting "35%" and by inserting "30%" in lieu thereof; and

   c. the "Rates of Duty 1-General" column of subheading 9903.45.06 is modified by deleting "35%" and by inserting "30%" in lieu thereof.

[FR Doc. 2021–01466
Filed 1–19–21; 11:15 a.m.]
Billing code 7020–02–C

Presidential Documents

Executive Order 13975 of January 14, 2021

Encouraging Buy American Policies for the United States Postal Service

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Policy.* As expressed in Executive Order 13788 of April 18, 2017 (Buy American and Hire American), Executive Order 13858 of January 31, 2019 (Strengthening Buy-American Preferences for Infrastructure Projects), and Executive Order 13881 of July 15, 2019 (Maximizing Use of American-Made Goods, Products, and Materials), it is the policy of the United States to buy American and to maximize, consistent with law, the use of goods, products, and materials produced in the United States.

Sec. 2. *Definitions.* As used in this order:

(a) ''Buy American'' means all policies that require, or provide a preference for, the purchase or acquisition of goods, products, or materials produced in the United States, including iron, steel, and manufactured goods; and

(b) ''Buy American Laws'' means all statutes, regulations, rules, and Executive Orders relating to Federal procurement or Federal grants—including those that refer to ''Buy America'' or ''Buy American''—that require, or provide a preference for, the purchase or acquisition of goods, products, or materials produced in the United States, including iron, steel, and manufactured goods.

Sec. 3. *Purpose.* (a) In certain competitive procurements, the United States Postal Service (USPS) currently applies its own Buy American domestic procurement preferences similar to Buy American Laws implemented across executive departments and agencies. Under such circumstances, and as expressed in section 2–36 of the USPS Supplying Principles and Practices (SPP), USPS procurement policies state that:

(i) When the relative importance of price is more important than the other evaluation factors, 6 percent is added to the proposed price of the non-qualifying end product and this adjusted price is used for evaluation; and

(ii) An end product qualifies as manufactured in the United States if the cost of its components mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components, similar to domestic content requirements under the Buy American Laws.

(b) Executive Order 13881 required the Federal Acquisition Regulatory Council (FAR Council) to consider proposing new rules in the Federal Acquisition Regulation (FAR), title 48, Code of Federal Regulations, to strengthen Buy American preferential price differentials and domestic content requirements. To ensure consistency across the Federal Government as a whole and to further promote my Administration's Buy American policy goals, USPS is strongly encouraged to consider similar changes to its Buy American domestic procurement preferences.

Sec. 4. *Encouraged Rules.* Within 90 days of the date of the FAR Council's issuance of any final rule discussed in section 2 of Executive Order 13881, the United States Postmaster General is encouraged to consider:

(a) An amendment or amendments to the applicable sections of the SPP to conform with the FAR provisions regarding price differentials when the

relative importance of price is more important than the other evaluation factors; and

(b) An amendment or amendments to the applicable sections of the SPP to conform with the FAR provisions regarding when materials shall be considered to be of foreign origin.

Sec. 5. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

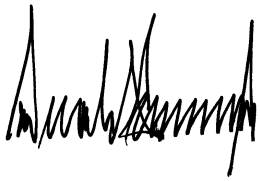
(i) the authority granted by law to an executive department or agency, or the head thereof;

(ii) the authority granted by law to the USPS, its officers, or its Board of Governors; or

(iii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order 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.



THE WHITE HOUSE,
January 14, 2021.

[FR Doc. 2021–01469
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Presidential Documents

Executive Order 13976 of January 14, 2021

Establishing the Wildland Fire Management Policy Committee

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose.* Federal wildland fire management lacks a single focal point of responsibility for policy leadership and accountability for cost controls. While executive departments and agencies (agencies) have implemented Executive Order 13855 of December 21, 2018 (Promoting Active Management of America's Forests, Rangelands, and Other Federal Lands To Improve Conditions and Reduce Wildfire Risk), and similar Administration efforts, more must be done to continue to improve interagency coordination.

In contrast to effective ground-level coordination with States, including at the National Interagency Fire Center on suppression activity and the Wildland Fire Leadership Council (WFLC) on Federal-State policy coordination, agencies do not adequately or effectively coordinate with each other at the policy level to reduce hazardous fuels and wildfire severity. This order will ensure that agencies effectively work together in coordinating Federal wildland fire management policy to improve funding allocations for hazardous fuel projects, performance measures for suppression operations and hazardous fuels mitigation, procurement, Federal-State cooperation and cost sharing, cross-jurisdictional post-wildfire rehabilitation, monitoring of electric transmission lines and other critical infrastructure, and other functions.

Sec. 2. *Policy.* It is the policy of the United States to:

(a) Improve coordination among agencies on wildland fire management policy, implementation, and oversight issues;

(b) Reduce unnecessary duplication across the Federal Government by coordinating and consolidating existing wildland fire-related councils, working groups, and other formal cross-agency initiatives, as appropriate;

(c) Efficiently and effectively manage preparedness resources, initial attack response, extended attack and large-fire support, post-wildfire rehabilitation, and hazardous fuels at a cross-boundary, landscape scale;

(d) Promote integrated planning and procurement among agencies for Federal investments in wildland fire management infrastructure;

(e) Support workforce development and efforts to recruit, train, and retain Federal wildland firefighters to efficiently and effectively respond to wildfire on public lands, and to protect life, property, and community infrastructure; and

(f) Coordinate Federal engagement with State, local, and tribal government entities, including Federal policy positions in the WFLC.

Sec. 3. *Interagency Wildland Fire Subcabinet.* To promote efficient and effective coordination across agencies engaged in Federal wildland firefighting and to facilitate coordinated and strategic wildland fire management actions, an interagency Wildland Fire Management Policy Committee (to be known as the Wildland Fire Subcabinet) is hereby established.

(a) The Wildland Fire Subcabinet shall be co-chaired by the Secretary of Agriculture and Secretary of the Interior (Co-Chairs), and shall include the Secretary of Defense, the Secretary of Energy, the Secretary of Homeland Security, the Chairman of the Council on Environmental Quality (CEQ), the Director of the Office of Science and Technology Policy (OSTP), the Administrator of the Environmental Protection Agency (EPA), the Director of the National Economic Council (NEC), and the heads of such other agencies, or their designated representatives, as the Co-Chairs deem appropriate.

(b) The Wildland Fire Subcabinet shall meet quarterly.

Sec. 4. *Reducing Inefficiencies and Duplication.* Currently, several Federal wildfire-related councils, task forces, working groups, and other formal cross-agency initiatives (Federal interagency working groups) exist to address wildland fire management policy. Within 90 days of the date of this order, the Wildland Fire Subcabinet shall, to the extent practicable, identify all such Federal interagency working groups and provide recommendations to the Secretary of the Interior, the Secretary of Agriculture, and the Director of the Office of Management and Budget (OMB) on coordinating and consolidating these Federal interagency working groups, as appropriate and consistent with applicable law.

Sec. 5. *Improving Wildland Fire Management Policy Coordination, Implementation, and Oversight.* Within 180 days of the date of this order, the Wildland Fire Subcabinet shall develop, publish, and implement a strategic plan addressing the issues described in this section. To implement this strategic plan, the Wildland Fire Subcabinet shall develop specific measurable goals, performance targets, and dashboard reporting for consideration by each Federal agency represented on the Wildland Fire Subcabinet, using common data standards at the wildfire and hazardous fuels program level. This strategic plan shall address the issues described below:

(a) Effectively managing preparedness resources, initial attack response, extended attack and large-fire support, post-wildfire rehabilitation, and hazardous fuels at a cross-boundary, landscape scale;

(b) Developing and adopting additional hazardous fuels performance measures that go beyond the traditional output reporting of total acreage for fuel removal to transparently demonstrate a strategic focus on projects that, by consensus agreement, pose the highest risks to life, property, and community infrastructure;

(c) Developing and adopting additional wildland fire suppression operations performance measures for large wildfires, and for aviation asset deployment, that go beyond the traditional output reporting of acres burned, dollars spent, and gallons of retardant dropped to demonstrate strategic use of high-cost human capital, equipment, and aircraft as opposed to traditional reliance on overwhelming force;

(d) Developing and adopting new technologies to bring to bear cutting-edge management of the wildland fire program to improve the safety, efficiency, and effectiveness of suppression operations;

(e) Developing and adopting data-driven decision-making in order to support infrastructure, allowing for better integration of wildland fire research and development into ground-level suppression operations and hazardous fuel mitigation;

(f) Evaluating personnel policies to ensure that they allow for the year-round availability of a well-trained firefighting force at all levels, from apprentice to incident command, and the most efficient division of responsibility between line officers and incident commanders to support wildfire response and hazardous fuels reduction;

(g) Strengthening government and industry collaboration with critical infrastructure owners and operators, including electric utilities, to better manage and mitigate risks, improve and invest in technology research and development, deploy technologies in concert with the private sector, exchange lessons learned in training and monitoring capabilities, and share operational practices;

(h) Examining regulatory and other issues that negatively impact hazardous fuel reduction and post-wildfire rehabilitation program performance, including coordination across agencies on projects requiring compliance with the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.*;

(i) Coordinating among Federal land managers to assure efficient and consistent approaches between agencies to review and approve utility vegetation management actions to improve or maintain the reliability of the grid or reduce wildfire risk; and

(j) Developing a coordinated budget strategy that addresses the trade-offs between suppression, preparedness, post-wildfire rehabilitation, and fuels treatment to ensure a balanced commitment of resources and investment in areas at risk or affected by wildfire.

Sec. 6. *Report.* Within 1 year of the date of this order, and annually thereafter, the Wildland Fire Subcabinet shall update the Chairman of CEQ, the Director of OMB, the Director of OSTP, and the Director of the NEC on the status of the strategic plan and the specific actions identified in this order.

Sec. 7. *Administration.* The Department of Agriculture shall, to the extent permitted by law and subject to the availability of appropriations, provide administrative support as needed for the Wildland Fire Subcabinet to implement this order. The Departments of the Interior and Agriculture shall consult with WFLC, as appropriate, to effectively carry out the requirements of this order.

Sec. 8. *Federal Advisory Committee Act.* The members of the Wildland Fire Subcabinet should, pursuant to and consistent with the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and in the interest of obtaining advice or recommendations for the Wildland Fire Subcabinet, use their advisory committees, as appropriate.

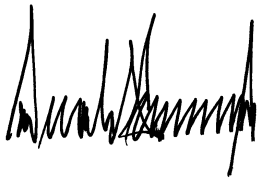
Sec. 9. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented in a manner consistent with applicable law and subject to the availability of appropriations.

(c) This order 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.



THE WHITE HOUSE,
January 14, 2021.

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